Actinium Pharmaceuticals, Inc.
Form S-3
March 16, 2017
As filed with the Securities and Exchange Commission on March 16, 2017

Registration No.____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Actinium Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**88-0378336**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

275 Madison Avenue, 7th Floor

New York, New York 10016

(646) 677-3875

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Sandesh Seth

Executive Chairman

Actinium Pharmaceuticals, Inc.

275 Madison Avenue, 7th Floor

New York, New York 10016

(646) 677-3875

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Thomas Slusarczyk, Esq.

The Matt Law Firm, PLLC
1701 Genesee Street

Utica, NY 13501

Tel. (315) 235-2299

Fax (315) 624-7359

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462 I under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement filed pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per security(2)	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, $0.001 par value per share(2)	—	$ —	$—	$ —
Preferred Stock, $0.001 par value per share(2)	—	—	—	—
Debt Securities	—	—	—	—
Warrants(2)	—	—	—	—
Rights	—	—	—	—
Purchase Contracts	—	—	—	—
Units	—	—	—	—
Total Offering	$200,000,000	$ —	$200,000,000	$ 8,206 (3)

(1) There are being registered hereunder such indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities, such indeterminate number of warrants to purchase common stock, preferred stock or debt securities, and such indeterminate number of rights, purchase contracts, or units as shall have an aggregate initial offering price not to exceed $200,000,000, less the aggregate dollar amount of all securities previously sold hereunder. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be in such greater principal amount as shall result in an aggregate initial offering price not to exceed $200,000,000, less the aggregate dollar amount of all securities previously issued hereunder. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. Any securities registered hereunder may be sold separately or as units with the other securities registered hereunder. The proposed maximum offering price per unit will be determined, from time to time, by the registrant in connection with the issuance by the registrant of the securities registered hereunder. The securities registered hereunder also include such indeterminate number of shares of common stock, preferred stock and principal amounts of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, upon exercise of warrants or pursuant to the antidilution provisions of any of such securities. In addition, pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock, preferred stock or debt securities as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) The proposed maximum offering price per security will be determined from time to time by the registrant in connection with, and at the time of, the issuance of the securities and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3, as amended.

(3)

Pursuant to Rule 415(a)(6) under the Securities Act, this registration statement includes a total of $129,200,000 of unsold securities that had previously been registered under the registrant's registration statement on Form S-3 initially filed on March 24, 2014 and amended on April 10, 2014, File Number 333-194768 (the "Prior Registration Statement"). The Prior Registration Statement registered securities for a maximum aggregate offering price of $200,000,000. After sales by the registrant of securities thereunder, the Prior Registration Statement has a balance of unsold securities with an aggregate offering price of $129,200,000. In connection with the registration of such unsold securities on the Prior Registration Statement, the registrant paid a registration fee of $14,975. Pursuant to Rule 415(a)(6) under the Securities Act, the offering of $129,200,000 of the unsold securities registered under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of this registration statement.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

EXPLANATORY NOTE

This Registration Statement contains two prospectuses:

- a base prospectus which covers the offering, issuance and sale by us of up to $200,000,000 of our common stock, preferred stock, debt securities, warrants, rights, purchase contracts, and/or units; and

- a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of $75,000,000 of our common stock that may be issued and sold under a sales agreement with FBR Capital Markets & Co.

The base prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the base prospectus will be specified in a prospectus supplement to the base prospectus. The sales agreement prospectus immediately follows the base prospectus. The $75,000,000 of common stock that may be offered, issued and sold under the sales agreement prospectus is included in the $200,000,000 of securities that may be offered, issued and sold by us under the base prospectus.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 16, 2017

PROSPECTUS

ACTINIUM PHARMACEUTICALS, INC.

$200,000,000

Common Stock

Preferred Stock

Debt Securities

Warrants

Rights

Purchase Contracts

Units

We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in this prospectus, up to an aggregate amount of $200,000,000.

We will provide specific terms of any offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby.

These securities may be offered and sold in the same offering or in separate offerings; to or through underwriters, dealers, and agents; or directly to purchasers. The names of any underwriters, dealers, or agents involved in the sale of our securities, their compensation and any over-allotment options held by them will be described in the applicable prospectus supplement. See “Plan of Distribution.”

Our common stock is presently traded on the NYSE MKT under the symbol “ATNM.” On March 10, 2017, the last reported sale price of our common stock was $1.42 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision. We will provide information in any applicable prospectus supplement regarding any listing of securities other than shares of our common stock on any securities exchange.

You should carefully read this prospectus, any prospectus supplement relating to any specific offering of securities, and all information incorporated by reference herein and therein.

Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under “Risk Factors” beginning on page 10 and in the documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2017

TABLE OF CONTENTS

	Page
ABOUT THIS PROSPECTUS	2
PROSPECTUS SUMMARY	3
RISK FACTORS	10
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	10
USE OF PROCEEDS	10
DESCRIPTION OF CAPITAL STOCK	11
DESCRIPTION OF DEBT SECURITIES	19
DESCRIPTION OF WARRANTS	25
DESCRIPTION OF RIGHTS	27
DESCRIPTION OF UNITS	29
PLAN OF DISTRIBUTION	30
LEGAL MATTERS	31
EXPERTS	31
WHERE YOU CAN FIND MORE INFORMATION	32
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	32

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission using a "shelf" registration process. Under this shelf process, we may, from time to time, sell any combination of the securities described in this prospectus in one or more offerings up to a total amount of $200,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add to, update or change information contained in the prospectus and, accordingly, to the extent inconsistent, information in this prospectus is superseded by the information in the prospectus supplement.

The prospectus supplement to be attached to the front of this prospectus may describe, as applicable: the terms of the securities offered; the public offering price; the price paid for the securities; net proceeds; and the other specific terms related to the offering of the securities.

You should only rely on the information contained or incorporated by reference in this prospectus and any prospectus supplement or issuer free writing prospectus relating to a particular offering. No person has been authorized to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement and any related issuer free writing prospectus in connection with the offering described herein and therein, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement nor any related issuer free writing prospectus shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits.

You should read the entire prospectus and any prospectus supplement and any related issuer free writing prospectus, as well as the documents incorporated by reference into this prospectus or any prospectus supplement or any related issuer free writing prospectus, before making an investment decision. Neither the delivery of this prospectus or any prospectus supplement or any issuer free writing prospectus nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement or issuer free writing prospectus is correct as of any date subsequent to the date hereof or of such prospectus supplement or issuer free writing prospectus, as applicable. You should assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference is accurate only as of the date of the applicable documents, regardless of the time of delivery of this prospectus or any sale of securities. Our business, financial condition, results of operations and prospects may have changed since that date.

2

PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus, the information incorporated by reference and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under "Risk Factors" in this prospectus and the documents incorporated by reference and our financial statements and notes thereto that are incorporated by reference in this prospectus. As used in this prospectus, unless the context otherwise indicates, the terms "we," "our," "us," or "the Company" refer to Actinium Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries taken as a whole.

The Company

Business Overview

Our most advanced products are Iomab™-B, an antibody-drug construct containing iodine 131 (I-131), used in myeloconditioning for hematopoietic stem cells transplantation (HSCT) in various indications and Actimab™-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (AML). We are currently conducting a pivotal Phase 3 trial of Iomab™-B for bone marrow conditioning for HSCT in patients with relapsed or refractory AML age of 55 and older, which upon successful completion of our clinical trials we intend to submit for marketing approval. We are currently also considering filing an application with the U.S. Food and Drug Administration (FDA) for breakthrough therapy designation for Actimab™-A and/or Iomab™-B. We are developing our cancer drugs using our expertise in radioimmunotherapy. In addition, our Ac-225 based drug development relies on the patented Alpha Particle Immunotherapy Technology (APIT) platform technology co-developed with Memorial Sloan Kettering Cancer Center (MSKCC). The APIT technology couples monoclonal antibodies (mAb) with extremely potent but comparatively safe alpha particle emitting radioactive isotopes, in particular actinium 225. The final drug construct is designed to specifically target and kill cancer cells while minimizing side effects. We intend to develop a number of products for different types of cancer and derive revenue from partnering relationships with large pharmaceutical companies and/or direct sales of its products in specialty markets in the United States.

In December 2015, we announced that the FDA cleared our IND filing for Iomab-B. In June 2016, we announced the pivotal Phase 3 clinical trial for Iomab-B was initiated and assuming that the trial meets its end points, it will form the basis for a Biologics Licensing Application (BLA). We established an agreement with the FDA that the path to a BLA submission would include a single, pivotal Phase 3 clinical study if it is successful. The population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed AML patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months and the secondary endpoint will be overall survival at one year. We believe there are currently no effective treatments approved by the FDA for AML in

this patient population and there is no defined standard of care. Iomab-B has completed several physicians sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers, including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in over 300 patients have demonstrated the potential of Iomab-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

In September 2016, we initiated the Phase 2 clinical trial for Actimab-A. This Phase 2 clinical trial is a multicenter, open-label study that will enroll 53 patients. Patients will receive 2.0 μCi/kg/fractionated dose of Actimab-A via two injections given at day 1 and day 7. The Phase 2 trial is designed to evaluate complete response rates at up to day 42 after Actimab-A administration, where complete response is defined as complete remission (CR) or complete remission with incomplete platelet recovery (CRp). A formal interim analysis is expected to occur in mid-2017 with topline results expected in the second half of 2017. The Phase 2 clinical trial includes peripheral blast burden as an inclusion criteria and in patients with high peripheral blast (PB) burden, the use of Hydroxyurea will be mandated with the goal of bringing PB burden below a key threshold number that we have identified from two previously complete Phase 1 clinical trials totaling 38 patients. In addition, the use of granulocyte colony-stimulating factors (GCSF) will be mandated. Low dose cytarabine has been eliminated from the protocol and the Phase 2 clinical trial will evaluate Actimab-A as a monotherapy. The secondary endpoint of the Phase 2 clinical trial will be overall survival.

In February 2017, we initiated a Phase 1 investigator initiated clinical trial to study Actimab-M in multiple myeloma (MM). Multiple myeloma is a cancer of plasma cells that is currently incurable. The Phase 1 trial will enroll up to 12 patients with relapsed or refractory multiple myeloma who have positive CD33 expression. This Phase 1 study is designed as a dose escalation study intended to assess safety, establish maximum tolerable dose (MTD) and assess efficacy. Patients will be administered Actimab-M on day 1 at an initial dose of 0.5 μCi/kg and then assessed at day 42 for safety and efficacy. The dose can be increased to 1.0 μCi/kg or reduced to 0.25 μCi/kg based on safety assessment that will evaluate dose limiting toxicities (DLTs). Patients may receive up to 8 cycles of therapy but in no event will cumulative administration exceed 4.0 μCi/kg of Actimab-M.

Business Strategy

We intend to potentially develop our most advanced clinical stage product candidates through approval in the case of Iomab™-B, and up to and including a Phase 2 proof of concept human clinical trial (a trial designed to provide data on the drug's efficacy) in the case of Actimab™-A. If these efforts are successful, we may elect to commercialize Iomab™-B on our own or with a partner in the United States and/or outside of the United States to out-license the rights to develop and commercialize the product to a strategic partner. In the case of Actimab™-A, we will most likely seek to enter into strategic partnerships whereby the strategic partner(s) co-fund(s) further human clinical trials of the drug that are needed to obtain regulatory approvals for commercial sale within and outside of the United States. In parallel, we intend to identify and begin initial human trials with additional actinium-225 product candidates in other cancer indications. We intend to retain marketing rights for our products in the United States whenever possible and out-license marketing rights to our partners for the rest of the world. We may also seek to in license other applicable opportunities should such technology become available.

Market Opportunity

We compete in the marketplace for cancer treatments estimated to reach over $83 billion in 2016 sales, according to "The Global Use of Medicines: Outlook Through 2016 Report by the IMS Institute for Healthcare Informatics, July 2012." While surgery, radiation and chemotherapy remain staple treatments for cancer, their use is limited by the fact that they often cause substantial damage to normal cells. On the other hand, targeted monoclonal antibody therapies exert most or all of their effect directly on cancer cells, but often lack sufficient killing power to eradicate all cancer cells with just the antibody. A new approach for treating cancer is to combine the precision of antibody-based targeting agents with the killing power of radiation or chemotherapy by attaching powerful killing agents to precise molecular carriers called monoclonal antibodies (mAb). We use mAbs labeled with radioisotopes to deliver potent doses of radiation directly to cancer cells while sparing healthy tissues. The radioisotopes we use are the alpha emitter Ac-225 and the beta emitter I-131. I-131 is among the best known and well characterized radioisotopes. It is used very successfully in treatment of papillary and follicular thyroid cancer as well as other thyroid conditions. It is also attached to a monoclonal antibody in treatment of Non-Hodgkin's Lymphoma ("NHL"). It is also used experimentally with different carriers in other cancers. Ac-225 has many unique properties and we believe we are a leader in developing this alpha emitter for clinical applications using our proprietary APIT technology.

Our most advanced products are Iomab™-B, I-131 labeled mAb for preparation of relapsed and refractory AML patients for HSCT; and Actimab™-A, Ac-225 labeled mAb for treatment of newly diagnosed AML, a cancer of the blood, in patients ineligible for currently approved therapies. Iomab™-B offers a potentially curative treatment for these patients, most of whom do not survive beyond a year after being diagnosed with this condition. Iomab™-B has also demonstrated efficacy in HSCT preparation for other blood cancer indications, including myelodysplastic syndrome ("MDS"), acute lymphoblastic leukemia ("ALL"), Hodgkin's Lymphoma, and Non-Hodgkin's Lymphoma ("NHL"). These are all follow-on indications for which Iomab™-B can be developed and it is our intention to explore these opportunities at a future date. We believe the aggregate worldwide market potential for the treatment of AML, MDS, ALL, Hodgkin's Lymphoma, multiple myeloma and NHL is approximately $4.1 billion.

In December 2015, we announced that the FDA cleared our IND filing for Iomab-B, and that we will proceed with a pivotal, Phase 3 clinical trial. We anticipate the Phase 3, controlled, randomized, pivotal trial will complete enrollment of patients by 2018 and assuming that the trial meets its endpoints, it will form the basis for a BLA. We, in our recently approved IND filing, established an agreement with the FDA that the path to a BLA submission would include a single, pivotal Phase 3 clinical study if it is successful. The population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed AML patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least six months and the secondary endpoint will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. Iomab-B has completed several physicians sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers, including the Phase 1/2 clinical trial in relapsed and/or refractory AML patients. The results of these clinical trials in over 300 patients have demonstrated the potential of Iomab-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

Other potential product opportunities in which significant preclinical work is being undertaken include metastatic colorectal cancer, metastatic prostate cancer and antiangiogenesis which reduces the blood supply to solid tumors. We believe the worldwide market potential for the treatment of metastatic colorectal cancer is approximately $4.8 billion, and we believe the worldwide market potential for the treatment of metastatic prostate cancer is approximately $6.0 billion. We also believe the worldwide market potential for the treatment of Glioblastoma Multiforme, a potential indication based on an antiangiogenesis approach, is approximately $1.1 billion. We estimate the market potential for these indications based on company research, published rates of disease incidence and company calculations based on costs of currently used therapies.

We believe that our biggest market opportunity lies in the applicability of our APIT platform technology to a wide variety of cancers. A broad range of solid and blood borne cancers can be potentially targeted by mAbs to enable treatment with the APIT technology. The APIT technology could potentially be applied to mAbs that are already approved by the FDA to create more efficacious and/or safer drugs (“biobetters”).

In March 2016, the FDA granted orphan drug designation for Ioamb-B and in October 2016 the European Medicines Agency (EMA) granted orphan designation in the European Union (EU) for Iomab-B. In November 2014, the FDA granted orphan-drug designation for Actimab™-A and in December 2016, we submitted an application to the EMA for orphan designation in the EU for Actimab-A. The FDA, through its Office of Orphan Products Development, grants orphan status to drugs and biologic products that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan drug designation provides a drug developer with certain benefits and incentives, including a period of marketing exclusivity if regulatory approval is ultimately received for the designated indication; potential tax credits on United States clinical trials; eligibility for orphan drug grants; and waiver of certain administrative fees. The EMA, through its Committee for Orphan Medicinal Products (COMP), examines applications for orphan designation. To qualify for orphan designation, the prevalence of the condition must be less than 5 in 10,000, it must be life threatening or chronically debilitating and there must be no satisfactory method of treating the condition. Sponsors who obtain orphan designation receive numerous incentives including protocol assistance, a reduction or waving of fees and 10 years of market exclusivity should the therapy be approved. The process of filing and receiving the orphan medicines designation can take between eight to fourteen months in most cases.

Clinical Trials

Iomab™-B

Iomab™-B is our lead product candidate currently in a pivotal Phase 3 multicenter clinical trial. It consists of the monoclonal antibody BC8 and beta emitting radioisotope iodine 131 (I-131). The indication for that trial is bone marrow conditioning for HSCT in patients with relapsed and refractory AML over the age of 55.

Previous Iomab™-B clinical trials leading to the planned Phase 3 trial currently in preparation included:

Indications	**N**	**Key Findings**
AML, MDS, ALL (adult)	34	–7/34 patients with median disease free state (DFS) of 17 years. –18/34 patients in remission at day 80
AML >1st remission (adult)	23	–15/23 in remission at day 28
AML 1st remission (age 16-50)	43	–23/43 DFS from 5-16 years –30/43 in remission at day 28 –33/43 in remission at day 80
High-risk MDS, advanced AML (age 50+)	68 in dose escalation study 31 treated at MTD	–CR (complete remission) in all patients –1 yr survival ~40% for all patients –1 yr survival ~45% for pts treated at MTD maximum tolerated dose)
High-risk MDS, AML (age 18–50)	14 in dose escalation	All patients achieved full donor chimerism by day 28 post-transplant
High-risk MDS, AML –haploidentical donors (adult)	8 in dose escalation	–6/8 treated patients achieved CR by day 28 –8/8 patients 100% donor chimerism by day 28

5

Ongoing Iomab™-B clinical trials include:

Indications	**Phase**
Relapsed and refractory Hodgkin Lymphoma and NHL (adult)	Phase 1
Advanced AML, ALL and MDS (adult)	Phase 2
AML 1st remission (age 16-50)	Phase 2
High-risk MDS, advanced AML (age 16-50)	Phase 2

There are additional ongoing clinical trials with BC8 antibody labeled with yttrium 90 (Y-90).

Phase 3 Iomab™-B clinical trial in preparation:

We have obtained FDA's comment and guidance on the Iomab™-B Phase 3 clinical trial design, and the FDA has identified the following design features as generally acceptable, dependent on the results of the trial:

~~Si~~ngle pivotal study, pending trial results;