

INSMED INC  
Form FWP  
September 28, 2012

Developing Innovative Inhaled Treatments for Serious  
Lung Infections  
August 2012  
Free Writing Prospectus  
Registration Statement No. 333-182124

This presentation contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this presentation, including statements relating to our financial position, projected year end cash and cash runway, the status and the results of preclinical studies and clinical trials and preclinical and clinical data described herein, the timing of responses to information and data requests from FDA, the development of our products, our estimates of the size of the potential markets for our product candidates, and the business strategies, evaluations, plans and objectives of management, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-

looking  
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Our  
results  
may  
be  
affected  
by  
such  
factors  
as  
the  
receipt  
and  
timing  
of  
FDA  
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other

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December

31,

2011

and

our

Quarterly

Report

on

Form

10-Q

for

the

quarter

ended

June

30,

2012.

Investors

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Safe Harbor Statement

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Insmed: Value Proposition

Attractive

Late-Stage

Opportunity

ARIKACE has strong Phase 2 efficacy and safety data in CF

Amikacin is an FDA-approved antibiotic, long recognized as one of the most effective treatments for gram-negative infections

Compelling

Business Model

Two orphan indications with high unmet need and combined global market potential of over \$1 billion

Limited commercial infrastructure required

Strong IP and potential for extended exclusivity

Strong Balance

Sheet &

Experienced

Management

As of 6/30/12, company reported ~\$75 million in cash, investments & CD

We believe cash is sufficient to take Company through the availability of top-line data for both CF CLEAR-108 trial and TARGET-NTM trial

Management has extensive anti-infective development, regulatory, and commercial experience

ARIKACE

®

\* is a highly differentiated product that offers a compelling business opportunity in two orphan diseases

\* ARIKACE

®

is a registered trademark of Insmmed Incorporated

ARIKACE (liposomal amikacin for inhalation), is in Phase 3 (CLEAR-108)

for cystic fibrosis (CF) *Pseudomonas (Pa)* lung infections and Phase 2

(TARGET-NTM) for non-TB mycobacteria (NTM) lung infections

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**ARIKACE: Amikacin Summary**

Amikacin is an FDA-approved antibiotic with proven efficacy in the treatment of gram-negative infections, including Pseudomonas and NTM

Aminoglycoside antibiotic

Value of the IV use has been limited

by nephro-toxicity and ototoxicity

ARIKACE (liposomal amikacin for inhalation) delivers high, sustained levels of drug to

the lung while reducing systemic exposure to well below established toxicity levels

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ARIKACE: Proprietary Liposomal Formulation Provides Basis  
for Important Potential Benefits

Potential Benefit

Lipid Polar Head Groups

(at Both Surfaces)

Lipid Hydrophobic Chains

(Bi-Layer Interior)



Water Core (where Amikacin resides)

ARIKACE delivers the potency of Amikacin at the site of the lung infection;

engineered specifically for improved PK-PD\* profile in the lung providing for potential enhanced efficacy, safety and convenience benefits

Greater efficacy by reaching infection site

Greater efficacy by reaching infection site

Greater efficacy and once-a-day dosing

Reduces potential for systemic toxicity

Engineered Specifically for Lung Delivery

Prolonged lung residence time

Biofilm penetration

Preferential uptake into macrophages

Minimal systemic exposure

\* Pharmacokinetic-Pharmacodynamic (PK-PD)

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ARIKACE: Delivery Using Proprietary eFlow

®

Technology

ARIKACE is delivered once daily via the state-of-the-art PARI Optimized, Investigational eFlow Nebulizer System with Advanced Mesh Technology

Fast

drug delivery with efficient

lung deposition  
Small, portable, silent and  
cordless  
device weighs less than  
10 ounces.  
eFlow Technology Device  
exclusivity  
from PARI Pharma for  
15 years after first commercial  
sale of ARIKACE

\* eFlow

®

is a registered trademark of PARI Pharma GmbH

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ARIKACE: Development Plan

Target-NTM

Study in U.S.

ARIKACE vs. placebo in recalcitrant patients who are on a stable ATS/IDSA

guidelines-based

multi-drug

treatment

regimen;  
N  
100  
No  
inhaled  
antibiotics  
approved  
for  
treating  
NTM  
lung  
infections  
and  
little  
known competitive activity in clinic  
Study  
initiated  
in  
May-2012  
top-line  
results  
from  
randomized  
portion  
of  
trial projected in 4Q13  
CLEAR-109  
CF Pseudomonas  
Study for U.S.  
FDA  
removed  
the  
clinical  
hold  
for  
CF  
Pa  
Phase  
3  
study  
in  
May  
Insmmed  
will  
defer  
plans  
to  
initiate  
a  
Phase

3

study

of

ARIKACE

in

the

U.S.

for

CF patients until the Company reviews top-line results from CLEAR-108

Insmed is focusing on CLEAR-108 (CF Pa Phase 3 Study) and TARGET-NTM

(NTM Phase 2 Study)

CLEAR-108

CF Pseudomonas

Study for

EU/Canada

ARIKACE

vs.

Tobi

®

(inhaled

tobramycin

solution);

N

300

Builds off of strong Phase 2 efficacy and safety data

Broad population with preferred trial design

Trial

initiated

in

April

2012

top-line

results

projected

in

mid-2013

Eligible

patients

roll-over

into

open-label

ARIKACE®

long

term

safety

and

tolerability study, CLEAR-110

\* Tobi

®

is a Registered Trademark of Novartis Pharmaceuticals Corporation

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Arikace Cystic Fibrosis

Epidemiology and Disease Description

Cystic fibrosis is a life-threatening disease with significant unmet needs

Affects about 70,000 children

and adults worldwide (30,000 in

U.S. and Europe, each)

Inherited disease that causes

thick, sticky mucus to build up  
in the lungs

Despite expanded use of current  
products, lung function often  
continues to decline

High treatment burden  
major compliance issue

Source: Adapted from Cystic Fibrosis Foundation, Patient Registry  
Annual Data Reports 2010

Mean = 51.2%

Pseudomonas Lung Infections Increase with Patient Age

Age (Years)

0.0

10.0

20.0

30.0

40.0

50.0

60.0

70.0

80.0

<2

2 to 5

6 to 10

11 to 17

18 to 24

25 to 34

35 to 44

45+



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ARIKACE: Cystic Fibrosis

Need for New Inhaled Antibiotics

Current inhaled antibiotics produce modest efficacy in a limited patient

population providing an opportunity for ARIKACE to become first-line treatment

Current inhaled antibiotics are not indicated for a significant segment of the

CF population --

patients with FEV-1 % predicted of greater than 75%

Improvement in lung function with current inhaled antibiotics is not sustained

in the off-treatment period, and appears to decline over multiple cycles

Lung function continues to decline at an average rate of 1% to 3% per year with some patients experiencing much greater declines

9  
Cayston  
®  
vs. Tobi  
®  
CF Phase 3 Trial Results: Pulmonary Function  
Lung Function  
Adjusted

Mean  
Relative  
Change  
in  
FEV  
1  
%

Predicted

Source: 2010 North American CF Conference Poster 305 and Slide Presentation, 10/10.

\* Cayston

®

(aztreonam

for

inhalation

solution)

is

a

registered

trademark

of

Gilead

Sciences.

\*\* Tobi

®

(Tobramycin Inhalation Solution) is a registered trademark of Novartis.

\*\*\* AZLI = Cayston; TIS = Tobi

Lung function returned to baseline or lower during each off treatment period and at the end of 24 weeks, both treatment groups showed a decline in lung function from baseline

Week:

2

AZLI

TIS

+ 7.8

P

= 0.0001

95% CI (3.86, 11.73)

-6

-4

-2

0

2

4

6

8

10

12

0

4

8

12

16

20

24

AZLI/

TIS

28 Days

AZLI/

TIS

28 Days

AZLI/

TIS

28 Days

10  
Off-Treatment  
Period  
P = 0.033  
P = 0.003  
(36/36)  
(36/35)  
(33/36)

(32/35)

(34/35)

(34/34)

(N=ARIKACE/Placebo)

ARIKACE: Cystic Fibrosis

Phase 2 Pooled Results (560mg QD): Pulmonary Function

(N)

Mean (SE)

ARIKACE demonstrated statistically significant and clinically meaningful improvement in pulmonary function throughout the 28-day treatment period that was sustained through the off-treatment period

-6%

-3%

0%

3%

6%

9%

12%

15%

18%

0

7

14

21

28

56

Visit Day

% Change in FEV

1

(ml) vs. Baseline

Arikace

560mg

Placebo

11

Visit Days

ARIKACE: Cystic Fibrosis

Open Label Extension (TR02-105): Durability of Response

Treatment

Period

\* Significance at end of treatment over 6 cycles

\*\* Significance 56 days off-treatment over 6 cycles



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An open label extension study demonstrated the sustained efficacy  
of ARIKACE during and between multiple cycles of therapy

Patients Receiving 560 mg ARIKACE Once Daily for 28 Days and Off-Treatment for 56 Days

$p=0.0001^{**}$

$p<0.0001^{*}$

Cycle

1

Cycle

2

Cycle

3

Cycle

4

Cycle

5

Cycle

6

0

5

10

15

20

14

28

56

70

85

98

112

140

154

169

182

196

224

238

253

266

280

308

322

337

350

364

392

406

421

434

448

476

490  
504

12

ARIKACE: Cystic Fibrosis

Phase 3 Program Has Been Initiated in Europe and Canada

Insmed has reached agreement with EMA and Health Canada on pivotal study requirements for CF patients with Pseudomonas lung infections

\* Patients who complete CLEAR-108 are eligible to participate in CLEAR-110, which is a long term open-label extension study in which patients receive ARIKACE every other month for up to 2 years

CLEAR-108: Phase 3 Primary Efficacy Study (vs. Tob)

®

, N

300)\*

Primary End-Point: Relative Change in FEV-1 at week 24

Key Secondary End-Point: Time to First Pulmonary Exacerbation

Patient

Population:

Patients

ages

6

and

above

with

FEV-1

%

Predicted

25%

Approximately 260 patients required to demonstrate non-inferiority at agreed upon

Top-Line results projected in mid-2013

margin with 80% power

13  
ARIKACE: Non-TB Mycobacteria  
Disease Description and High Unmet Need  
NTM  
are  
intracellular  
organisms  
that

invade  
and  
multiply  
chiefly  
within  
macrophages  
in  
the lung and are characteristically resistant to most antibiotics  
NTM lung infections occurs commonly in patients with structural lung disease (e.g. COPD, bronchiectasis and CF), patients taking immunosuppressive medications, and in postmenopausal women without clear risk factors  
NTM lung infections are often debilitating and progressive  
Virtually all patients experience chronic or recurring cough  
Other frequent symptoms including sputum production, fatigue, malaise, dyspnea, fever, hemoptysis, chest pain and weight loss  
Non-TB mycobacteria (NTM) are intracellular pathogens that can cause severe, chronic pulmonary disease with limited effective treatment options  
ATS -  
American Thoracic Society;  
IDSA -  
Infectious Disease Society of America  
Current  
treatment  
for  
NTM  
lung  
disease  
requires  
lengthy  
multi-drug  
regimens  
that  
can  
be  
poorly  
tolerated  
and  
have  
limited  
efficacy,  
especially  
in  
patients  
with  
severe  
disease  
or  
in  
those  
who

have  
failed  
prior  
treatment  
attempts  
David  
E.  
Griffith,  
M.D.,  
Lead  
author  
of  
the  
ATS/IDSA's  
diagnosis  
and  
treatment  
guidelines  
for  
NTM,  
and  
Professor  
of  
Medicine  
at  
the  
University  
of  
Texas  
Health  
Science  
Center  
at  
Tyler;(Insmed  
Press  
Release,  
6/27/12)

14

ARIKACE: Non-TB Mycobacteria

Market Opportunity

The prevalence of this debilitating chronic disease continues to grow, and

the current NTM treatment paradigm lacks acceptable treatment options \*

Sources: 1. Clarity Pharma Research, Patient Chart Study, 2012.

2.



Adjemian et al. Prevalence of Pulmonary Nontuberculous Mycobacterial Disease among Medicare Beneficiaries, USA, 1997-2007, American Journal of Respiratory and Critical Care Medicine. Apr 2012.

3. SDI Healthcare Database, July 2009.

Mycobacterium avium Complex; M. abscessus

Mycobacterium abscessus

U.S. Patients Diagnosed with NTM Lung Infections in 2011

50K

40K

21K

Diagnosis

growing

at~

8%

annually

2

MAC and M. abscessus\* account for 75%-85% of NTM lung disease in U.S.

Mean age is ~ 57 years with 53%

treated

with

antibiotics

1

Treated patients use an average of 7.6

antibiotic

courses

per

year

3

Average length of inpatient hospital

stay

is

10.2

days

3

Patients over the age of 65 years were

40% more likely to die than those

without

NTM

from

1997

to

2007

2

\* Mark Rolfe, M.D. FCCP, President of New Lung Associates P.A., Medical Director of the Lung Transplant and Adult Cystic Fibrosis Programs at Tampa General Hospital; Insmmed press release, June 27, 2012

0

10,000

20,000

30,000

40,000

50,000  
60,000  
NTM Patients  
Diagnosed  
NTM Patients  
Diagnosed with  
MAC or M.  
Abscessus  
MAC & M.  
abscessus  
Patients Treated  
with Anitbiotics  
1

15

ARIKACE: Non-TB Mycobacteria

Rationale for ARIKACE

NTM lung infections are difficult to treat since NTM are taken up and multiply inside lung macrophages and most antibiotics have poor macrophage penetration

Amikacin IV is a recommended treatment for MAC and

M. abscessus in the ATS/IDSA's NTM diagnosis and treatment

guidelines

1

but

use

is

limited

due

to

nephro-

and

oto-toxicity

The proprietary liposomal formulation enables ARIKACE to be

preferentially

taken

up

and

concentrated

in

the

lung

macrophages

while

potentially

decreasing systemic exposure and related toxicities

ARIKACE

was

shown

to

have

superior

in

vitro

activity

against

MAC

and

M.

abscessus

vs.

free

amikacin

2

ARIKACE

is

well

positioned

to

become

the

first

drug  
approved  
for  
NTM  
lung  
infections

ARIKACE opportunity: achieve superior efficacy in NTM treatment by better penetrating lung macrophages where NTM bacteria reside while limiting systemic drug exposure

Sources: 1. Griffith et al. ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of NTM Diseases, American Journal of Respiratory and Critical Care Medicine, 2007.

2.

Study conducted by L. E. Bermudez at Oregon State University. (Data on File)

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ARIKACE: Non-TB Mycobacteria  
TARGET-NTM Clinical Study Initiated in Mid-2012  
Trial Design and Patient Population (N  
100):

Randomized, double-blind, placebo controlled Phase 2 study in patients with  
recalcitrant/persistent NTM lung infections who are on a stable ATS/IDSA

guidelines-based multi-drug treatment regimen

Patients receive ARIKACE or placebo daily for 84 days; then all patients can receive ARIKACE 560 mg in an open-label manner for an additional 84 days

Study population: patients ages 18 to 75

Key Inclusion Criteria: History of chronic infection with either Mycobacterium avium complex

(MAC)

or

Mycobacterium

abscessus

or

mixed

infection

with

both

species

Primary endpoint: Change in mycobacterial culture results from baseline to end of treatment [Time

Frame:

84 days]

Insmmed appears to be the only company with an NTM clinical program;

top-line Phase 2 data projected in 4Q 2013

There have been very few clinical trials to support current NTM treatment recommendations, and no new drugs have been assessed in randomized trials for NTM lung disease in many years. (Insmmed Press Release, June 27, 2012)

according to Kenneth N. Olivier, M.D., M.P.H., Principal Investigator of the study and staff pulmonologist at the NIAID, part of NIH

17  
Projected  
Cash at year  
end 2012  
(including cash,  
investments & CD  
)  
Approximately \$60 to \$64 million currently forecast



We believe cash is sufficient to take Company through the availability of top-line data for both CLEAR-108 and TARGET-NTM top-line results

Current Overview: Capital Structure and Key Financials

Balance Sheet

Cash of ~\$75 million as of June 30, 2012 consisting of cash, investments & CD

Present Capital

Structure

(INSM)

26.5 million fully diluted shares:

24.9 million Common Shares

1.6 million options, restricted stock units, and warrants

Insmmed has a strong cash position

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Appendix  
Addressing the Potential for Cross-Resistance of ARIKACE

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Summary: Addressing Potential for Cross-Resistance in  
ARIKACE

While resistance to TOBI (tobramycin) has been [documented](#), we believe there is no cross-resistance in ARIKACE (amikacin) for the following reasons.

Well-characterized clinical isolates of *Pseudomonas aeruginosa* (Pa) from Dr. Burns collection have been tested against amikacin

and

ARIKACE.

ARIKACE

has  
shown  
activity  
against  
aminoglycoside-resistant  
and  
multi-drug  
resistant  
isolates.

Dr.

Burns

felt

ARIKACE performed a bit better than free amikacin. (Report on file.)

Overall, amikacin has lower potential for inducing resistance as compared to tobramycin (literature).

Additionally,

aminoglycoside-inactivating enzymes elaborated by Pa are different for these two aminoglycosides. Thus, there is no complete cross resistance. The issue of emerging tobramycin resistance secondary to TOBI (inhaled antibiotic) use is not completely quantified.

However,

it

is

primarily

due

to

poor

compliance

with

the

prescribed

regimen

of

TOBI.

Patients

do

not take

the drug twice a day consistently. This leads to drug levels much below the MICs of most phenotypes of Pa for prolonged periods and thus increased potential for emergence of resistance.

Additionally, there is non-specific binding of cationic tobramycin to sputum and further low levels available to microbes. Typically, levels >10x of the MICs are needed for entire dosing interval.

Thus, compliance with dosing regimen is critical as is penetration of antibiotics into biofilms.

Features of ARIKACE that overcome some of the issues responsible

for resistance include: charge neutral liposomes shield

amikacin, providing penetration into biofilm, and high C<sub>max</sub> and AUC, enabling once a day dosing and improved compliance.

unique features of ARIKACE will reduce potential for emergence of amikacin resistance vs. free aminoglycoside for inhalation.

Most importantly, the sustained clinical benefit of Arikace in the off month

and convenience of once a day will shape the use of

inhalation antibiotics in CF patients.

Use of ciprofloxacin is known to contribute to emergence of Pa isolates with antimicrobial resistance. Tobramycin is also used

IV  
for  
treatment  
of  
exacerbations  
and  
for  
tune-ups.

This  
may  
also  
be  
contributing  
to  
emergence  
of  
resistance  
as  
low  
levels  
of  
drug reach the lung after IV use.

Our phase 2 data have shown that 65% of isolates were resistant to aminoglycosides and ~90% were mucoid variant. However, we were able to demonstrate reduction in bacterial density and improvement in lung function and pros. Thus, we expect to have significant treatment effect in phase 3 studies even if isolates are resistant. We have also done in vitro work against mdr isolates and shown ARIKACE to be effective.



21  
Percent Change in FEV  
1  
ITT  
Visit Day  
Arikace 560 \*  
15.4% (16.5)  
18.4% (21.3)

13.2% (15.3)

13.2% (16.2)

11.5% (16.4)

13.2% (24.3)

Arikace 280 \*

10.9% (10.6)

9.4% (12.6)

9.6% (12.5)

10.1% (12.8)

1.7% (9.0)

2.0% (8.6)

Placebo \*

0.6% (11.7)

-3.2% (12.2)

1.8% (10.9)

2.2% (11.9)

-0.3% (12.0)

-4.4% (13.0)

\* Mean (SD)

Arikace 280

Placebo

Arikace 560

p=0.016

p=0.005

p=0.07

p=0.04



22  
Change in FEV  
1  
(% predicted) ITT  
Visit Day  
Arikace 560 \*  
12.9% (17.2)  
15.8% (22.5)

10.5% (15.6)

11.0% (16.4)

8.6% (17.7)

13.8% (26.2)

Arikace 280 \*

10.8% (10.8)

9.2% (13.1)

9.4% (12.9)

9.6% (13.7)

1.6% (9.6)

1.8% (8.8)

Placebo \*

-0.9% (10.7)

-4.4% (11.3)

0.3% (9.9)

0.5% (10.5)

0.7% (9.6)

-3.8% (13.5)

Arikace 280

Placebo

Arikace 560

P=0.009

P=0.019

P=0.124

P=0.021

\* Mean (SD)

23  
ARIKACE TR02-05  
PFT: Prior Use of Inhalation Antibiotic  
Arikace  
( N = 8 )  
Placebo  
( N = 4 )  
Day 28

10 %

-5 %

Day 56

5 %

-1 %

Relative Change FEV

1

(ml)

24  
Tobramycin  
FEV  
1  
(L) Absolute

25  
ARIKACE TR02-05  
By Prior Tobramycin Use  
Patients With Prior  
Tobramycin Use  
Patients Without Prior  
Tobramycin Use  
Arikace

N=5  
Placebo  
N=3  
Arikace  
N=16  
Placebo  
N=8  
Day 28  
0.326 (0.290)  
5  
-0.083 (0.123)  
3  
0.126 (0.203)  
16  
-0.016 (0.144)  
8  
Day 56  
0.152 (0.186)  
5  
-0.040 (0.284)  
3  
0.001 (0.161)  
15  
-0.120 (0.168)  
8  
\*  
Absolute  
Change  
from  
Baseline  
-  
FEV  
1  
(L)  
Cohort I  
280 mg

ARIKACE TR02-05  
By Prior Tobramycin Use  
26  
\* Mean (SD)  
280mg Cohort  
Patients without Tobramycin  
280mg Cohort  
Patients with Tobramycin



Arikace  
Placebo  
Arikace  
Placebo  
Visit Day  
Visit Day  
Arikace \*  
326 (290)  
152 (186)  
Placebo \*  
-83 (123)  
-40 (284)  
Arikace \*  
126 (203)  
1 (161)  
Placebo \*  
-16 (144)  
-120 (168)  
RUN12AUG2008  
26

27  
Tobramycin  
FEV  
1  
(L) Relative

28  
ARIKACE TR02-05  
By Prior Tobramycin Use  
Patients With Prior  
Tobramycin Use  
Patients Without Prior  
Tobramycin Use  
Arikace

N=5

Placebo

N=3

Arikace

N=16

Placebo

N=8

Day 28

0.136 (0.088)

5

-0.052 (0.075)

3

0.091 (0.138)

16

-0.002 (0.067)

8

Day 56

0.051 (0.093)

5

-0.010 (0.148)

3

0.009 (0.084)

15

-0.053 (0.083)

8

\* Mean (SD)

\*

Relative

Change

from

Baseline

-

FEV

1

(L)

RUN12AUG2008

Cohort I

280 mg

29  
ARIKACE TR02-05  
By Prior Tobramycin Use  
\* Mean (SD)  
RUN12AUG2008  
280mg Cohort  
Patients without Tobramycin  
280mg Cohort

Patients with Tobramycin

Arikace

Placebo

Arikace

Placebo

Visit Day

Visit Day

Arikace \*

13.6% (8.8)

5.1% (9.3)

Placebo \*

-5.2% (7.5)

-1.0% (14.8)

Arikace \*

9.1% (13.8)

0.9% (8.4)

Placebo \*

-0.2% (6.7)

-5.3% (8.3)

30

Arikace

-

Efficacy in Patients with Prior Tobramycin Use:

TR02-106

Mean

Change in Log

10

CFU

Subjects with 5-6 Cycles of TOBI in  
prior 12 months

Change in FEV<sub>1</sub>  
(ml)

Subjects with 5-6 Cycles of TOBI in  
prior 12 months

Placebo

Visit Day

Visit Day

Arikace 560

90 (220)

90 (30)

230 (60)

90 (90)

Placebo

-140 (210)

-110 (350)

-200 (20)

-290 (10)

Arikace 560

Arikace 560

-1.99

(0.70)

-1.26

(0.86)

-0.93

(1.19)

-1.43

(0.89)

-0.27

(0.44)

Placebo

0.15

0.03

-0.55

-0.29

0.08

Placebo

Arikace 560

Mean

-3

-2

-1

0

1

2

3

0

7



14  
21  
28  
35  
-300  
-250  
-200  
-150  
-100  
-50  
0  
50  
100  
150  
200  
250  
0  
28  
56  
70  
84

31

Insmed has filed a registration statement (including a prospectus) with the Securities and Exchange Commission (the SEC) for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents Insmed has filed with the SEC for more complete information about Insmed and this offering. You may get these documents for free by visiting EDGAR on the SEC web site at [www.sec.gov](http://www.sec.gov).

Alternatively,

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