

UNITED STATES  
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): June 6, 2015

**ANTRIABIO, INC.**

(Name of registrant in its charter)

**Delaware**  
(State or jurisdiction  
of incorporation or  
organization)

**000-54495**  
(Commission File  
Number)

**27-3440894**  
(IRS Employer  
Identification No.)

**1450 Infinite Drive**  
**Louisville, CO 80027**  
(Address of principal executive offices)

**(303) 222-2128**  
(Registrant's telephone number)

\_\_\_\_\_  
(Former name or former address, if changed since last report)

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 (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01. Regulation FD Disclosure.**

On June 6, 2015, Dr. Brian Roberts gave an oral presentation at the American Diabetes Association 75th Scientific Sessions® in Boston (the “**Presentation**”) which is attached hereto herein as Exhibit 99.1. On June 8, 2015, we issued the press release attached hereto as Exhibit 99.2 announcing the Presentation and providing a link to the Presentation in the press release. In accordance with General Instruction B.2 of Form 8-K, the information set forth herein, the Presentation and in the press release is deemed to be “furnished” and shall not be deemed to be “filed” for purposes of the Securities Exchange Act of 1934, as amended. The information set forth in Item 7.01 of this Current Report on Form 8-K shall not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is required to be disclosed solely to satisfy the requirements of Regulation FD.

**Item 9.01 Financial Statements and Exhibits**

**EXHIBIT DESCRIPTION**

99.1	Presentation **
99.2	Press Release of AntriaBio, Inc. dated June 8, 2015 **

\*\* The following exhibits relating to Item 7.01 is intended to be furnished to, not filed with, the SEC pursuant to Regulation FD.

**SIGNATURES**

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.

**ANTRIABIO, INC.**

DATE: June 8, 2015

By: /s/ Morgan Fields  
Morgan Fields  
Chief Accounting Officer

## EXHIBIT INDEX

EXHIBIT	DESCRIPTION
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99.1	Presentation **
99.2	Press Release of AntriaBio, Inc. dated June 8, 2015 **

\*\* The following exhibits relating to Item 7.01 is intended to be furnished to, not filed with, the SEC pursuant to Regulation FD.



# **The in Vitro and in Vivo Pharmacology of AB101, a Potential Once-Weekly Basal Subcutaneous Insulin**

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BRIAN K ROBERTS, XUEYAN WANG, MARY S ROSENDAHL,  
SANKARAM MANTRIPRAGADA, *Louisville, CO*

97-OR

American Diabetes Association 75<sup>th</sup> Scientific Sessions®

June 6, 2015



## **Forward-Looking Statements**

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This presentation contains forward-looking statements about AntriaBio, Inc. (the “Company”). These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to the Company’s lead product candidate AB101, AB101’s potential and related matters, which involve known and unknown risks and uncertainties. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publically update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

## **Disclosures**

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All authors are employees and stock option holders of AntriaBio, Inc., the sponsor/company developing AB101

## **AB101 Addresses an Unmet Need for a Longer-Acting Basal Insulin**

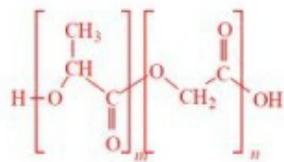
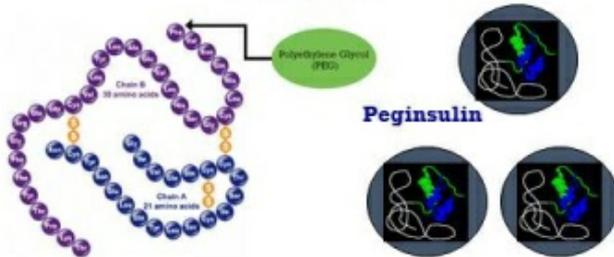
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- **Barriers to adequate insulin utilization may include**
  - Insulin/needle-averse patients
  - Safety concerns, including hypoglycemia
  - Weight gain
- **A longer-acting basal insulin represents a convenient, effective, and safe treatment option**
  - AB101 is being developed as a once-weekly subcutaneous insulin injection
  - In contrast to currently available basal insulin analogs, AB101 requires no modification to the native recombinant insulin structure

# AB101 is a Slow Release Microsphere Encapsulated Peg (5 kDa)-insulin

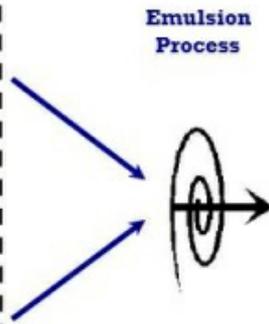
PEG + native Insulin = soluble insulin

5 kDa PEG attached to the N-terminus of insulin's B-Chain using site-specific amine PEGylation.

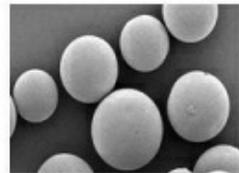


Poly(lactic-co-glycolic acid) (PLGA)

Peginsulin + PLGA = slow release microspheres



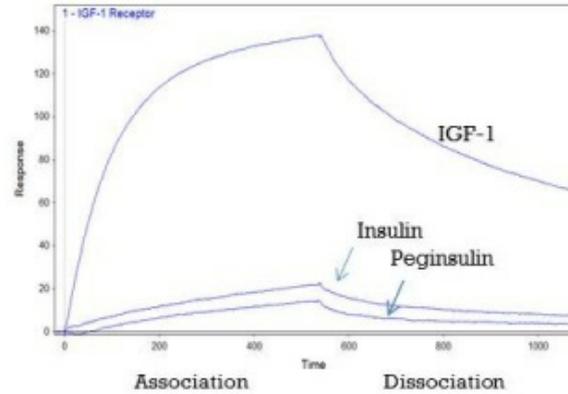
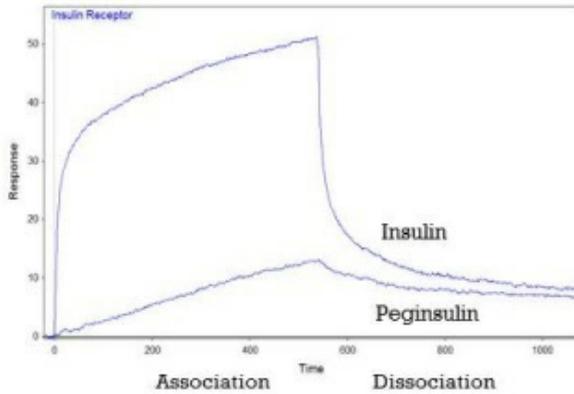
End Result: AB101  
Drug dispersed evenly  
throughout microspheres



# Peginsulin (Drug Substance) Exhibits Receptor Binding Kinetics Predictive of Desired Pharmacology with Low Mitogenic Potential

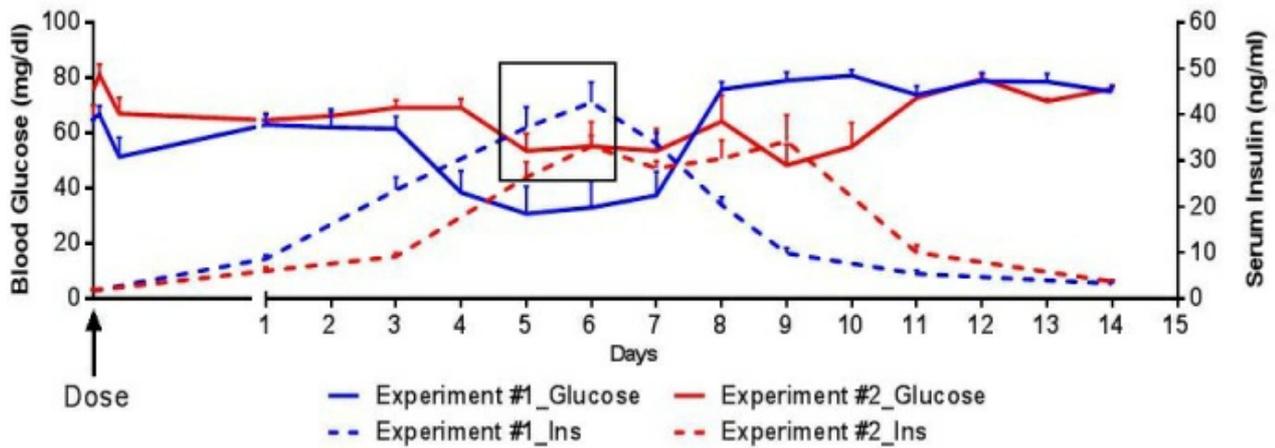
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Insulin and IGF-1 receptor binding kinetics Using Surface Plasmon Resonance (Biacore 3000)



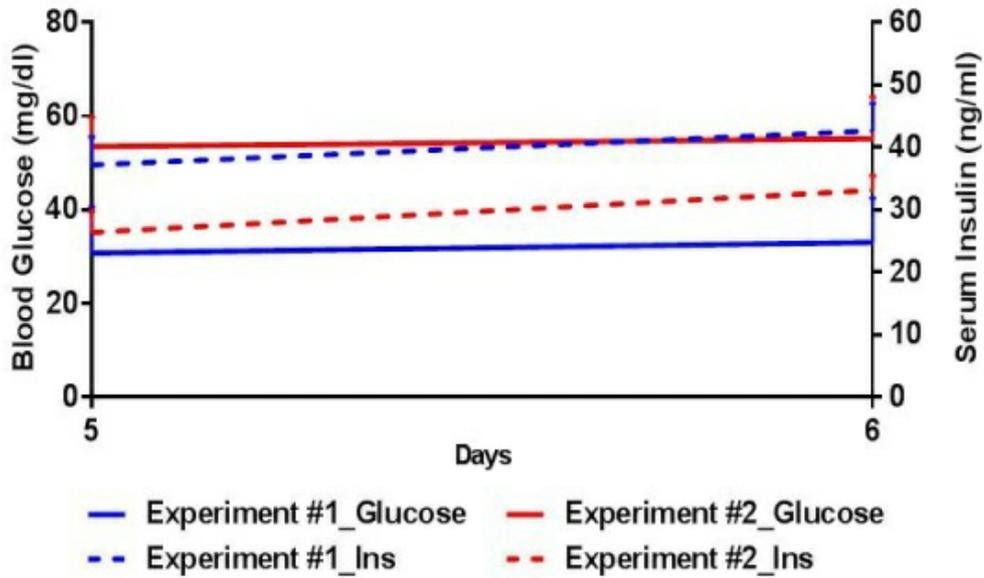
# AB101 Single Dose SC Administration to Normal Rats Results in Slow Onset, Sustained PK-PD

Serial Fasting Glucose and Insulin Measurements After a Single Dose of 37.5 mg/kg in Normal Sprague Dawley Rats (N=6)



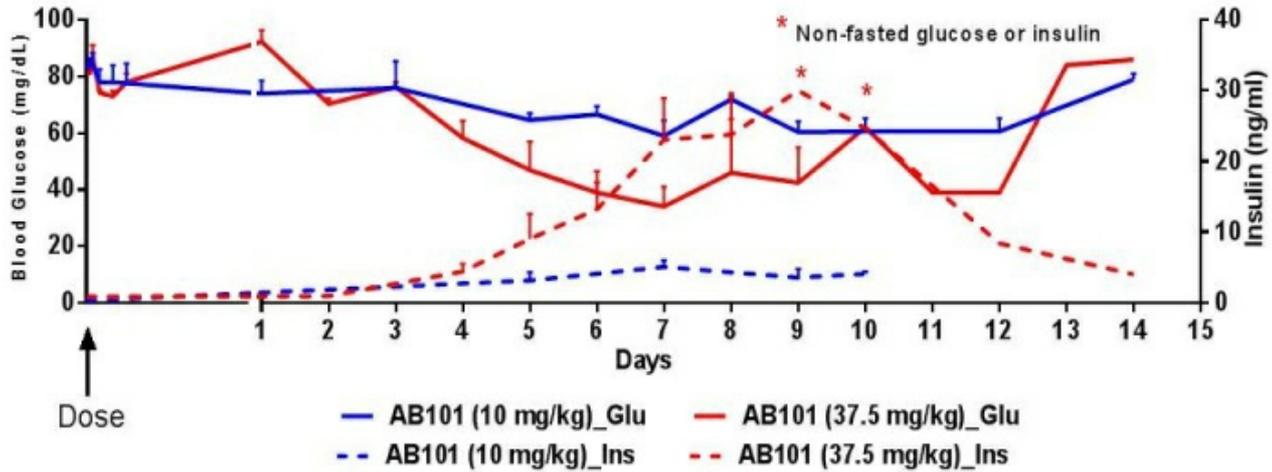
## AB101 Produces Peakless Pharmacology Over the Time-Action Duration Associated with Currently Available Basal Insulins (24h)

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# AB101 Single Dose SC Administration to Normal Dogs Results in Slow Onset, Sustained PK-PD

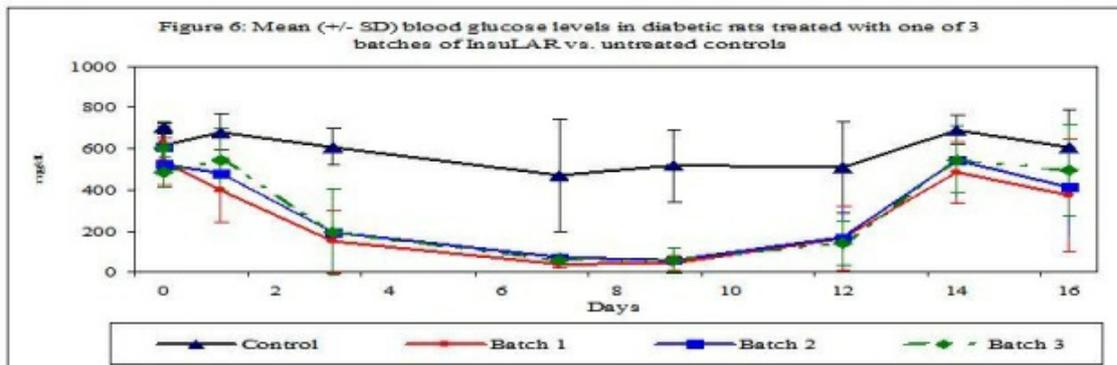
Serial Fasting Glucose and Insulin Measurements After a Single Dose in Normal Beagle Dogs (N=3/dose group)



## Pharmacology Summary

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- Potency and activity are comparable to recombinant human insulin
- Slow onset, sustained insulin increases and corresponding glucose reductions over the course of ~1 week in 2 species (rats and dogs)
- No acute insulin release or glucose reduction observed
- Data support weekly dosing as a basal insulin
- To our knowledge, only non-analog (native human insulin) to have an extended duration of action
- Similar results previously reported in a STZ-induced diabetes rat model



Hinds et al, JCR, 2005

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## **How Does this Translate to the Treatment of Diabetes?**

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- Inter-species homology of insulin/receptor predicts insulin activity in humans
- No expected differences in activity in diabetes compared to non-diabetes (time-action profile or pharmacodynamics)
- Pharmacology in dogs observed at predicted doses based on:
  - Typical daily insulin needs supplied over one week
  - Allometric predictions
  - Adjustments for minor differences in receptor potency/activity
- Efficacious doses in dogs can be readily translated to human clinically relevant doses
- Projected human doses can be administered via acceptable volumes and needle gauge
- IND-enabling work is ongoing and an IND application for clinical trials is forthcoming

## Acknowledgements

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- **AntriaBio, Inc. Scientists:**
  - Aimee Stutts
  - James Vardas
- **Contract Research Labs:**
  - ZenBio (CA)
  - 7<sup>th</sup> Wave Labs (MO)
  - High Quality Research Labs (CO)
- **Scientific/Clinical Advisory Board**
  - Andrew R. Hoffman
  - Philip Home
  - C. Ronald Kahn
  - Fredrick B. Kraemer
  - Jerrold Olefsky





## **AntriaBio Announces Promising Preclinical Results for Once-Weekly Basal Insulin AB101**

- *AB101 drug substance retained similar receptor binding affinity and receptor-mediated biological activity compared to native insulin*
- *Single dose subcutaneous administration of AB101 in rats and dogs led to slow onset, sustained insulin increases and corresponding glucose reductions over the course of a week*
- *PK/PD profiles support the target product profile of AB101 as a once-weekly basal insulin therapy for type 1 and type 2 diabetes*

**LOUISVILLE, CO – (Marketwired) – 06/08/15 – AntriaBio, Inc.** (“AntriaBio” or the “Company”) (OTCQB: ANTB), a biopharmaceutical corporation developing novel extended release therapies, released preclinical results for its lead product candidate, AB101, at the American Diabetes Association 75<sup>th</sup> Scientific Sessions® in Boston. The results demonstrated that AB101 has comparable in vitro pharmacology to native insulin, and in two animal species exhibited a prolonged subcutaneous insulin absorption profile, resulting in slow onset, peakless and sustained insulin levels and glucose reduction, without acute hypoglycemia caused by an insulin burst. These observations occurred at clinically relevant dose projections, demonstrating proof of concept of the potential for AB101 as a weekly subcutaneous basal insulin therapy in patients with diabetes mellitus.

"We are delighted by the results of our preclinical proof of concept pharmacology studies of AB101," said Brian Roberts, M.D., Vice President of Clinical Development at AntriaBio. "In addition to enabling significant progress toward filing our IND, these results affirmed our predicted dose-response and can be readily translated to clinically relevant doses and dose volumes in humans. We now have even greater confidence that similar safety and long-acting clinical pharmacology will be observed in clinical trials, which we are hopeful will one day translate into an important new treatment option for clinicians and patients."

"The availability of a longer-acting basal insulin therapy would provide physicians with a new treatment tool for their patients," said Philip Home, M.A., D. Phil., D.M., F.R.C.P., Professor of Diabetes Medicine at Newcastle University and previous clinical lead to the International Diabetes Federation (IDF) guidelines. "These results are encouraging, as they show that AB101 could be a promising new insulin therapy option for people with diabetes."

In receptor binding studies, the AB101 drug substance was found to have an affinity for the insulin receptor that is similar to native insulin once bound, which predicts insulin activity in humans. The drug substance also displayed a low affinity for the IGF-1 receptor, which would indicate a low risk of mitogenicity. In liver cells, the AB101 drug substance inhibited glucose production to the same magnitude and with the same potency as native insulin. The inhibitory effect on glucose production occurred at an IC<sub>50</sub> of 0.24 nM, which was nearly identical to that of native insulin at an IC<sub>50</sub> of 0.23 nM.

In vivo studies were conducted in rats and dogs. Fasting insulin and glucose were measured at baseline and multiple times over a 14-day period after a single subcutaneous dose (37.5 mg/kg or vehicle control in rats [n=6/group]; 10 mg/kg or 37.5 mg/kg in dogs [n=3/group]). In both species, slow and sustained increases in insulin were observed, with a C<sub>max</sub> of >30 ng/mL at 7 – 9 days post dose, and corresponding dose and species-dependent maximum reductions in glucose of 30 – 50%. The ratio of AUC<sub>(0-24h)</sub> to AUC<sub>(0-total)</sub> for insulin and glucose was <1%. A similar sustained PK/PD profile was demonstrated in a diabetes animal model.

The data presentation that was presented by Dr. Roberts during the “Basal Insulin Analogs – New Evidence” oral session at the American Diabetes Association 75<sup>th</sup> Scientific Sessions® in Boston can be found [here](#).

AntriaBio is currently engaged in additional studies for AB101 that support the filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration.

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**About AntriaBio, Inc.**

AntriaBio is a biopharmaceutical company that develops novel extended release therapies by combining proprietary formulation and manufacturing capabilities with well-known molecules to significantly improve standards of care. AntriaBio's lead product candidate is AB101, an injectable once-weekly basal insulin for type 1 and type 2 diabetes that addresses a \$11 billion market where the current standard of care is a once-daily basal insulin injection. For more information visit: [www.antriabio.com](http://www.antriabio.com).

**Forward-Looking Statements**

This release, like many written and oral communications presented by AntriaBio, Inc., and our authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies 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. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of the Company, are generally identified by use of words "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, AntriaBio undertakes no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made.

**AntriaBio, Inc. Contact:**

Noopur Liffick  
VP of Corporate Development  
(650) 549-4175  
[investor-relations@antriabio.com](mailto:investor-relations@antriabio.com)

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