

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): **September 30, 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.

Representatives of AntriaBio, Inc. will use the investor presentation (“Investor Presentation”) attached hereto as Exhibit 99.1 with various meetings with investors from time to time. In accordance with General Instruction B.2 of Form 8-K, the information set forth herein and in the Investor Presentation 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	Investor Presentation *

* The following exhibit 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: September 30, 2015

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

EXHIBIT INDEX

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antriabio

www.antriabio.com

(OTCQB: ANTB)

Forward-looking Statements

Statements in this presentation that are not descriptions of historical facts are forward-looking statements relating to future events, and as such all forward-looking statements are made pursuant to the Securities Litigation Reform Act of 1995. Statements may contain certain forward-looking statements pertaining to future anticipated or projected plans, performance and developments, as well as other statements relating to future operations and results. Any statements in this presentation that are not statements of historical fact may be considered to be forward-looking statements. Words such as "may," "will," "expect," "believe," "anticipate," "estimate," "intends," "goal," "objective," "seek," "attempt," or variations of these or similar words, identify forward-looking statements.

These forward-looking statements by their nature are estimates of future results only and involve substantial risks and uncertainties, including but not limited to risks associated with the uncertainty of future financial results, additional financing requirements, development of new products, successful completion of the Company's proposed restructuring, the impact of competitive products or pricing, technological changes, the effect of economic conditions and other uncertainties detailed from time to time in our reports filed with the Securities and Exchange Commission.

There can be no assurance that our actual results will not differ materially from expectations and other factors more fully described in our public filings with the U.S. Securities and Exchange Commission, which can be reviewed at www.sec.gov.

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**AntriaBio is a biopharmaceutical
company that develops novel, sustained
release injectable therapies**



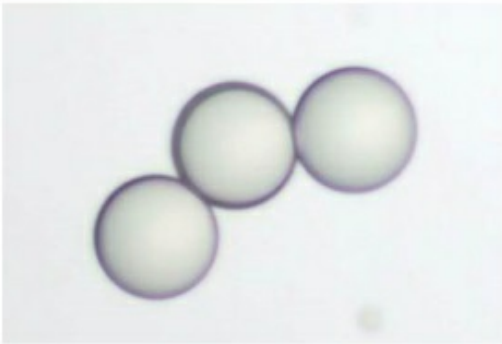
**We apply our proprietary formulation and
manufacturing capabilities to known, well-characterized
molecules to create differentiated, patent-protected
products that have the potential to significantly improve
existing standards of care**

Product Pipeline

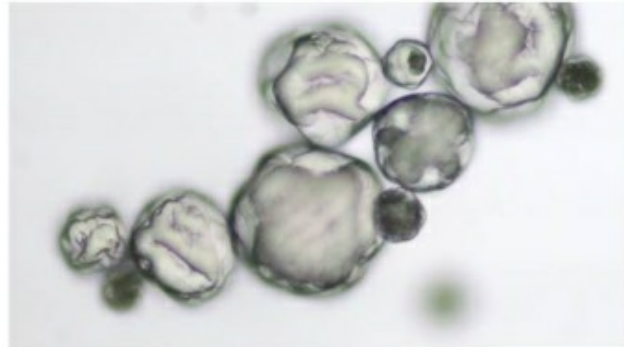
Compound	Discovery	Preclinical	Phase I	Phase II
AB101 Injectable once-weekly basal insulin for type 1 and type 2 diabetes				
AB301 Injectable once-weekly GLP-1 agonist/basal insulin combination for type 2 diabetes				

Superior Microsphere Technology

- Our products are formulated using proprietary PLGA microsphere technology
- Amylin/Astrazeneca's Bydureon (exenatide), a currently marketed GLP-1 agonist for type 2 diabetes, is also formulated using PLGA microspheres
- Light microscopy and particle size comparisons of our lead product candidate, AB101, vs. Bydureon demonstrate AntriaBio's superior microsphere technology used to create uniform and homogenous AB101 microspheres



AB101



Bydureon



AB101

Insulin: Role & Function

- Insulin is a hormone that keeps blood sugar in a normal range by moving glucose into the liver, fat and muscle
- **Bolus:** insulin released by pancreas when food is consumed
- **Basal:** background insulin continually released by pancreas to control blood sugar levels between meals and overnight

Insulin replacement therapy attempts to mimic healthy pancreatic function with long-acting injections (basal insulin) and short-acting injections with meals (bolus insulin)

Benefits of Long-Acting Insulin

- The benefits of long-acting insulin are well recognized, including:
 - **Less fasting blood glucose variability,**
 - **Lower risk of hypoglycemia,** and
 - **Less weight gain.**
- Recent studies suggest the beneficial effects of **early insulin initiation**
 - Early insulin initiation in older adults with type 2 diabetes who do not have adequate glycemic control was associated with:
 - Significantly greater reduction in HbA1c,
 - A 30% greater likelihood of achieving HbA1c less than 8.0%, and
 - No significant differences in total costs or hypoglycemia events.

Current Insulin Market: >\$22B

- Basal insulin market is ~50% of the total insulin market at ~\$11B
- There is no commercially available insulin in the US with a duration beyond 24 hours

Type	Brand/Generic Name	Duration	Insulin Market Share	2014 Sales
Basal Insulin	<ul style="list-style-type: none"> • Lantus (insulin glargine) • Levemir (insulin detemir) 	Up to 24 hours	~50%	<ul style="list-style-type: none"> • \$8.4B • \$2.55B
Human Insulin	<ul style="list-style-type: none"> • Humulin N (insulin NPH) • Novolin N (insulin NPH) 	12 – 16 hours	~15%	\$3.36B
	<ul style="list-style-type: none"> • Humulin R (insulin regular) • Novolin R (insulin regular) 	5 – 8 hours		
Fast-acting Insulins	<ul style="list-style-type: none"> • NovoLog (insulin aspart) • Apidra (insulin glulisine) • Humalog (insulin lispro) • Afrezza (insulin human) Inhalation Powder 	3 – 5 hours	~36%	\$8.06B

Emerging Basal Insulin Market

Many companies are validating the need for a basal insulin therapy with duration beyond 24 hours, but their products are complex insulin analogs

Compound	Dosing	Stage	Formulation
Novo Nordisk LAI287 (NN1436)	Weekly	Phase 1	Insulin Analog
Hanmi Pharmaceutical LAPS-Insulin 115 (HM12470)	Weekly	Phase 1	Insulin Analog
PhaseBio PE0139	Weekly	Phase 2	Insulin Analog
Eli Lilly Basal Insulin PEGlispro (BIL)	Daily	Phase 3 – FDA submission delayed	Insulin Analog
Novo Nordisk Tresiba (insulin degludec)	Every 1 to 2 days	FDA accepted resubmission	Insulin Analog
Ascendis Transcon Hydrogel Insulin (ACP-002)	Potentially weekly	Preclinical – Sanofi recently backed out of 2010 co-development deal	Insulin Analog



The Solution: AB101

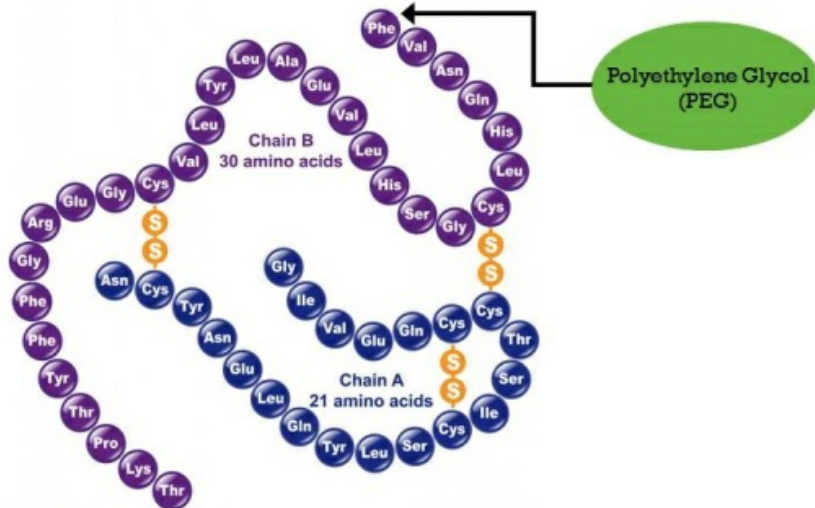
- **The Goal:** Develop a human recombinant insulin formulation that can be administered in a single, small volume injection to cover approximately one week of basal insulin requirements
- **The Challenge:** Insulin is a notoriously difficult molecule to formulate
- **The Solution:** A uniform biodegradable microsphere with PEGylated human recombinant insulin, which enables solubility and PLGA, which extends the release of insulin

AB101 Addresses Unmet Clinical Need

- **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

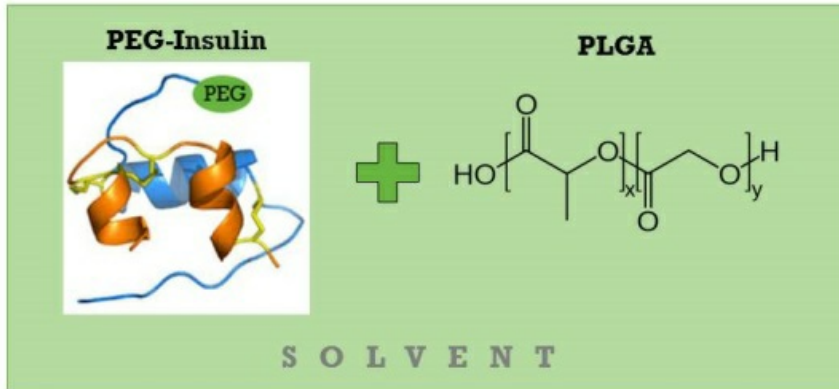
AB101 Formulation Step 1: PEGylation

- Using site-specific amine PEGylation, attach a low molecular weight PEG to the N terminus of human insulin's B peptide chain so that insulin dissolves uniformly in oil or water-based solutions



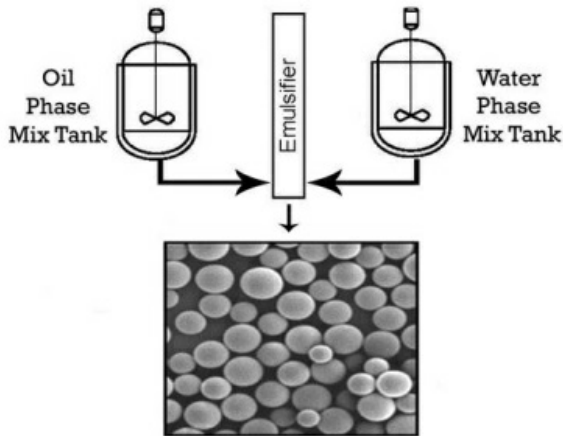
AB101 Formulation Step 2: Dissolution

- PEGylated insulin is co-dissolved with a polymer (poly-lactic co-glycolic acid, or PLGA), in a solvent [oil phase]
- PLGA is critical for determining the rate at which PEGylated insulin is released into the body by hydrolysis



AB101 Formulation Step 3: Emulsion

- Generate an oil-in-water emulsion by passing both the oil and water phases through a packed glass bead bed emulsifier to form uniform microspheres comprised of PEG-insulin and PLGA



Reconstitution:

Prior to being administered, the formulation is reconstituted in an aqueous phase that is isotonic, contains excipients present in FDA-approved products, and optimized for ease of delivery with small needles

AB101: in Vitro Pharmacology

The following preclinical results were presented in June at the American Diabetes Association 75th Scientific Sessions® in Boston

- **in Vitro Characterization of PEGylated Insulin** (drug substance):
 - Displayed an affinity for the IGF-1 receptor that is similar to native insulin, which would suggest a low risk of mitogenicity
 - Displayed an affinity for the insulin receptor that is similar to native insulin once bound, which predicts insulin activity in humans
 - Inhibited hepatic glucose production to the same magnitude and with the same potency as native insulin

AB101: in Vivo Pharmacology

The following preclinical results were presented in June at the American Diabetes Association 75th Scientific Sessions® in Boston

- **in Vivo Pharmacokinetics and Pharmacodynamics of AB101:**
 - Slow onset, sustained insulin increases and corresponding glucose reductions over the course of a week in rats and dogs as well as a diabetic rat model
 - No acute insulin release or glucose reduction
 - Supports weekly dosing as a basal insulin formulation
 - Efficacious doses in animals can be readily translated to human clinically relevant doses that can be administered via acceptable volumes and needle gauge

AB101: Clinical Development Plan

Preclinical

- **Completed:** Pharmacology and toxicology studies in dogs and rats

File IND

- **H1 2016:** File Investigational New Drug (IND) application with FDA

Phase 1

- **H2 2016:** Single and repeat ascending dose safety and efficacy studies (PK-PD) to establish once-weekly dosing regimen in type 1 and type 2 diabetes patients

Phase 2

- **2017:** Compare glycemic efficacy of once-weekly dosing regimen to Lantus (standard of care) in type 1 and type 2 diabetes patients

Phase 1 First-in-Human Study Design

- Single center
- Randomized, Open-Label, Single Ascending Dose
- Population: type 1 & type 2 diabetes patients and standard inclusion/exclusion criteria comparable to other insulin programs
- Sample size of 36-48 subjects per population in sequential ascending dose cohorts of 12-16/dose
- Euglycemic clamp(s) performed on dosing day and at selected time points throughout the anticipated duration of action (e.g., Days 3, 7, 10)
 - Characterize PK
 - Characterize PD (time-action profile of glucose lowering)
 - Goal to demonstrate absence of peak and sustained duration

AB301

Incretin-Based Therapies

- DPP-4 inhibitors and GLP-1 agonists are now well-established treatments for type 2 diabetes
- No validation needed for GLP-1 therapies
 - Numerous marketed daily and weekly GLP-1 agonists
- Therefore, focus of differentiation and advancement is on a combination therapy with extended duration of action

Emerging GLP-1/Basal Insulin Combinations

The world's leading diabetes care companies are validating the need for a GLP-1 agonist and basal insulin combination therapy, but their products are targeting daily dosing

Company	Compound	Dosing	Stage
Novo Nordisk	Xultophy (IDegLira) Tresiba (insulin degludec) and Victoza (liraglutide) fixed-dose combination	Daily	Phase 3 (US) Approved (EU)
Sanofi	LixiLan Lantus (insulin glargine) and Lyxumia (lixisenatide) fixed-ratio combination	Daily	Phase 3

AB301

- Potential **once-weekly** injectable combination of a PEGylated GLP-1 agonist + AB101
- Combination therapy has potential to complement glycemic control while attenuating weight gain and hypoglycemic risk
- Preclinical studies are ongoing

Key Intellectual Property

- **Existing issued patent, which expires in April 2024:**
 - Site-specific modification of selected proteins
 - ↳ PEG attached to insulin at residue PheB1
 - Methods to formulate a mixture of a PEGylated protein with a biodegradable polymer
 - ↳ PEG-insulin with PLGA
- **Pending patent applications that will expire in 2034 – 2035 when issued:**
 - Novel manufacturing processes for superior flowability of microspheres and injectability of the suspension
 - Novel compositions and systems used to create formulations for sustained release therapies that are used by themselves or in combination with other molecules
 - Improved methods for amine pegylation
- **We plan to file additional patent applications that are directed towards both technology enhancements and additional product pipeline candidates**

2015 Milestones

- ☑ Raised >\$20M to date
- ☑ Presented results of in vitro and multi-species PK/PD studies for AB101 at the American Diabetes Association 75th Scientific Sessions®
- ☑ Completed IND-enabling toxicology studies for AB101
- ☑ Announced additional pipeline candidate supported by in vitro and vivo data
- ☑ Completed construction of cGMP manufacturing suite

Upcoming Milestones

- File AB101 IND application with FDA
- Initiate AB101 phase 1 first-in-human clinical study
- Continue preclinical studies of AB301

Financials

As of June 30, 2015:

Shares Outstanding	24,338,219	
Options Outstanding	\$2.78 (weighted average exercise price)	8,702,418
Warrants Outstanding	\$2.33 (weighted average exercise price)	19,016,391
Fully Diluted	52,057,028	
Cash	\$5,278,706	
Exchange	OTCQB: ANTB	

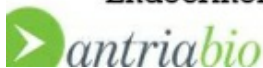


Senior Management Team

- **Nevan Elam, J.D.**, Chairman and Chief Executive Officer
 - Former Head of Nektar Therapeutics' Pulmonary Business Unit, which was acquired by Novartis in 2008
 - Spun out Nektar's asthma and COPD assets to form Pearl Therapeutics, which was acquired by AstraZeneca in 2013 for \$1 billion
 - Board Member of Savara Pharmaceuticals and Aerogen Limited
- **Hoyoung Huh, M.D., Ph.D.**, Board Member, SAB Chairman, Business Development
 - Former CEO of BiPar Sciences, which was acquired by Sanofi-Aventis in 2009 for \$500 million
 - Former Chairman of Epizyme (NASDAQ:EPZM)
 - Chairman of Geron Corporation (NASDAQ:GERN) & CytomX Therapeutics
- **Sankaram Mantripragada, Ph.D.**, Chief Scientific Officer
 - Former VP and Director of R&D at SkyePharma (now Pacira Pharmaceuticals)
 - Author/inventor of 70+ publications and patents, including Exparel, Pacira's lead compound
 - PhD in Molecular Biophysics and postdoctoral research at the Max Planck Institute for Biophysical Chemistry in Germany
- **Brian Roberts, M.D.**, VP of Clinical Development
 - Directed clinical development programs in diabetes, dyslipidemia, gout and renal anemia at Metabolex and Fibrogen (NASDAQ:FGEN)
 - Author/inventor of 20+ publications and patents in Endocrinology and Metabolism
 - Adjunct Assistant Professor in the Division of Endocrinology at Stanford University

Scientific Advisory Board

- **Hoyoung Huh, M.D., Ph.D. (Chair)**, former CEO of BiPar Sciences, Inc., former COO of Nektar Therapeutics, successful pharmaceutical entrepreneur
- **Andrew R. Hoffman, M.D.**, Professor of Medicine in the Division of Endocrinology, Gerontology and Metabolism at Stanford University and Chief of Endocrinology at the VA Palo Alto Health Care System
- **Philip Home, M.A., D. Phil., D.M., F.R.C.P.**, Professor of Diabetes Medicine at Newcastle University, former Vice-Chair of NICE and clinical lead to International Diabetes Federation (IDF)
- **C. Ronald Kahn, M.D.**, Head of Integrative Physiology and Metabolism of Joslin Diabetes Center, Professor of Medicine at Harvard Medical School
- **Fredrick B. Kraemer, M.D.**, Chief of the Division of Endocrinology, Gerontology and Metabolism at Stanford University
- **Jerrold Olefsky, M.D.**, Professor of Medicine in the Division of Endocrinology & Metabolism at the University of California, San Diego





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