



**Source:** Assembly Biosciences, Inc.  
January 09, 2017 08:00 ET

## Allergan Enters Into Licensing Agreement with Assembly Biosciences to Obtain Worldwide Rights to Microbiome Gastrointestinal Development Programs

*-- Expands Allergan's Innovative GI Pipeline with ABI-M201 and ABI-M301, Preclinical Compounds Targeting Ulcerative Colitis and Crohn's Disease, as well as Future Compounds for Irritable Bowel Syndrome --*

DUBLIN, Ireland and INDIANAPOLIS, Jan. 09, 2017 (GLOBE NEWSWIRE) -- Allergan plc (NYSE:[AGN](#)) and Assembly Biosciences, Inc. (NASDAQ:[ASMB](#)) today announced that Allergan has entered into a research, development, collaboration and license agreement for the worldwide rights to Assembly's microbiome gastrointestinal (GI) development programs. The agreement provides Allergan with worldwide rights to preclinical compounds ABI-M201 and ABI-M301, targeting ulcerative colitis (UC) and Crohn's disease (CD), as well as two additional compounds to be identified by Assembly for Irritable Bowel Syndromes (IBS); with Diarrhea (IBS-D), with Constipation (IBS-C) or Mixed (IBS-M).

Under the terms of the agreement, Allergan will make an upfront payment to Assembly of \$50 million for the exclusive, worldwide rights to develop and commercialize the UC, CD and IBS compounds. Additionally, Assembly will be entitled to receive success-based development and commercial milestone payments. Assembly is also eligible to receive tiered royalties based on net sales. Allergan and Assembly will generally share development costs through proof-of-concept (POC) studies, and Allergan will assume all post-POC development costs.

The Assembly microbiome program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practices and a patent-pending delivery system, GEMICEL®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal tract.

"The Microbiome -- the microbial populations that colonize the human body -- is rapidly gaining prominence in numerous fields of research relevant to Allergan's key areas of focus, including GI disorders," said David Nicholson, Chief R&D Officer, Allergan. "Assembly is well positioned to identify and select unique therapeutic candidates and deliver them to the optimal site in the GI tract through a novel oral delivery system."

This collaboration reinforces Allergan's commitment to building a robust portfolio through Open Science. As with most of our agreements, we enter into partnerships which, through creative structures, leverage the expertise of our partners to potentially deliver innovative treatments for improved patient care.

"Our fully-integrated microbiome platform reflects Assembly's commitment as one of the leaders in the exciting new field of microbiome therapeutics, which has the potential to address a range of diseases in entirely new ways," said Derek Small, Chief Executive Officer of Assembly. "We are delighted to enter into this collaboration with Allergan, an innovator in GI, as we work together to realize the potential of microbiome therapies and provide treatments to patients with serious GI disorders."

"Inflammatory diseases of the GI tract, including Crohn's disease and ulcerative colitis, are debilitating conditions that remain poorly treated for many patients," said Martin J. Blaser, MD, Director of the New York University Human Microbiome Program. "Therapies leveraging the microbiome may be able to address these disorders in fundamentally new ways. I am encouraged that microbiome innovators such as Assembly and Allergan are working to convert their promising new approaches into clinically useful products to help these patients."

The transaction is expected to close in the first quarter of 2017, subject to customary closing conditions, including the expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

### **About Crohn's Disease and Ulcerative Colitis<sup>1,2</sup>**

Crohn's disease and ulcerative colitis are chronic inflammatory conditions of the gastrointestinal tract. Crohn's disease most commonly affects the end of the small bowel (the ileum) and the colon (also called the large intestine), but it may affect any part of the gastrointestinal (GI) tract, from the mouth to the anus. Ulcerative colitis is limited to the colon. It is estimated that 1.6 million Americans and 2.2 million Europeans suffer from Crohn's disease or ulcerative colitis. The majority of patients are diagnosed in young adulthood and these incidence rates continue to rise, which will continue to place a significant burden on global healthcare systems.

## **About Allergan plc**

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, the Company's R&D model, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. This approach has led to Allergan building one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs in development.

Our Company's success is powered by our more than 16,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at [www.Allergan.com](http://www.Allergan.com).

## **About Assembly Biosciences**

Assembly Biosciences, Inc. is a clinical-stage public biotechnology company developing two innovative platform programs: an HBV program advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and a microbiome program developing novel oral biotherapeutics designed to address diseases associated with the microbiome. Assembly's HBV program is advancing multiple drug candidates with the aim of increasing cure rates in patients with chronic HBV. The company's microbiome program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practices and a patent-pending delivery system, GEMICEL®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal tract. Assembly is developing a robust pipeline of product candidates in multiple disease indications. For more information, visit [assemblybio.com](http://assemblybio.com).

## **Forward-Looking Statement**

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting future clinical results based on prior clinical results; the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2015 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 (certain of such periodic public filings having been filed under the "Actavis plc" name). Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

The information in this press release contains estimates and other forward-looking statements regarding future events, including statements about the clinical and therapeutic potential of Assembly's development programs, its ability to receive payments from Allergan under the collaboration agreement and plans, strategies, and intentions related to Assembly's programs. Certain forward looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as "developing," "potential," "projected," "positioned," "eligible" or "may." Such forward-looking statements, which Assembly intends to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the components, timing, cost and results of clinical trials and other development activities involving Assembly's product candidates (including those licensed to Allergan); the unpredictability of the preclinical and clinical development of Assembly's product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; Assembly's anticipated capital expenditures, Assembly's estimates regarding its capital requirements, and its need for future capital; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the heading "Risk Factors" in Assembly's Annual Report on Form 10-K for the year ended December 31, 2015, and Quarterly Report on Form 10-Q for the quarter ending September 30, 2016 filed with the Securities and Exchange Commission. It is not possible for Assembly management to predict all risks nor can Assembly assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements Assembly may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

<sup>1</sup> Crohn's & Colitis Foundation of America: What are Crohn's Disease and Ulcerative Colitis?: <http://www.cdfa.org/what-are-crohns-and-colitis/>

<sup>2</sup> Nature Reviews Gastroenterology & Hepatology 12, 720–727 (2015):  
<http://www.nature.com/nrgastro/journal/v12/n12/full/nrgastro.2015.150.html>

ALLERGAN

INVESTORS:

Lisa DeFrancesco  
(862) 261-7152

MEDIA:

Mark Marmor  
(862) 261-7558

ASSEMBLY

INVESTORS:

Lauren Glaser  
(415) 521-3828

MEDIA:

Barbara Lindheim  
(212) 584-2276  
barbara@assemblybio.com