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): **October 5, 2015**

ALKERMES PUBLIC LIMITED COMPANY
(Exact Name of Registrant as Specified in its Charter)

Ireland	**001—35299**	**98-1007018**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Connaught House
1 Burlington Road
Dublin 4, Ireland
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **+353-1-772-8000**

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 (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

On October 5, 2015, Alkermes plc issued the press release attached hereto as Exhibit 99.1 announcing that the U.S. Food and Drug Administration (the "FDA") has approved ARISTADA™ (aripiprazole lauroxil) extended-release injectable suspension for the treatment of schizophrenia. Concurrently with such approval, the FDA denied the Citizen Petition filed by Otsuka Pharmaceutical Development & Commercialization, Inc., a copy of which can be found at www.regulations.gov by searching for "aripiprazole lauroxil". The press release attached hereto as Exhibit 99.1 is incorporated by reference in this Item 7.01.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as expressly set forth by specific reference in such a filing.

Note Regarding Forward-Looking Statements

The press release attached as Exhibit 99.1 hereto and incorporated by reference in Item 7.01 above contains forward-looking statements that involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by these statements. Please refer to the cautionary notes above and in the press release regarding these forward-looking statements.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release issued by Alkermes plc dated October 5, 2015.

SIGNATURE

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.

ALKERMES PLC

Date: October 5, 2015

By: /s/ James M. Frates
James M. Frates
Senior Vice President, Chief Financial Officer and Treasurer

Exhibit 99.1

Alkermes Contacts:
For Investors: Rebecca Peterson, +1 781 609 6378
For Media: Jennifer Snyder, +1 781 609 6166

FDA APPROVES ARISTADA™ FOR TREATMENT OF SCHIZOPHRENIA

— First Long-Acting Atypical Antipsychotic With Both Once-Monthly and Six-Week Dosing Options —

— Product Features Include Range of Dose Strengths and Multiple Dosing Intervals Designed to Address Individual Patient Needs —

— Company to Host Conference Call at 7:30 a.m. EDT Tomorrow —

DUBLIN, Ireland, Oct. 5, 2015 — Alkermes plc (NASDAQ: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has approved ARISTADA™ (aripiprazole lauroxil) extended-release injectable suspension for the treatment of schizophrenia. ARISTADA is the first atypical antipsychotic with once-monthly and six-week dosing options for delivering and maintaining therapeutic levels of medication in the body through an injection. Alkermes is preparing to launch ARISTADA immediately.

“ARISTADA is a new treatment option designed to offer flexibility to meet the real-world needs of patients suffering from schizophrenia and the healthcare professionals providing their care,” said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “Building on nearly two decades of experience developing innovative medicines for chronic and serious CNS diseases, we are dedicated to helping to improve the lives of patients as well as meeting the needs within the treatment ecosystem of caregivers, physicians, payers and society. We look forward to making ARISTADA available to patients and healthcare providers as quickly as possible.”

ARISTADA’s features, including a range of dose strengths and dosing interval options, are designed to address the individual needs of patients and challenges in the treatment of schizophrenia. As a long-acting injectable medicine, ARISTADA provides patients, clinicians and families the certainty that patients receive medication for this serious brain disorder. Long-acting injectable antipsychotics provide patients with blood concentrations of active drug that

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remain within a therapeutic range for an extended period of time (1) and help healthcare providers to track patient adherence. (2)

“Schizophrenia is a serious and debilitating disease where, despite the existence of many medicines, there remains significant unmet medical need and suffering. New treatment options are needed to help patients and their families better manage this illness,” said David Henderson, M.D., Associate Professor of Psychiatry at Massachusetts General Hospital. “Long-acting therapies are rapidly evolving to the forefront of the treatment of schizophrenia as clinicians increasingly recognize the potential benefits of less frequent dosing and consider their use earlier in disease progression.”

The FDA approval of ARISTADA was based on a proven safety and efficacy profile, including data from a randomized, double-blind, placebo-controlled, phase 3 study in 623 patients with schizophrenia. Data from that trial showed that multiple dose strengths of ARISTADA met the primary endpoint with statistically significant and clinically meaningful reductions in Positive and Negative Syndrome Scale (PANSS) total scores at Week 12, met the key secondary endpoint and demonstrated significant improvements in schizophrenia symptoms versus placebo. The most common adverse events in the study were insomnia, akathisia and headache. The results of the phase 3 study were published in June 2015 by *The Journal of Clinical Psychiatry*, a peer-reviewed medical journal.

Conference Call

Alkermes will host a conference call on Tuesday, Oct. 6, 2015, at 7:30 a.m. EDT (12:30 p.m. BST). The conference call may be accessed by dialing +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 6037988. The conference call will also be webcast on the Investors section of Alkermes’ website at www.alkermes.com. In addition, a replay of the conference call will be available from 9:30 a.m. EDT (2:30 p.m. BST) on Tuesday, Oct. 6, 2015, through 5:00 p.m. EDT (10:00 p.m. BST) on Tuesday, Oct. 13, 2015, and may be accessed by visiting Alkermes’ website or by dialing +1 888 843 7419 for U.S. callers and +1 630 652 3042 for international callers. The replay access code is 6037988.

About Schizophrenia

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million American adults have schizophrenia,(3) with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, which is one of the most serious types of mental illness.

About ARISTADA™

ARISTADA is an injectable atypical antipsychotic with one-month and six-week dosing options for the treatment of schizophrenia. ARISTADA is administered by a healthcare professional. Once in the body, ARISTADA converts to aripiprazole.

INDICATION and IMPORTANT SAFETY INFORMATION for ARISTADA™ (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use

INDICATION

ARISTADA is indicated for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA is not approved for the treatment of patients with dementia-related psychosis.

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Cerebrovascular Adverse Reactions, Including Stroke: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with oral aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the

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atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension which can be associated with dizziness, lightheadedness and tachycardia. Monitor heart rate and blood pressure, and warn patients with known cardiovascular or cerebrovascular disease and risk of dehydration and syncope.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. Patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) and history of drug-induced leukopenia/neutropenia should have frequent complete blood count (CBC) during the first few months of receiving ARISTADA. Consider discontinuation of ARISTADA at the first sign of a clinically significant decline in WBC count in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue ARISTADA in patients with severe neutropenia (absolute neutrophil count $<1000/mm^3$) and follow their WBC until recovery.

Seizures: ARISTADA should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain ARISTADA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.

Concomitant Medication: Decreasing the ARISTADA dosage is recommended in patients taking strong CYP3A4 inhibitors and/or strong CYP2D6 inhibitors for longer than 2 weeks. Increasing the ARISTADA dosage is recommended in patients taking CYP3A4 inducers for longer than 2 weeks. No ARISTADA dosage changes are recommended for patients taking CYP450 modulators for less than 2 weeks.

Most Commonly Observed Adverse Reaction: The most common adverse reaction (≥5% incidence and at least twice the rate of placebo in patients treated with ARISTADA) was akathisia.

Injection-Site Reactions: Injection-site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA, 882 mg ARISTADA, and placebo, respectively. Most of these were injection-site pain and associated with the first injection and decreased with each subsequent injection. Other injection-site reactions (induration, swelling, and redness) occurred at less than 1%.

Dystonia: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first days of treatment and at low doses.

Pregnancy/Nursing: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider of a known or suspected pregnancy. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ARISTADA during pregnancy. Aripiprazole is present in human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for ARISTADA and any potential adverse effects on the infant from ARISTADA or from the underlying maternal condition.

Please see **FULL PRESCRIBING INFORMATION**, including **Boxed Warning** for ARISTADA.

About Alkermes

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning the timing of the launch of ARISTADA in the U.S., the commercialization of ARISTADA and the potential therapeutic and commercial value of ARISTADA for the treatment of schizophrenia. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: when ARISTADA will become commercially available; whether the safety and efficacy results demonstrated in our clinical study of ARISTADA for the treatment of schizophrenia will be predictive of safety and efficacy results when commercialized; whether ARISTADA will be commercialized successfully; whether third party payers will cover or reimburse ARISTADA for the treatment of schizophrenia; and those risks described in the Alkermes plc Quarterly Report on Form 10-Q for the period ended June 30, 2015 and Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014, and in any other subsequent filings made by the company with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or

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responsibility for updating or revising any forward-looking information contained in this press release.

ARISTADA™ is a trademark of Alkermes Pharma Ireland Limited.

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(1)Patel MX and David AS. Why aren't depot antipsychotics prescribed more often and what can be done about it? *Adv Psychiatr Treat*, 2005; 11: 203-213.

(2)Kane JM et al. Guidelines for depot antipsychotic treatment in schizophrenia. *Eur Neuropsychopharmacol*, 1998; 8(1): 55-66.

(3)National Alliance on Mental Illness. Accessed on Oct. 5, 2015 from http://www2.nami.org/Content/NavigationMenu/Mental_Illnesses/Schizophrenia9/Home.htm.

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