Ampio Pharmaceuticals, Inc. Form 424B5
February 28, 2014
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Filed pursuant to Rule 424(b)(5) Registration Nos. 333-177116 and 333-193096

PROSPECTUS SUPPLEMENT

(To Prospectuses Dated October 28, 2011 and January 22, 2014)

8,500,000 Shares

Ampio Pharmaceuticals, Inc.

Common Stock

\$7.00 per share

We are selling 8,500,000 shares of our common stock pursuant to this prospectus supplement and the accompanying prospectuses.

We have granted the underwriters an option to purchase up to an additional 1,275,000 shares from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus supplement.

Our common stock is quoted on the NYSE MKT LLC, or NYSE MKT, under the symbol $\,$ AMPE $\,$. The last reported sale price of our common stock on the NYSE MKT on February 27, 2014, was \$7.94 per share.

Investing in our common stock involves risks. See <u>Risk Factors</u> beginning on page S-15 of this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectuses are truthful or complete. Any representation to the contrary is a criminal offense.

	Per	Share	Total
Public Offering Price	\$	7.00	\$ 59,500,000
Underwriting Discount(1)	\$	0.49	\$ 4,165,000
Proceeds to Ampio Pharmaceuticals, Inc. (before expenses)	\$	6.51	\$ 55,335,000

(1) See Underwriting beginning on page S-40 for a detailed description of the compensation payable to the underwriters.

The underwriters expect to deliver the shares to purchasers on or about March 5, 2014, through book-entry facilities of the Depository Trust Company.

Joint Book-Running Managers

Citigroup Jefferies

February 27, 2014

We are responsible for the information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectuses and in any free-writing prospectus we prepare or authorize. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in or incorporated by reference into this prospectus supplement or the accompanying prospectuses is accurate as of any date other than its date.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectuses and the documents incorporated by reference into this prospectus supplement and the accompanying prospectuses. The second part, the accompanying prospectuses, gives more general information about securities we may offer from time to time, some of which does not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined together with all documents incorporated by reference. If the description of the offering varies between this prospectus supplement and the accompanying prospectuses, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference into this prospectus supplement or the accompanying prospectuses the statement in the document having the later date modifies or supersedes the earlier statement. You should not assume that the information appearing in this prospectus supplement, the accompanying prospectuses, any related free writing prospectus or any document incorporated by reference is accurate as of any date other than the date of the applicable document. Our business, financial condition, results of operations and prospects may have changed since that date. You should rely only on the information contained in or incorporated by reference into this prospectus supplement or contained in or incorporated by reference into the accompanying prospectuses to which we have referred you. We are responsible only for the information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectuses or information contained in a free writing prospectus that we authorize to be delivered to you. We and the underwriters have not authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in, or incorporated by reference into, this prospectus supplement and contained in, or incorporated by reference into, the accompanying prospectuses is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectuses or of any sale of securities. This prospectus supplement and the accompanying prospectuses may be used only for the purpose for which they have been prepared. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectuses, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions Where You Can Find More Information and Incorporation of Certain Information by Reference in this prospectus supplement.

We and the underwriters are not making an offer to sell these securities in any jurisdiction where such an offer or sale is not permitted. The distribution of this prospectus supplement and the accompanying prospectuses and the offering of the shares in certain jurisdictions or to certain persons within such jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectuses must inform themselves about and observe any restrictions relating to the offering of the shares and the distribution of this prospectus supplement and the accompanying prospectuses outside the United States. This prospectus supplement and the accompanying prospectuses outside the United States. This prospectus supplement and the accompanying prospectuses by any person in any jurisdiction of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectuses by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation. Neither this prospectus supplement nor either of the accompanying prospectuses constitutes an offer, or an invitation on our behalf or on behalf of the underwriters, to subscribe for and purchase any of the securities.

Unless otherwise mentioned or unless the context requires otherwise, throughout this prospectus supplement and any related free writing prospectus, the words Ampio Pharmaceuticals, Ampio, we, us, our, the company or similar references refer to Ampio Pharmaceuticals, In its subsidiaries on a consolidated basis. References to BioSciences in this prospectus supplement mean DMI BioSciences, Inc., now a wholly-owned subsidiary of ours. References to Life Sciences in this prospectus supplement mean DMI Life Sciences, Inc., which is our predecessor for accounting purposes and a wholly-owned subsidiary of ours. Life Sciences was

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formed in December 2008 and commenced operations when it acquired certain assets of BioSciences in April 2009. In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, Inc., a publicly traded Colorado corporation, which we refer to in this prospectus supplement as Chay Enterprises. Immediately after the merger, Chay Enterprises changed its name to Ampio Pharmaceuticals, Inc., and reincorporated in Delaware. We acquired BioSciences, now a wholly-owned subsidiary of ours, in March 2011. References to Luoxis in this prospectus supplement mean Luoxis Diagnostics, Inc., which is an 80.9% owned subsidiary of ours and was formed on January 24, 2013 to focus on the development and commercialization of the Oxidation Reduction Potential (ORP) technology platform. References to Vyrix in this prospectus supplement mean Vyrix Pharmaceuticals, Inc., which is a wholly-owned subsidiary of ours and was formed on November 18, 2013 to focus on developing and commercializing late-stage prescription pharmaceuticals to improve men shealth and quality of life.

This prospectus supplement and the information incorporated herein by reference includes trademarks, such as Optina, Zertane, Ampion, Luoxis and Vyrix, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This prospectus supplement may also contain trademarks, service marks, copyrights and trade names of other companies which are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this prospectus may appear without the [®] or symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

The industry and market data and other statistical information contained in the documents we incorporate by reference are based on management s own estimates, independent publications, government publications, reports by market research firms or other published independent sources, and, in each case, are believed by management to be reasonable estimates. Although we believe these sources are reliable, we have not independently verified the information.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into it contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as statements containing the words believe, expect, may, will, anticipate, estimate, project, plan, assume or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this prospectus and the documents incorporated by reference herein regarding our future strategy, plans and expectations regarding clinical trials, future regulatory approvals, our plans for the manufacturing and commercialization of our products, future operations, projected financial position, potential future revenues, projected costs, future prospects, and results that might be obtained by pursuing management s current plans and objectives are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

our expectations related to the use of proceeds, if any, from this offering; our need for, and ability to raise, additional capital;

the results and timing of our clinical trials;

the regulatory review process and any regulatory approvals that may be issued or denied by the Food and Drug Administration (FDA), the European Medicines Agency (EMA), or other regulatory agencies;

our manufacturing plans;

our need to secure collaborators to license, manufacture, market and sell any products for which we receive regulatory approval in the future:

the results of our internal research and development efforts;

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the commercial success and market acceptance of any of our product candidates that are approved for marketing in the United States or other countries;

the safety and efficacy of medicines or treatments introduced by competitors that are targeted to indications which our product candidates have been developed to treat;

the acceptance and approval of regulatory filings;

our current or prospective collaborators compliance or non-compliance with their obligations under our agreements with them, or decisions by our collaborators to discontinue clinical trials and return product candidates to us;

our plans to develop other product candidates; and

other factors discussed elsewhere in this prospectus or the documents incorporated by reference herein.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. Our forward-looking statements are based on the information currently available to us and speak only as of the date on the cover of this prospectus. New risks and uncertainties arise from time to time, and it is impossible for us to predict these matters or how they may affect us. We have included important factors in the cautionary forward-looking statements included in this prospectus, particularly in the section of this prospectus supplement entitled Risk Factors, which we believe over time, could cause our actual results, performance or achievements to differ from the anticipated results, performance or achievements that are expressed or implied by our forward-looking statements. We have no duty to, and do not intend to, update or revise the forward-looking statements in this prospectus after the date of this prospectus except to the extent required by the federal securities laws. You should consider all risks and uncertainties disclosed in our filings with the Securities and Exchange Commission, or the SEC, described in the sections of this prospectus supplement entitled Where You Can Find More Information and Incorporation of Certain Information by Reference and Where You Can Find Additional Information, all of which are accessible on the SEC s website at www.sec.gov.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in, or incorporated by reference into, this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, you should read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectuses, including the information incorporated by reference in this prospectus supplement and the accompanying prospectuses. If you invest in our common stock, you are assuming a high degree of risk. See Risk Factors in this prospectus supplement beginning on page S-15. All references in this prospectus supplement to our consolidated financial statements include, unless the context indicates otherwise, the related notes.

Company Overview

Ampio Pharmaceuticals, Inc. is a development stage biopharmaceutical company focused primarily on the development of therapies to treat prevalent inflammatory conditions for which there are limited treatment options. Ampio s two lead product candidates in development are Ampion for osteoarthritis of the knee and Optina for diabetic macular edema.

Background

Our product portfolio is primarily based on the work of Dr. David Bar-Or, the Director of Trauma Research LLC for both the Swedish Medical Center located in Englewood, CO and St. Anthony Hospital located in Lakewood, CO. For over two decades, while directing these two trauma research laboratories, Dr. Bar-Or and his staff have built a robust portfolio of product candidates focusing on inflammatory conditions. Ampio s initial clinical programs were culled from Dr. Bar-Or s research based on certain criteria, particularly the ability to advance the candidates rapidly into late-stage clinical trials. The benchmarks used to build our pipeline were products with: (i) potential indications to address large underserved markets; (ii) strong intellectual property protection and the potential for market and data exclusivity; and (iii) a well-defined regulatory path to marketing approval.

We are primarily developing compounds that decrease inflammation by (i) inhibiting specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level; (ii) activating specific phosphatase or depleting available phosphate needed for the inflammation process; and (iii) decreasing vascular permeability.

Business Overview

Our Product Pipeline

AMPION

Ampion for Osteoarthritis and Other Inflammatory Conditions

Ampion is a sub 5000 molecular weight (MW) fraction of commercial human serum albumin (HSA). The primary constituent ingredient is aspartyl-alanyl diketopiperazine, or DA-DKP, an endogenous immunomodulatory molecule derived from the N-terminus of HSA. Based on Ampio s published in-vitro findings, DA-DKP appears to play a significant role in the homeostasis of inflammation. DA-DKP is believed to reduce inflammation by suppressing pro-inflammatory cytokine production in T-cells. Ampion also contains other known small molecules that confer anti-inflammatory effects to complement the activity of DA-DKP and derive in-vitro and in-vivo effects. We believe the non-steroidal, low molecular weight, anti-inflammatory biologic has the potential to be used in a wide variety of acute and chronic inflammatory conditions as well as

immune-mediated diseases. Ampio is currently developing Ampion as an intra-articular injection for acute treatment of osteoarthritis of the knee.

Ampion is manufactured as the low molecular weight filtration product of commercial human serum albumin containing DA-DKP, N-acetyltryptophan, caprylate, and other small molecules either contained in HSA or added to HSA during the processing and production of commercial HSA products. DA-DKP, the primary constituent ingredient contained in Ampion, is a locally generated molecule formed as a physiological result of the cleavage and cyclization of the N-terminal aspartic acid and alanine residues of human albumin. The molecule was originally discovered in the blood and cerebrospinal fluid of patients several days after suffering severe closed head injuries. A high concentration of DA-DKP has also been detected in biofilms found on endotracheal tubes recovered from intubated patients and on implanted orthopedic plates and screws. Together these findings suggest a mechanism by which DA-DKP contributes to the ability to reduce the body s inflammatory response following insult or injury.

DA-DKP is believed to reduce inflammation through the activation of Ras-related protein 1 (Rap1). Rap1 interrupts the kinase cascade by regulating the amount of rapidly accelerated fibrosarcoma (Raf) kinases available for interaction with Ras, inhibiting antigen-specific Ras activation. This decrease disrupts the mitogen-activation protein kinase (MAPK) cascade and results in decreased immunoinflammatory cytokine gene transcription. The clinical results which are detailed below also suggest an effect other than anti-inflammatory properties are at work and imply more prolonged healing-like effects.

Market Opportunity.

According to a 2008 independent report, osteoarthritis is the most common form of arthritis, affecting over 27 million people in the United States. It is a progressive disorder of the joints involving degradation of the intra-articular cartilage, joint lining, ligaments, and bone. According to a 2008 Centers for Disease Control study, the incidence of developing osteoarthritis of the knee over a lifetime is approximately 45%. According to a 2010 independent report, the incidence of developing osteoarthritis of the hip over a lifetime is approximately 25%. Certain risk factors in conjunction with natural wear and tear lead to the breakdown of cartilage. Osteoarthritis is caused by inflammation of the soft tissue and bony structures of the joint, which worsens over time and leads to progressive thinning of articular cartilage. Other progressive effects include narrowing of the joint space, synovial membrane thickening, osteophyte formation and increased density of subchondral bone. According to a 2006 independent report, the global osteoarthritis therapeutics market continues to expand and is expected to exceed \$7 billion by 2015 and the global demand for osteoarthritis of the knee treatment is expected to be fueled by favorable demographics and increasing awareness of treatment options. Despite the size and growth of the osteoarthritis of the knee market, few adequate treatment options currently exist.

Inflammation of the synovium interrupts the natural chondrocyte metabolism, which is responsible for the production and maintenance of the components of cartilage s extracellular matrix. Osteoarthritic synovial fluid activates pro-inflammatory cytokines in active chondrocytes through autocrine and paracrine mechanisms. The cytokines, such as tumor necrosis factor-a (TNF-a), interleukin-17 (IL-17), and interleukin-18 (IL-18), stimulate the synthesis of matrix metalloproteinase (MMPs) whose enzymatic activity leads to the digestion of cartilage.

Phase I Clinical Trial Results.

In October 2011, we announced results from the first part of our Ampion-in-Knee (AIK) study of Ampion in the acute treatment of osteoarthritis of the knee. We conducted our Phase I trial in Australia because the biologics legislation governing the Australian Therapeutic Goods Administration (TGA) allowed us to move Ampion directly into human clinical trials as the TGA recognized that HSA has an already

established safety profile in humans by virtue of its longstanding commercial use. The AIK trial was conducted in patients diagnosed with moderately-severe to severe osteoarthritis of the knee. 60 patients were enrolled in a 3 arm randomized double-

blind trial designed to establish tolerability and efficacy of Ampion. In the three arms of the trial, patients were injected in the knee with either: (i) steroid, lidocaine, and saline; (ii) steroid, lidocaine, and Ampion, or; (iii) steroid, saline, and Ampion. There were very few moderate to severe adverse events with those subjects receiving the standard of care (Lidocaine/Steroids, 3 patients or 15%) and even fewer in either arm receiving Ampion in addition to steroids (2 patients or 10%). Overall, there were 4 treatment-related adverse events reported, but no moderate to severe treatment-related adverse events were reported. These favorable results allowed us to proceed to the second part of the Phase I trial evaluating Ampion as a monotherapy against saline.

In April 2012, we announced results from the second part of our AIK study of Ampion for the acute treatment of osteoarthritis of the knee. The second part of the AIK study was a 30 patient randomized (1:1), double-blind, placebo controlled trial designed to evaluate the safety and efficacy of Ampion 4mL in osteoarthritis of the knee patients. The 30 patients represented the efficacy evaluable population who did not receive a betamethasone injection as rescue medication of the intent-to-treat population of 43 patients. The primary endpoint was mean change in pain from baseline for Ampion compared to saline at 84 days following a single intra-articular injection into the knee measured on the pain scale known as the Numerical Rating Scale (NRS). Secondary endpoints included evaluating the safety as well as responder rate, defined as a 2 point reduction in pain on the NRS. A brief summary of the combined Ampion topline results is as follows:

Patients receiving Ampion achieved a significantly greater reduction in pain from baseline to 12 weeks compared to saline placebo control (1.76; p=0.04).

Patients receiving Ampion achieved a greater responder rate, defined as a 2 point shift on the NRS, from baseline to 12 weeks compared to saline placebo control (63% vs. 33%; p=0.10).

Overall, patients receiving Ampion achieved a statistically significant -2.22 reduction in pain from baseline (p<0.05) to 12 weeks compared to saline placebo control (-0.46; p=0.34). A graph depicting the least squares (LS) mean change in pain from baseline for both Ampion and saline placebo control is depicted below.

LS Mean change from baseline

Note: Bars = \pm /- 1 Standard Error

Model represented in the figure is adjusted for baseline pain NRS

Clinical Development Pathway.

Upon conclusion of the AIK trial which yielded the positive results summarized above, we presented a package containing both pre-clinical and clinical data to the blood products division of the Center for Biologics

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Evaluation and Research (CBER) of the FDA. The original guidance toward an Ampion Biologics License Application (BLA) filing included instruction to conduct customary toxicology work inclusive of animal studies prior to progressing into U.S. human trials. However, following the FDA s recognition of the established safety profile and standardization of production of HSA, the FDA allowed us to progress directly into U.S. human clinical trials. The FDA initially indicated that we should design and conduct two well-controlled trials with a 12 week primary endpoint measured on the Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain subscale (WOMAC A). If we wished to request a chronic use label for Ampion, we would need to expose 1,500 patients to Ampion, including exposure of 300-600 patients for at least six months and 100 patients for at least one year, according to the FDA s ICH-E1A guidance.

In February 2013, in response to our Investigational New Drug (IND) application and two submissions describing two concurrent Phase III study protocols enrolling in excess of 1,600 patients, the FDA did not object to two sequential well-conducted trials in support of a license application. Under such a development program the first trial would be a dose ranging trial, and the dose ranging trial objectives would be twofold: compare two volumes for efficacy and safety and demonstrate statistical power. We referred to the dose ranging trial as our SPRING study.

Dose Ranging SPRING Pivotal Trial Results.

On August 14, 2013, we announced results of the SPRING study of Ampion for the acute treatment of osteoarthritis of the knee. The SPRING study was a U.S. multicenter randomized (1:1:1:1), double-blind, placebo controlled trial designed to evaluate the safety and efficacy of Ampion in osteoarthritis of the knee patients. 329 patients were randomized to receive one of two doses (4 mL or 10 mL) of Ampion or corresponding saline placebo control via intra-articular injection. The primary study objective was to evaluate the relative efficacy of Ampion 4 mL versus Ampion 10 mL. The primary endpoint was mean change in pain as measured on the WOMAC A, from baseline for Ampion compared to the same volume of saline. Secondary endpoints included evaluating safety and disease severity, as well as stiffness and function. Both Ampion dose cohorts experienced statistically significant reductions in pain compared to control and there were no significant differences between the efficacy of the two Ampion doses. A brief summary of the combined Ampion topline results is as follows:

Patients receiving Ampion achieved significantly greater reduction in pain, WOMAC A, from baseline to 12 weeks compared to saline placebo control -0.25 (95% CI: -0.41 to -0.08, p = 0.004).

Patients receiving Ampion achieved significantly greater reduction in pain, WOMAC A, across 12 weeks compared to saline placebo control (p = 0.01).

Patients receiving Ampion also achieved significantly greater improvement in function, (WOMAC C), from baseline to 12 weeks compared to saline placebo control (p = 0.044).

Patients receiving Ampion also demonstrated significantly greater improvement in Patient Global Assessment (PGA) of disease severity from baseline to 12 weeks compared to saline placebo control (p = 0.012).

Clinical efficacy defined as pain reduction was evident as early as four weeks after the injection (p = 0.025) and continued to show improvement through 12 weeks (p = 0.0038).

Severe patients, defined as Kellgren-Lawrence IV, receiving Ampion achieved significantly greater reduction in pain, WOMAC A, from baseline to 12 weeks compared to severe patients receiving saline placebo control (p = 0.017).

Ampion was well tolerated with minimal adverse events (AEs) reported in the study. AEs were well balanced between Ampion and control groups. There were no drug-related serious adverse events (SAEs).

Patients in the SPRING trial receiving Ampion experienced, on average, approximately a 42% reduction in pain from baseline, whereas saline placebo control patients experienced approximately a 32% reduction in pain from baseline. Saline is generally used as the placebo control in mono articular injection therapy clinical trials and it also is recognized as being a partial therapeutic; therefore, any results reported using saline as a control can obscure the efficacy of the test drug.

On February 4, 2014, we announced that an article reporting the results was published in PLOS ONE, an international, open-access, online publication. The article entitled: A Randomized Clinical Trial to Evaluate Two Doses of an Intra-Articular Injection of LMWF-5A in Adults with Pain Due to Osteoarthritis of the Knee details the efficacy and safety outcomes of the use of Ampion in the SPRING study. The tables below show the results.

Demographics and baseline characteristics: ITT population

	Randomized arms				Combined arms		
	Control,	Control,	LMWF-5A,	LMWF-5A,			
	4mL	10mL	4mL	10mL	Control	LMWF-5A	
N (%)	(N=83)	(N=81)	(N=83)	(N=81)	(N=164)	(N=165)	
Female sex	57 (69%)	50 (62%)	56 (67%)	46 (56%)	107 (65%)	102 (62%)	
White race	74 (89%)	77 (95%)	74 (89%)	74 (90%)	151 (92%)	148 (90%)	
Hispanic	0 (0%)	2 (2%)	0 (0%)	2 (2%)	2 (1%)	2 (1%)	
Age Mean (SD)	60.7 (8.3)	63.8 (10.0)	62.7 (9.3)	62.8 (8.4)	62.2 (9.3)	62.7 (8.8)	
BMI Mean (SD)	34.5 (8.0)	32.1 (6.5)	33.2 (7.8)	32.8 (6.6)	33.3 (7.4)	33.0 (7.2)	
Left study knee	42 (51%)	40 (49%)	35 (42%)	41 (50%)	82 (50%)	76 (46%)	
Previous injection	58 (70%)	54 (67%)	49 (59%)	58 (71%)	112 (68%)	107 (65%)	
Injection Type							
Steroid	32 (55%)	24 (44%)	25 (51%)	26 (45%)	56 (50%)	51 (48%)	
Hyaluronic acid	20 (34%)	19 (35%)	17 (35%)	20 (34%)	39 (35%)	37 (35%)	
Other	6 (10%)	11 (20%)	7 (14%)	12 (21%)	17 (15%)	19 (18%)	
K-L Grade							
II	29 (35%)	26 (32%)	28 (34%)	32 (39%)	55 (34%)	60 (36%)	
III	32 (39%)	34 (42%)	38 (46%)	35 (43%)	66 (40%)	73 (44%)	
IV	22 (27%)	21 (26%)	17 (20%)	15 (18%)	42 (26%)	32 (19%)	
PGA Mean (SD)	3.4 (0.8)	3.4 (0.8)	3.4 (0.65)	3.4 (0.8)	3.4 (0.8)	3.4 (0.7)	
WOMAC Mean (SD)							
Pain	2.3 (0.5)	2.2 (0.6)	2.2 (0.5)	2.2 (0.5)	2.3 (0.5)	2.2 (0.5)	
Stiffness	2.4 (0.8)	2.4 (0.8)	2.3 (0.7)	2.4 (0.8)	2.4 (0.8)	2.3 (0.8)	
Function	2.3 (0.6)	2.2 (0.6)	2.1 (0.6)	2.2 (0.6)	2.2 (0.6)	2.2 (0.6)	

Key Primary and Secondary 12 Week Results: ITT Population

Randomized Arms					Combined Arms			
Type N of Group	Control, 4ml 83	Control, 10ml 81	LWFA-5A, 4ml 83	LWFA-5A, 10ml 82	Control 164	LWFA-5A, 165		
WOMAC A Pain	-0.71 (0.752)	-0.73 (0.964)	-0.93 (0.764)	-0.92 (0.791)	-0.72 (0.86)	-0.93 (0.775)	p = 0.004	
WOMAC C Function	-0.58 (0.08)	-0.69 (0.11)	-0.72 (0.09)	-0.83 (0.09)	-0.64 (0.07)	-0.78 (90.06)	p = 0.04	
N of Group K-L III	32	34	38	35	66	73		
Mean (SD) of Change	-0.62 (0.643)	-0.76 (0.801)	-0.95 (0.794)	-0.82 (0.865)	-0.69 (0.727)	089 (0.825)	p = 0.042	
N of Group K-L IV	22	21	17	15	43	32		
Mean (SD) of Change	-0.67 (0.866)	-0.34 (0.938)	-0.88 (0.917)	-0.83 (0.599)	-0.51 (0.906)	-0.86 (0.772)	p = 0.017	

Improvement in Pain Across a Broad Spectrum of OA-Knee Patients