WRIGHT MEDICAL GROUP INC
Form 425
October 27, 2014

Wright Announces Receipt of FDA Approvable Letter for Augment®

Bone
Graft
October 27, 2014
Filed by Wright Medical Group, Inc.
pursuant to Rule to Rule 425
Under the Securities Act of 1933
Deemed filed pursuant to Rule 14a-12
Under the Securities Exchange Act of 1934
Subject Company: Wright Medical Group, Inc.
Commission File No. 001-35823

Forward-Looking Statements
2
This press release contains forward-looking statements, as defined under U.S. federal securities laws, Bone Graft, and the positive effects such final approval is anticipated to have for patients, surgeons and our business, our plans to address the FDA inspection requirements set forth in the approvable letter, our revised 2014 guidance, and the potential for future growth in our business. These statements reflect management's current knowledge, assumptions, beliefs, estimates, and expectations and express management's current view of future performance, results, and trends. Forward-looking statements may be

identified by their use of terms such as anticipate, believe, could, estimate, expect, intend, may, plan, predict, project, will, and other similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. The reader should not place undue reliance on forward-looking statements. Such statements are made as of the date of this press release, and we undertake no obligation to update such statements after this date. Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements in this press release include the risk that we are unable to complete the requirements for FDA approval of Augment® Bone Graft, the risk that, when approved, market acceptance of Augment® concerning, among other things, the approvable status and anticipated final PMA approval of Augment® product quality or patient safety issues have an adverse impact on our product development plans, the risk that we are unable to achieve our operations targets for the balance of fiscal 2014; and the additional risks and uncertainties are discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013, and as may be supplemented in our Quarterly Reports on Form 10-Q).

Bone
Graft
is
less
than
anticipated,
the
risk
that

Leverages direct sales
force, training capabilities
Further accelerate
growth
Bone repair, soft tissue
indications

Roughly a $300M U.S. Market Opportunity

Final approval subject to customary preapproval inspections

Assuming satisfactory completion of this activity and receipt of a final approval order from the FDA, commercial sale and distribution of Augment® Bone Graft can begin in the U.S.

First clinically proven cost-effective alternative to autograft for ankle and/or hindfoot fusion

3

Breakthrough biologic

Unique solution for ankle and/or hindfoot fusion

Platform for future growth opportunities

Augment
®
Bone Graft
A Breakthrough Product!

In the North American pivotal trial, Augment demonstrated equivalent safety & efficacy and less pain compared to autograft.

Recombinant human platelet-derived growth factor (rhPDGF) intended to provide biological stimulus for in-growth and proliferation of osteoblasts (cells responsible for bone formation)

Beta-tricalcium phosphate (TCP) provides a framework or scaffold for new bone growth to occur

Avoids unwanted bone formation in surrounding tissues observed with BMP-based products
First clinically proven, cost-effective alternative to autograft for ankle and/or hindfoot fusion indications
4

Augment adds high margin, breakthrough product to
Wright s comprehensive suite of biologic technologies
WRIGHT
WRIGHT
Biologic
Biologic
Solutions
Solutions

Calcium Sulfate®
Technology
PRO-DENSE®
Technology
PRO-STIM®
Technology
DBM/CBM Technology
FUSIONFLEX®
Technology
GRAFTJACKET®
Matrix
Wedge Technology
IGNITE®
Technology
5

Augment
®
Accelerates Wright s Growth Opportunities
Demonstrated
results
Eliminates harvest
site complications
Patients avoid any

donor site pain
6
Hindfoot
Fusions
Ankle
Fusions

Augment
®
Bone
Graft
rhBMP
Stem Cells
Demineralized
Bone Matrix

(DBM)
FDA approvable for
ankle and/or hindfoot
fusion indications
YES
Level I evidence
YES
Demonstrated safety
YES
?
Reliable/consistent
quality
YES
?
?
Available off-the-shelf
YES
Cost effective
(relative to autograft)
YES
7
Compelling Value Proposition

In ankle and/or hindfoot fusion procedures, delayed union / nonunion still a major concern

Current literature suggests nonunion rates for ankle/hindfoot fusions are ~15-20% (1)

Much higher rates (16-41%) in high
risk groups
(2)
:

smokers

diabetics

revision surgery

post-traumatics

Both a mechanical and biological
problem
8

1. Easley et al, JBJS 2000; Thordarson et al, Foot Ankle Int 2003; Haddad et al, JBJS 2007
2. Frey et al, Foot Ankle Int 1994; Perlman and Thordarson, Foot Ankle Int 1999; Myers et al, Foot Ankle Intl 2012

Autograft has been used to enhance fusion rates

Stimulates the biological
healing process

Fills any joint irregularities
(voids/gaps)

Acts as a scaffold for new
bone formation
9
Iliac Crest Autograft Harvest

But autograft comes with a price
Harvest site
pain

~12% of patients who received autograft in Augment pivotal trial had clinically significant harvest site pain at 24 weeks

~9% had clinically significant harvest site pain at 52 weeks

Increases
Complication
Potential
(1-4)

Up to 49% complication rate for iliac crest bone graft

Potential for more serious complications and infections
Higher
Procedure
Costs

Direct costs to harvest autograft include additional surgeon/anesthesia/clinician time and instruments

Indirect cost of complications can further increase cost
Variable Quality

Variable quality across donor sites

Especially
problematic
for
compromised
patients

diabetics,
smokers, osteoporotics, elderly, etc.; these represent a significant portion of foot & ankle patient population
10
1. Arrington ED, et al, Clin Orthop. 1996
3. Springfield DS, Orthopaedics 1992
2. Kurz LT, et al, Spine 1989
4. Fowler BL, et al, Am J Orthop. 1995

Augment
®
Bone Graft: A Proven Therapeutic Option
11
Effective
When used as bone graft substitute in
ankle and/or hindfoot fusion procedures,
Augment

®
Bone Graft was shown to
achieve comparable:

Clinical and functional improvements
in outcomes
Safe
Augment
®
Bone Graft offers:

Comparable safety profile to
autograft

Comparable clinical healing to
autograft
Augment offers a synthetic alternative to autograft that:
-
Eliminates
complications
and
morbidity
associated
with
autograft
harvest
-
Patients avoid any donor site pain associated with autograft harvest

IN SUMMARY
A Breakthrough Biologic that Accelerates Wright s Growth Opportunities
12
Unique solution for
ankle and/or hindfoot
fusion
Breakthrough

biologic
Platform for future
growth opportunities

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