

INTEGRA LIFESCIENCES HOLDINGS CORP

Form 8-K

November 16, 2009

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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):

November 16, 2009

Integra LifeSciences Holdings Corporation

\_\_\_\_\_  
(Exact name of registrant as specified in its charter)

Delaware

000-26244

510317849

\_\_\_\_\_  
(State or other jurisdiction  
of incorporation)

\_\_\_\_\_  
(Commission  
File Number)

\_\_\_\_\_  
(I.R.S. Employer  
Identification No.)

311 Enterprise Drive, Plainsboro, New Jersey

08536

\_\_\_\_\_  
(Address of principal executive offices)

\_\_\_\_\_  
(Zip Code)

Registrant's telephone number, including area code:

609-275-0500

Not Applicable

\_\_\_\_\_  
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 8.01 Other Events.**

Suspension of Clinical Trial for DuraGen Plus® Adhesion Barrier Matrix

On November 16, 2009, the Company announced that it will suspend the enrollment of new patients in the clinical trial for DuraGen Plus® Adhesion Barrier Matrix for evaluating the safety and effectiveness as an adhesion barrier in spinal surgery. As previously announced, the Company, through its study contract research organization, conducted an interim analysis of the results of the clinical trial to date. The analysis concluded that a significantly larger number of patients than originally planned for in the current protocol would be necessary to demonstrate a statistically significant difference between the control arm (surgery alone) and the study arm (DuraGen Plus® Adhesion Barrier Matrix) for either of the two primary endpoints, pain/functional outcomes and the formation of scar as determined by magnetic resonance imaging (MRI). Accordingly, the Company has suspended recruitment and enrollment of new patients into the trial. The Company is working with the U.S. Food and Drug Administration (FDA) to determine the extent to which the trial will continue for patients already enrolled, and with the investigators to determine the potentially significant scientific value in data developed in the trial to date.

The safety profile of the DuraGen® product was well-characterized during the study, and safety considerations played no part in the decision to suspend new enrollment in the clinical trial.

This result does not disprove the fundamental science behind the collagen matrix technology, which is known to suppress the scar response. After the Company has completed the necessary requirements and obligations for the trial in accordance with FDA regulations and requirements and the requirements of the investigators and their governing Institutional Review Boards (IRBs), and in the interests of science, it will consider other possible studies to prove the effectiveness of its collagen matrix technology for this, or related indications. The DuraGen Dural Regeneration Matrix family of products has been used in over 750,000 patients as dural replacements in the cranium and spine.

The interim futility analysis was conducted by an independent group of statisticians in order to monitor the progress of the clinical trial and to determine whether the study will meet the objectives of the co-primary endpoints that were established under the protocol for the clinical trial and approved by the FDA under an Investigational Device Exemption (IDE).

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**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.

*November 16, 2009*

Integra LifeSciences Holdings Corporation

By: *Stuart M. Essig*

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*Name: Stuart M. Essig*

*Title: President and Chief Executive Officer*