INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
April 10, 2013

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): April 10, 2013

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**0-26224**	**51-0317849**

(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

311 Enterprise Drive

Plainsboro, NJ 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))

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On April 10, 2013, Integra LifeSciences Holdings Corporation (the Company) issued a press release announcing, among other things, its preliminary financial results on revenues, adjusted net income and adjusted earnings per share for the first quarter ended March 31, 2013 (the Press Release). A copy of the Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item. In the financial tables portion of the Press Release, the Company has included a reconciliation of GAAP net loss to adjusted net income and GAAP loss per diluted share to adjusted earnings per diluted share used by management for its preliminary financial results for the quarter ended March 31, 2013. The information contained in Item 2.02 of this Current Report on Form 8-K (including the Press Release and the financial tables) is being furnished and shall not be deemed filed for the 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. The information contained in Item 2.02 of this Current Report on Form 8-K (including the Press Release and selected historical financial information) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended (the Securities Act), or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Discussion of Adjusted Financial Measures

In addition to our GAAP results, we provide adjusted net income and adjusted earnings per diluted share. The measure of adjusted net income consists of GAAP net income, excluding: (i) manufacturing facility remediation costs; (ii) certain expenses associated with product recalls; (iii) global ERP implementation charges; (iv) facility optimization charges; (v) acquisition-related charges; (vi) convertible debt non-cash interest; (vii) intangible asset amortization expense; and (viii) income tax impact from adjustments and other items. The adjusted earnings per diluted share measure is calculated by dividing adjusted net income attributable to diluted shares by diluted weighted average shares outstanding. Because the low end of the Company s GAAP results may record a net loss, the calculation of GAAP diluted weighted average shares outstanding for the low end of the estimate excludes the effects of stock options and unvested restricted stock, as the effect of these equity awards would be anti-dilutive. The Company included the dilutive effects of these equity awards in the calculation of adjusted diluted weighted average shares outstanding used to calculate adjusted earnings per diluted share for the first quarter of 2013 because their effects are dilutive in relation to adjusted net income. A reconciliation of GAAP preliminary net loss to adjusted preliminary net income for the quarter ended March 31, 2013 appears in the financial tables in the Press Release.

The Company believes that the presentation of adjusted net income and adjusted earnings per diluted share measures provides important supplemental information to management and investors regarding financial and business trends relating to the Company s financial condition and results of operations. Management uses non-GAAP financial measures in the form of adjusted net income and adjusted earnings per diluted share when evaluating operating performance because we believe that the inclusion or exclusion of the items described below, for which the amounts and/or timing may vary significantly depending upon the Company s acquisition, integration, and restructuring activities, for which the amounts are non-cash in nature, or for which the amounts are not expected to recur at the same magnitude as we implement certain tax planning strategies, provides a supplemental measure of our operating results that facilitates comparability of our operating performance from period to period, against our business model objectives, and against other companies in our industry. We have chosen to provide this information to investors so they can analyze our operating results in the same way that management does and use this information in their assessment of our core business and the valuation of our Company.

Adjusted net income and adjusted earnings per diluted share are significant measures used by management for purposes of:

- supplementing the financial results and forecasts reported to the Company s board of directors;
- evaluating, managing and benchmarking the operating performance of the Company;
- establishing internal operating budgets;
- determining compensation under bonus or other incentive programs;
- enhancing comparability from period to period;

comparing performance with internal forecasts and targeted business models; and

evaluating and valuing potential acquisition candidates.

The measure of adjusted net income reflects GAAP net income adjusted for one or more of the following items, as applicable:

Manufacturing facility remediation costs. These costs represent expenses associated with remediation and related unplanned idle time and underutilization at the Plainsboro, NJ and Añasco, Puerto Rico manufacturing facilities. Management excludes this item when evaluating the Company s operating performance because of the variability and the magnitude of this item.

Certain expenses associated with product recalls. These costs represent expenses associated with a voluntary recall of certain products manufactured in the Añasco, Puerto Rico facility between December 2010 and May 2011 and between November 2012 and March 2013. Management excludes these items when evaluating the Company s operating performance because of the infrequent and/or large scale nature of these activities.

Global ERP implementation charges. Systems implementation charges consist of the non-capitalizable portion of internal labor and outside consulting costs related to the implementation of a global ERP system. We have inherited many diverse business processes and different information systems through our numerous acquisitions. Accordingly, we are undertaking this initiative in order to standardize business processes globally and to better integrate all of our existing and acquired operations using one information system. Although recurring in nature given the expected timeframe to complete the implementation for our existing operations and our expectation to continue to acquire new businesses and operations, management excludes these charges when evaluating the operating performance of the Company because the frequency and amount of such charges vary significantly based on the timing and magnitude of the Company s implementation activities. In addition, with the global ERP project entering the application development phase, more costs of the project will be capitalized and, therefore, are not comparable to earlier periods.

Facility optimization charges. These charges, which include employee termination and other costs associated with exit or disposal activities, costs related to acquisition integration, costs related to transferring manufacturing and/or distribution activities to different locations, result from rationalizing and enhancing our existing manufacturing, distribution and administrative infrastructure. Some of these cost-saving and efficiency-driven activities are identified as opportunities in connection with acquisitions that provide the Company with additional capacity or economies of scale. Although recurring in nature given management s ongoing review of the efficiency of our manufacturing, distribution and administrative facilities and operations, management excludes these items when evaluating the operating performance of the Company because the frequency and amount of such charges vary significantly based on the timing and magnitude of the Company s rationalization activities and are, in some cases, dependent upon opportunities identified in acquisitions, which also vary in frequency and magnitude.

Acquisition-related charges. Acquisition-related charges include up-front fees and milestone payments that are expensed as incurred in connection with acquiring licenses or rights to technology for which no product has been approved for sale by regulatory authorities and such approval is not reasonably assured at the time such up-front fees or milestone payments are made, and in-process research and development charges when accounting rules require them to be expensed, inventory fair value purchase accounting adjustments, and legal, accounting and other outside consultants expenses directly related to acquisitions. Inventory fair value purchase accounting adjustments consist of the increase to cost of goods sold that occur as a result of expensing the step up in the fair value of inventory that we purchased in connection with acquisitions as that inventory is sold during the financial period. Although recurring given the ongoing character of our development and acquisition programs, these acquisition and in-licensing related charges are not factored into the evaluation of our performance by management after completion of development programs or acquisitions because they are of a temporary nature, they are not related to our core operating performance and the frequency and amount of such charges vary significantly based on the timing and magnitude of our development and acquisition transactions as well as the level of inventory on hand at the time of acquisition.

Convertible debt non-cash interest. The convertible debt accounting requires separate accounting for the liability and equity components of the Company s convertible debt instruments, which may be settled in cash upon conversion, in a manner that reflects an applicable nonconvertible debt borrowing rate at the time that we issued such convertible debt instruments. Management excludes this item when evaluating the Company s operating performance because of the non-cash nature of the expense.

Intangible asset amortization expense. Management excludes this item when evaluating the Company s operating performance because it is a non-cash expense.

Income tax impact from adjustments and other items. Estimated impact on income tax expense related to the following:

(i) Adjustments to income tax expense for the amount of additional tax expense that the Company estimates that it would record if it used non-GAAP results instead of GAAP results in the calculation of its tax provision, based on the statutory rate applicable to jurisdictions in which the above non-GAAP adjustments relate.

(ii) Adjustments to income tax expense in the current quarter for the cumulative impact in that quarter of changes in income tax rates (statutory and estimated effective tax rates) and certain other infrequently occurring items that relate to prior periods. Management excludes these items when evaluating the Company s current quarter operating performance because the cumulative impact in the current quarter of these items applies to prior periods and thus distorts the Company s adjusted income tax rate in the current quarter. The year-to-date adjusted net income and adjusted diluted earnings per share measures are not adjusted by these items, as the cumulative impact is properly reflected in the year-to-date adjusted results.

Adjusted net income and adjusted earnings per diluted share are not calculated in accordance with GAAP, and should be considered supplemental to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. Non-GAAP financial measures have limitations in that they do not reflect all of the revenues, costs or benefits associated with the operations of the Company s business as determined in accordance with GAAP. As a result, you should not consider these measures in isolation or as a substitute for analysis of the Company s results as reported under GAAP. The Company expects to continue to acquire businesses and product lines and to incur expenses of a nature similar to many of the non-GAAP adjustments described above, and exclusion of these items from its adjusted financial measures should not be construed as an inference that all of these revenue adjustments or costs are unusual, infrequent or non-recurring. Some of the limitations in relying on the adjusted financial measures are:

The Company periodically acquires other companies or businesses, and we expect to continue to incur acquisition-related expenses and charges in the future. These costs can directly impact the amount of the Company s available funds or could include costs for aborted deals which may be significant and reduce GAAP net income.

The Company has initiated a long term effort to implement a global enterprise resource planning system, and we expect to continue to incur significant systems implementation charges until that effort is completed. These costs can directly impact the amount of the Company s available funds and reduce GAAP net income.

All of the adjustments to GAAP net income have been tax affected at the Company s actual tax rates. Depending on the nature of the adjustments and the tax treatment of the underlying items, the effective tax rate related to adjusted net income could differ significantly from the effective tax rate related to GAAP net income.

In the financial tables portion of the Press Release, the Company has included a reconciliation of GAAP net loss to adjusted net income and GAAP loss per diluted share to adjusted earnings per diluted share used by management for its preliminary financial results for the quarter ended March 31, 2013.

ITEM 7.01 REGULATION FD DISCLOSURE

On April 10, 2013, the Company issued the Press Release announcing, among other things, that on April 10, 2013 it initiated a voluntary recall of certain products manufactured in its Añasco, Puerto Rico facility between December 2010 and May 2011 and between November 2012 and March 2013. Specific lots of these products, described below, have been recalled because the Company identified that there may have been deviations from approved processes in their production.

There have been no reports of patient injuries or other adverse events attributable to the products subject to the recall. The Company continues to manufacture all such products in its Añasco facility.

The Company identified through an internal quality assurance review that it may have deviated from a production process during the manufacture of specific lots of collagen products during the periods described above. The product lots in question passed all product finished goods testing, are sterile, and were tested and accepted for release. However, due to the process deviation they may have been released with higher levels of endotoxins than permitted by the product specifications. Higher levels of endotoxins may result in a fever in the immediate postoperative period.

The Company believes that most of the recalled product lots manufactured between December 2010 and May 2011 have already been consumed, and that therefore the recall of those lots will not have a material financial impact. However, the Company expects that the return of products manufactured from November 2012 and March 2013 will directly reduce revenues in the first quarter of 2013 by $2 million to $4 million. In addition, the Company anticipates that it will not be able to produce all the affected products quickly enough to meet the demand from customers for at least several months. Such supply shortages resulted in lower revenues in the first quarter of 2013 of $6 million to $7 million and will result in lower revenues for the second quarter than originally anticipated. The Company expects that the recall and expected supply shortages will have the greatest impact on the U.S. Neurosurgery, U.S. Spine and Other, and International segments during the first and second quarters.

In addition, the Company incurred incremental expense in the first quarter, including scrap of affected finished good products that were not released to customers, affected work in process, and legal and consulting costs, of approximately $2.5 million to $4.5 million, which it will exclude from the calculation of adjusted earnings per share.

Finally, during the rest of 2013 the Company anticipates incremental expense in the second and third quarters to remediate quality systems in its Añasco and Plainsboro facilities. We expect to exclude such expenses from the calculation of adjusted earnings per share.

The Company expects that it will not be able to meet all the demand for the affected products during the second quarter of 2013. The Company now expects that consolidated revenues for the second quarter of 2013 will be between $205 million and $211 million.

Integra is currently evaluating its financial guidance for the full year of 2013 and expects to update that guidance to incorporate the full impact of the recall on its first quarter 2013 financial results conference call, which is scheduled for May 2, 2013.

The Company met with the Office of Compliance at the Center for Devices and Radiological Health on March 26, 2013. We presented our plans for both immediate remediation and our corporate plan for the development and implementation of one Quality System. We have engaged former FDA professionals as third party consultants to work with us on our remediation plans. The Company also met with the Office of Compliance at the FDA San Juan, PR office to discuss the remediation plans at the Añasco facility. We have prioritized senior level quality and regulatory staff to addressing the quality system improvement plans at all our facilities.

The recall applies to limited and specific lots of DuraGen® Dural Graft Matrix, DuraGen® Plus Dural Regeneration Matrix, DuraGen® Suturable Dural Regeneration Matrix, DuraGen XS Dural Regeneration Matrix, Layershield® Adhesion Barrier Matrix, NeuraWrap Nerve Protector, NeuraGen® Nerve Guide, BioMend® Absorbable Collagen Membrane, OraMem® Absorbable Collagen Membrane, BioMend® Extend Absorbable Collagen Membrane, CollaCote® Absorbable Collagen Wound Dressing for Dental Surgery, CollaTape® Absorbable Collagen Wound Dressing for Dental Surgery, CollaPlug® Absorbable Collagen Wound Dressing for Dental Surgery, HeliTape® Absorbable Collagen Wound Dressing for Dental Surgery, HeliPlug® Absorbable Collagen Wound Dressing for Dental Surgery, OraTape® Absorbable Collagen Wound Dressing for Dental Surgery, OraPlug® Absorbable Collagen Wound Dressing for Dental Surgery, Instat® Microfibrillar Collagen Hemostat, Helistat® Absorbable Collagen Hemostatic Sponge (ACS/Helistat), and Helitene® Absorbable Collagen Hemostatic Agent. The Absorbable Collagen Sponge (ACS) is not a final product, but a component of a product assembled by another company.

The Company received a warning letter dated February 13, 2013 from the FDA. Since that time, the Company has taken several actions to address the concerns identified in the warning letter, including engaging third-party consultants to independently certify the evaluation of process validations, Corrective Action and Preventive Action robustness, and an initial assessment of our overall Quality Management System improvements. These actions in part resulted in the Company s decision to voluntarily initiate the recall. A copy of the warning letter redacted to remove confidential information is attached as Exhibit 99.1 to the Current Report on Form 8-K filed by the Company on February 19, 2013. The warning letter relates to quality systems issues at its manufacturing facility in Añasco, Puerto Rico. The Company, cannot, however, give any assurances that the FDA will be satisfied with its response to, and actions taken in connection with, the warning letter or as to the expected date of the resolutions of the matters identified in the warning letter. Until the violations are corrected, the Company may be subject to additional regulatory action by the FDA, including seizure, injunction and/or civil money penalties. Additionally, requests for Certificates to Foreign Governments related to products manufactured at the Añasco facility will not be granted and premarket approval applications for Class III devices to which the quality system regulation deviations are reasonably related will not be approved until the violations have been corrected. The Company presently has no such applications before the FDA.

A copy of the Press Release is attached as Exhibit 99.1, to this Current Report on Form 8-K and is incorporated by reference into this Item 7.01. The information contained in this Item 7.01 of this Current Report on Form 8-K (including the Press Release) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

99.1 Press release with attachments, dated April 10, 2013, issued by Integra LifeSciences Holdings Corporation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: April 10, 2013

By: /s/ John B. Henneman, III
John B. Henneman, III
Title: Corporate Vice President, Finance and Administration, and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release with attachments, dated April 10, 2013, issued by Integra LifeSciences Holdings Corporation.