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            SECURITIES AND EXCHANGE COMMISSION
            Washington, D.C. 20549
                    FORM 10-Q
            QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D)
                OF THE SECURITIES EXCHANGE ACT OF 1934
            For the quarterly period ended September 30, 1997
                    Commission file number 0-26224
                    INTEGRA LIFESCIENCES CORPORATION
(Exact name of registrant as specified in its charter)
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Delaware
(State or other jurisdiction of incorporation or organization)

105 Morgan Lane
Plainsboro, New Jersey
(Address of principal executive offices)

51-0317849
(I.R.S. Employer Identification No.)

08536
(Zip code)
(609) 275-0500
(Registrant's telephone number, including area code)
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or $15(\mathrm{~d})$ of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

$$
[x] \text { - Yes [ ]-No }
$$

As of November 12, 1997 the registrant had outstanding 29,808,700 shares of Common Stock, $\$ .01$ par value.

# INTEGRA LIFESCIENCES CORPORATION 

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Item 1. Financial Statements

## INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(Dollars in thousands)

## September 30, 1997 December 31, 1996

ASSETS


The accompanying notes are an integral part of the condensed consolidated financial statements

## INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES <br> CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(In thousands)

REVENUE

| Product sales | \$ | 3,754 | \$ | 2,591 | \$ | 10,844 | \$ | 8,132 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Research grants. |  | 113 |  | 177 |  | 411 |  | 610 |
| Product license fees |  | 6 |  | - |  | 11 |  | 500 |
| Royalties. |  | 73 |  | 66 |  | 175 |  | 205 |
| Contract product development |  | - |  | 42 |  | - |  | 76 |
| Total revenue. |  | 3,946 |  | 2,876 |  | 11,441 |  | 9,523 |
| COSTS AND EXPENSES |  |  |  |  |  |  |  |  |
| Cost of product sales. |  | 1,731 |  | 1,575 |  | 5,574 |  | 4,462 |
| Research and development |  | 1,439 |  | 1,591 |  | 4,525 |  | 4,814 |
| Selling, general and administrative. |  | 3,745 |  | 2,350 |  | 9,192 |  | 6,874 |
| Total costs and expenses |  | 6,915 |  | 5,516 |  | 19,291 |  | 16,150 |
| Operating income (loss) |  | $(2,969)$ |  | $(2,640)$ |  | $(7,850)$ |  | $(6,627)$ |
| Other income. |  | 507 |  | 563 |  | 1,519 |  | 1,444 |
| Net income (loss). | \$ | $(2,462)$ | \$ | $(2,077)$ | \$ | $(6,331)$ | \$ | $(5,183)$ |
| Net income (loss) per share. | \$ | (0.08) | \$ | (0.07) | \$ | (0.21) | \$ | (0.19) |
| Weighted average number of common and common equivalent shares outstanding.......... |  | 29,797 |  | 28,535 |  | 29,511 |  | 27,967 |

The accompany notes are an integral part of the condensed consolidated financial statements


The accompanying notes are an integral part of the condensed consolidated financial statements

1. In the opinion of management, the September 30 unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring accruals) which the Company considers necessary for a fair presentation of the financial position and results of operations of the Company. Operating results for the periods ended September 30, 1997 are not necessarily indicative of the results to be expected for the entire year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosures of contingent assets and liabilities and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 1996 included in the Company's Annual Report on Form 10-K.
2. Inventories consist of the following (In thousands):

September 30, 1997 December 31, 1996

|  | September 30, 1997 |  | December 31, 1996 |  |
| :---: | :---: | :---: | :---: | :---: |
| Finished goods | \$ | 780 | \$ | 1,007 |
| Work-in-process |  | 914 |  | 1,270 |
| Raw materials. |  | 230 |  | 358 |
|  | \$ | 924 | \$ | 2,635 |

3. A former customer of the Company has claimed that the Company owes $\$ 393,000$ in connection with a terminated contract. The Company believes that it does not have any liability in connection with this matter, and accordingly, the Company's financial statements due not reflect any such liability.
4. In May 1997, the Company's Stock Option Committee and Board of Directors approved an option exchange program pursuant to which employees with options having an exercise price in excess of $\$ 4.00$ per share under the Company's Stock Option Plans could elect to exchange such options for new stock options with an exercise of $\$ 4.00$. Under the exchange program, (i) the number of replacement options issued in exchange for the original options was determined by the utilization of a formula based on the percentage decrease in exercise price from the original grant (not to exceed $25 \%$ of the original options and excluding the first 1,000 options), (ii) the replacement options expiration dates were adjusted to one year later than the original options expiration dates, and (iii) the vesting terms of the replacement options were adjusted to proportionately reflect
the decrease in options, when applicable. Under the exchange program, $1,134,417$ options with exercise prices ranging from $\$ 4.25$ to $\$ 12.50$ were exchanged for 903,317 options granted with an exercise price of $\$ 4.00$.

To date, the Company has not calculated the pro-forma affect of the exchange program under the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation". The Company believes the exchange program is likely to increase the pro forma expense associated with the stock option plans because a significant amount of the original grants were prior to 1995 and therefore did not impact the disclosure previously.
5. In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130"). SFAS 130 establishes standards of disclosure and financial statement display for reporting comprehensive income and the components thereof. This statement defines comprehensive income as the change in equity of a business during a period from transactions and other events and circumstances from non-owner sources. SFAS 130 requires that comprehensive income be presented in the financial statements as a separate statement, in the statement of changes in equity or below the total of net income or loss in the income statement. SFAS 130 is effective for fiscal years beginning after December 15, 1997, with earlier application permitted. The Company is currently evaluating the effect SFAS 130 will have on its financial statements.
6. In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131"). SFAS 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports issued to shareholders. Operating segments are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance This Statement requires that a public business enterprise report descriptive information about the way that the operating segments were determined and the products and services provided by the operating segments.

This statement requires that a public business enterprise report a measure of segment profit or loss, certain specific revenue and expense items, and segment assets. It requires reconciliations of total segment revenues, total segment profit or loss, total segment assets, and other amounts disclosed for segments to corresponding amounts in the enterprise's general-purpose financial statements. It also requires that all public business enterprises report information about the revenues derived from the enterprise's products and services, about the countries in which the enterprise earns revenues and holds assets, and about major customers
regardless of whether that information is used in making operating decisions. SFAS 131 is effective for financial statements for periods beginning after December 15, 1997. The Company is currently evaluating the effect SFAS 131 will have on its financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains trend information and other forward-looking statements related to the future use of INTEGRA(TM) Artificial Skin and anticipated expenditure levels and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Such statements involve risks and uncertainties which may cause results to differ materially from those set forth in these statements. In addition, the economic, competitive, governmental, technological and other factors identified in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission could affect such results.

General
The Company is dedicated to the development and marketing of BioSmart(TM) absorbable products to regenerate specific body tissues and organs. The Company has developed principally by combining existing businesses, acquiring synergistic technologies and forming strategic business and technological alliances.

## Results of Operations

Three Months Ended September 30, 1997 Compared to Three Months Ended September 30, 1996

Total revenues increased to approximately $\$ 3.9$ million for the three months ended September 30, 1997 from $\$ 2.9$ million for the three months ended September 30,1996, as an increase in product sales was offset by decreases in research grant and contract product development revenues. Product sales increased to $\$ 3.8$ million for the three months ended September 30, 1997 from $\$ 2.6$ million for the three months ended September 30, 1996. Sales of INTEGRA(TM) Artificial Skin ("INTEGRA") increased to $\$ 1.6$ million for the three months ended September 30, 1997 compared to $\$ 860,000$ in the third quarter of 1996. INTEGRA received U.S. Food and Drug Administration premarket approval in March 1996. In the third quarter of 1997, North American INTEGRA sales represented $67 \%$ of total INTEGRA product sales. Since FDA approval, the product has been used in hospitals making up over $50 \%$ of the specialized burn care beds in the United States. The Company believes that INTEGRA has overcome the early adopter threshold and is now entering what the Company calls an "intensity of use" stage. The Company is focusing on increasing the annual per bed use of INTEGRA in centers where the product has already been used.

The primary application of INTEGRA has been for patients with severe life-threatening burns. The Company is also aware of its application in reconstructive and wound healing procedures and is continuing to focus its strategy on expanding the approved indications for use of INTEGRA. The Company believes that INTEGRA can offer improved results compared to existing treatments for relief of painful scars, wound contractures and hypertrophic scarring. The Company believes that the following factors will have the greatest influence on the use and sale of INTEGRA; i) physician training prior to product use, ii) the collection of pharma-economic data to address initial product reimbursement
issues, iii) the publication of positive clinical results, iv) the continued expansion into international markets, and v) the Company's ability to obtain FDA approvals for additional indications.

Sales of the Company's other medical products were approximately $\$ 2.2$ million for the three months ended September 30, 1997 compared to $\$ 1.7$ million for the three months ended September 30, 1996. Increases in the Company's Infection Control and Dental product lines offset a decline in international Surgical and Hemostasis product sales. Sales of the Company's other medical products can vary significantly on a quarter to quarter basis depending on the timing of shipments to private label customers and contract distributors. The Company is currently in negotiations to extend a license and distribution agreement for one of its Infection Control products, which is likely to result in a decline in 1997 fourth quarter sales compared to the prior year. The Company believes that finalizing such an agreement establishes the long-term commitment of our marketing partner to the product.

Export sales for the three months ended September 30, 1997 were flat with the three months ended September 30, 1996 at approximately $\$ 550,000$. International INTEGRA sales increased by $\$ 220,000$ to $\$ 530,000$ for the three months ended September 30, 1997 compared to the three months ended September 30, 1997, which was offset by declines in sales of other medical products. In July 1997, the Company has entered into an exclusive importation and sales agreement for INTEGRA in Japan with Century Medical, Inc., a wholly owned subsidiary of ITOCHU Corporation. Under the agreement, Century Medical will oversee and manage the Company's clinical trials required for approval by the Japanese government, and will then serve as the Company's exclusive distributor and importer in Japan for regenerative products. The Company has also recently received approval to import and market INTEGRA in Taiwan, bringing the total number of countries INTEGRA can be marketed in to nineteen.

Other revenue, which includes grant revenue, license fees, contract development revenue and royalties, was approximately $\$ 190,000$ for the three months ended September 30, 1997 compared to $\$ 285,000$ for the three months ended September 30, 1996. The largest decline was in grant revenue due to the completion of a three-year National Institute of Standards and Technology (NIST) grant as of December 31, 1996. The Company was recently awarded a three-year $\$ 2$ million grant from NIST targeted to further develop the Company's BioSmart(TM) absorbable polymers especially designed for tissue engineering with the initial application expected to stimulate in-vivo cartilage regeneration. In addition, the Company announced that it was awarded a research and development grant totaling $\$ 96,500$ from the National Cancer Institute. The purpose of the grant is to support the Company's development of an RGD-based drug to inhibit angiogenesis. The Company continues to seek research grants, licensing arrangements and development funding for several of its technologies, although the timing and amount of such revenue, if any, can not be predicted.

Cost of product sales increased to approximately $\$ 1.7$ million (46\% of product sales) for the three months ended September 30, 1997 from $\$ 1.6$ million ( $61 \%$ of product sales) for the three months ended September 30, 1996. The
decrease in cost of product sales as a percentage of product sales is partially attributable to an increase in sales of higher gross margin products including INTEGRA, and a decline in inventory write-offs and product reserves related to the Company's Ophthalmic product line and INTEGRA, respectively. The Company has discontinued its production of the Ophthalmic product. The Company's INTEGRA manufacturing unit is currently operating at a lower utilization compared to the prior year as the Company continues to reduce inventory levels. Due to the high fixed costs of the manufacturing facility for INTEGRA, the Company is anticipating higher unit costs until there is a requirement for higher production volume. The Company believes its current capacity to produce INTEGRA and its other medical products is sufficient to support significant growth, and that better utilization of this capacity will improve its gross margin on product sales.

Research and development expense decreased to approximately $\$ 1.4$ million for the three months ended September 30, 1997 from $\$ 1.6$ million for the three months ended September 30, 1996. A decline in animal studies related to prior grant awards offset increases in research efforts associated with the Company's California operations and costs associated with the Company's post-approval clinical study for INTEGRA and additional INTEGRA development activities. The Company expects the level of research and development expenditures in 1997 to remain around 1996 expenditure levels as expenditures related to the post-approval study of INTEGRA and pre-clinical and clinical trials for the Company's regenerative and matrix medicine technologies continue. The amount of resources and the allocation of those resources to fund research and development will vary depending upon a number of factors, including the progress of development of the Company's technologies, the timing and outcome of pre-clinical and clinical results, changing competitive conditions and determinations with respect to the commercial potential of the Company's technologies.

Selling, general and administrative expense increased to approximately $\$ 3.7$ million for the three months ended September 30, 1997 from $\$ 2.4$ million for the three months ended September 30, 1996. Sales and marketing expenses increased significantly due to the addition of marketing personnel and
consultants as well as additional promotional activities involving INTEGRA.
General and administrative expense also increased significantly due to increased legal and professional costs and additional management and business development personnel. The Company is anticipating continued increases in sales and marketing expenses over 1996 levels as a result of additional personnel and continued promotional activities involving INTEGRA. General and administrative expenses will continue to increase over 1996 levels due to the increase in personnel and the Company's patent litigation lawsuit. The extent of such increases will, in part, depend on the progress of the Company's patent litigation lawsuit.

Nine Months Ended September 30, 1997 Compared to Nine Months Ended September 30, 1996

Total revenues increased to approximately $\$ 11.4$ million for the nine months ended September 30, 1997 from $\$ 9.5$ million for the nine months ended September 30,1996, as an increase in product sales was offset by decreases in research grant revenue and product license fees. Product sales increased to $\$ 10.8$ million for the nine months ended September 30, 1997 from $\$ 8.1$ million for the nine months ended September 30, 1996. Sales of INTEGRA increased to \$4.6 million for the nine months ended September 30,1997 compared to $\$ 1.8$ million for the nine months ended September 30, 1996. Included in the first nine-month sales of 1997 is $\$ 1.3$ million in international INTEGRA sales, including over \$250,000 in sales in Germany, France and Australia, and compared to \$580,00 in sales for the prior year period

Product sales of the Company's other medical products were
approximately $\$ 6.3$ million for both the nine months ended September 30, 1997 and the nine months ended September 30, 1996. Increases in the Company's Dental product line were offset by a decline in the Company's Surgical and Hemostasis and Infection Control product lines. The Company also experienced a decline in its Ophthalmic product line as it has ceased sales of its corneal shield product. The Company does not believe that the loss of this product will have a significant impact on the Company as the ophthalmic product accounted for only $3 \%$ of product sales for the year ended December 31, 1996 and the nine months ended September 30, 1997. Sales of the Company's other medical products can vary significantly on a period to period basis depending on the timing of shipments to private label customers and contract distributors. Export sales, including INTEGRA, for the nine months ended September 30, 1997 increased to $\$ 1.5$ million from \$1.2 million for the nine months ended September 30, 1996.

Other revenue was approximately $\$ 600,000$ for the nine months ended September 30, 1997 compared to $\$ 1.4$ million for the nine months ended September 30,1996 . The largest decline was in product license fees due to a $\$ 500,000$ licensing fee received in 1996 as part of an agreement with Cambridge Antibody Technology Limited involving the Company's human antibody development program. Grant revenue also declined due to the completion of a three-year National Institute of Standards and Technology grant as of December 31, 1996.

Cost of product sales increased to approximately $\$ 5.6$ million (51\% of product sales) for the nine months ended September 30, 1997 from $\$ 4.5$ million (55\% of product sales) for the nine months ended September 30, 1996. The decrease in cost of product sales as a percentage of product sales is partially attributable to sales growth in higher gross margin products compared to the prior year.

Research and development expense was approximately $\$ 4.5$ million for the nine months ended September 30, 1997 compared to $\$ 4.8$ million for the nine months ended September 30, 1996. Decreases in animal study costs associated with the prior year grant funding were offset by increases in costs associated the Company's post-approval clinical study for INTEGRA and the addition of full-time clinical and research personnel.

Selling, general and administrative expense increased to approximately $\$ 9.2$ million for the nine months ended September 30, 1997 from $\$ 6.9$ million for the nine months ended September 30, 1996. Sales and marketing expenses increased due to domestic and international costs associated with INTEGRA. A decline in national training session costs was offset by increased costs associated with
additional
technical personnel and consultants as well as additional promotional activities. General and administrative expenses increased due to additional legal and professional costs and additional management personnel.

## Liquidity and Capital Resources

At September 30, 1997, the Company had cash, cash equivalents and short-term investments of approximately $\$ 30.4$ million and no long-term debt. The Company's principal uses of funds during the nine-month period ended September 30, 1997 were $\$ 3.8$ million for operations and $\$ 500,000$ in purchases of property and equipment. The Company also received $\$ 330,000$ in funds from the exercise of stock options under the Company's stock option plans. The Company anticipates that it will continue to use its liquid assets to fund operations until sufficient revenues can be generated through product sales and collaborative arrangements. There can be no assurance that the Company will be able to generate sufficient revenues to obtain positive operating cash flows or profitability.

Other Information
In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130"). SFAS 130 establishes standards of disclosure and financial statement display for reporting comprehensive income and the components thereof. This statement defines comprehensive income as the change in equity of a business during a period from transactions and other events and circumstances from non-owner sources. SFAS 130 requires that comprehensive income be presented in the financial statements as a separate statement, in the statement of changes in equity or below the total of net income or loss in the income statement. SFAS 130 is effective for fiscal years beginning after December 15, 1997, with earlier application permitted. The Company is currently evaluating the effect SFAS 130 will have on its financial statements.

In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131"). SFAS 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports issued to shareholders. Operating segments are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. This Statement requires that a public business enterprise report descriptive information about the way that the operating segments were determined and the products and services provided by the operating segments.

SFAS 131 requires that a public business enterprise report a measure of segment
profit or loss, certain specific revenue and expense items, and segment assets. It requires reconciliations of total segment revenues, total segment profit or loss, total segment assets, and other amounts disclosed for segments to corresponding amounts in the enterprise's general-purpose financial statements. It also requires that all public business enterprises report information about the revenues derived from the enterprise's products and services, about the countries in which the enterprise earns revenues and holds assets, and about major customers regardless of whether that information is used in making operating decisions. SFAS 131 is effective for financial statements for periods beginning after December 15, 1997. The Company is currently evaluating the effect SFAS 131 will have on its financial statements.

PART II. OTHER INFORMATION
Item 6. Exhibits and Reports on Form 8-K
(a) Exhibits

11 Statement re Computation of Per Share Amounts
27 Financial Data Schedule
(b) Reports on Form 8-K None

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 thereunto duly authorized.

INTEGRA LIFESCIENCES CORPORATION
Date: September 14, 1997
/s/ Richard E. Caruso
Richard E. Caruso, Ph.D.
Chairman, President and Chief Executive Officer

Date: September 14, 1997 /s/ David B. Holtz
David B. Holtz
Vice President, Treasurer

|  | Three Mo Septe | s Ended 30, | Nine Mo Septe | s Ended 30, |
| :---: | :---: | :---: | :---: | :---: |
|  | 1997 | 1996 | 1997 | 1996 |
| Primary: |  |  |  |  |
| Net loss for the period | \$ (2,462) | \$ ( 2,077 ) | \$ (6, 331) | \$ $(5,183)$ |
| Weighted average number of shares of common stock outstanding | 29,797 | 28,535 | 29,511 | 27,967 |
| Shares issuable upon exercise of outstanding options and warrants | - - | - - | - - | - - |
| Shares assumed to be acquired in accordance with the treasury stock method ................... | -- | -- | -- | -- |
| Shares used in computing per share loss Net loss per share | $\begin{gathered} \\ \\ \$ \quad 29,797 \\ (0.08) \end{gathered}$ | $\begin{gathered} 28,535 \\ \$ \quad(0.07) \end{gathered}$ | $\begin{gathered} 29,511 \\ \$ \quad(0.21) \end{gathered}$ | $\begin{array}{r} 27,967 \\ \$ \quad(0.19) \end{array}$ |
|  | $\begin{aligned} & \text { \$ }(0.08) \\ & ====== \end{aligned}$ | $\begin{aligned} & \text { \$ } \quad(0.07) \\ & ====== \end{aligned}$ | ======== | $\begin{aligned} & \text { \$ }(0.19) \\ & ======= \end{aligned}$ |
| Fully Diluted: |  |  |  |  |
| Net loss for the period | \$ (2,462) | \$ (2,077) | \$ (6, 331) | \$ (5, 183) |
| Weighted average number of shares of common stock outstanding | 29,797 | 28,535 | 29,511 | 27,967 |
| Shares issuable upon exercise of outstanding options and warrants | 256 | 1,367 | 514 | 3,371 |
| Shares assumed to be acquired in accordance with the treasury stock method ........ | (126) | (57) | (85) | $(1,549)$ |
| Shares used in computing per share loss | 29,927 | 29,845 | 29,940 | 29,789 |
| Net loss per share | \$ (0.08) | \$ (0.07) | \$ (0.21) | \$ (0.17) |

