



FOR FURTHER INFORMATION  
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## **Radiance Meets Important Milestones and Reports**

### **Results For Second Quarter 2001**

Irvine, CA -- Thursday, July 26, 2001 -- Radiance Medical Systems, Inc., (NASDAQ: RADX) today announced that revenue for the second quarter of 2001 totaled \$1,834,000 compared to 2000 second quarter revenues of \$2,542,000. Revenues for the second quarter of 2001 and 2000 included certain product-licensing fees of \$1,479,000 and \$1,840,000, respectively. For the six months ended June 30, 2001 total revenues were \$3,859,000, compared to \$4,904,000 for the six months ended June 30, 2000. Revenues for the six months ended June 30, 2001 and 2000 included product-licensing fees of \$3,037,000 and \$3,520,000, respectively.

The decrease in revenues for the three and six months ended June 30, 2001 was due primarily to a decrease in royalties recorded from Guidant Corporation in connection with a 1998 license agreement of limited rights to Radiance Focus™ Technology. The decrease in revenues also was due to a decrease in product sales attributable to the Company's decision to concentrate on the development of radiation delivery technology.

The Company reported a net loss for the second quarter 2001 of \$3,151,000, or \$0.24 per share, compared to a second quarter 2000 loss of \$1,171,000, or \$0.10 per share. For the six months ended June 30, 2001, the Company's net loss was \$6,386,000, or \$0.49 per share, compared to a loss of \$2,618,000, or \$0.23 per share in 2000 for the same period. The increase in net loss for the second quarter and first six months of 2001, compared with the results for the same periods of 2000, was due primarily to higher spending for clinical trials, including BRITE II and BRITE SVG, and research and development projects including the establishment of a European, third-party manufacturing facility.

“During the second quarter Radiance has met some challenging milestones,” said Jeff Thiel, Radiance's President & CEO. “With the initiation of the RAPID Study, Radiance has taken the leadership position in the use of beta radiation for the treatment of restenosis in the peripheral vascular system, a large and emerging market. In addition, just prior to the

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close of the quarter, we announced that we had received notification of CE Mark approval for the RDX™ Coronary Radiation Delivery System. This will allow us to begin selling this second generation technology in Europe and other countries throughout the world.”

### **RDX Coronary Radiation Delivery System**

The RDX is a balloon catheter based system used to deliver a therapeutic dose of radiation to arteries to prevent restenosis. Because the radiation is encapsulated in the balloon membrane, and when inflated the radioactive source is apposed to the vessel wall, the device is designed to deliver a more consistent dose to the target tissue in the vessel.

CE Mark status provides Radiance with the regulatory approval required to begin marketing the RDX to prevent restenosis in *de novo* (not previously treated) lesions, in stents and in vessels where the blockage has reoccurred (restenosis). Sales of the product are scheduled to begin during the third quarter in a limited launch to key customers in select countries. During the fourth quarter, a full-scale product launch will begin in all European countries and select countries around the world.

### **BRITE (Beta Radiation to Reduce In-Stent Restenosis) I and BRITE II**

The objective of the U.S. phase I BRITE Study was to evaluate the safety of the RDX System in preventing the recurrence of atherosclerotic blockage in patients who have had a coronary stent implanted and have returned to the hospital with a restenosis. Data from this study was provided to the Food and Drug Administration (FDA) in support of the commencement of the BRITE II Study.

The BRITE II Study is a multi-center, randomized study to be conducted in approximately 40 clinical centers in the United States and enroll approximately 480 patients. Enrollment began in January 2001. The Study will determine the safety and effectiveness of the RDX System in patients who have had a coronary stent implanted and have returned to the hospital with restenosis. It has been estimated that there are over 250,000 in-stent restenosis patients treated annually on a worldwide basis. Dr. Ron Waksman, Director of Vascular Brachytherapy, Washington Hospital Center, Washington D.C. serves as the Principal Investigator for the Study. Data from this study will be provided to the FDA in support of the Pre-Market Approval (“PMA”) application which, if and when approved, would allow for the U.S. marketing of the RDX System for the treatment of in-stent restenosis.

## **BRITE-SVG**

The BRITE-SVG Study is a Phase I safety study designed to evaluate the safety of the RDX System for the treatment of *de novo* lesions and in-stent restenosis in saphenous vein bypass grafts (“SVG”). The BRITE-SVG protocol is designed to enroll 50 patients at 6 centers worldwide treating blockages up to 45mm in length in graft diameters of 3.0mm to 4.5mm. Gregg Stone M.D., Director of Cardiovascular Research and Education at the Cardiovascular Research Foundation and at Lenox Hill Hospital, New York, N.Y., is the principal investigator for the study. Enrollment in the study was completed in July 2001 and results are expected to be presented at the American College of Cardiology meeting in March 2002.

## **RAPID (Radiation After PTA Is Done)**

RAPID is an international clinical study designed to evaluate the use of a larger diameter RDX System in the superficial femoral and popliteal arteries, the primary vessels in the mid and lower leg. The principal investigator is Professor Erich Minar of the University of Vienna, a leading expert in the use of vascular brachytherapy for treatment of peripheral vessels. European enrollment for RAPID began in May 2001. In late June 2001, Radiance filed an IDE with the U.S. FDA to expand this trial to the U.S. It is estimated that 500,000 patients are treated annually for peripheral vascular disease, representing an annual market of approximately \$500 million.

Radiance Medical Systems, Inc. develops radiation delivery catheters intended for use in the cardiovascular or coronary and peripheral vascular systems to prevent restenosis following the interventional treatment of atherosclerosis. In addition, Radiance markets coronary stents, coronary stent delivery systems and balloon dilatation catheters for coronary applications. For more information about Radiance, visit the Company’s website at: [www.Radiance.net](http://www.Radiance.net).

*Except for historical information contained herein, this news release contains forward-looking statements, the accuracy of which are necessarily subject to risks and uncertainties. Actual results may be affected by, among other things, risks and uncertainties related to new product development and introduction cycles, research and development activities, including failure to demonstrate clinical efficacy, delays by regulatory authorities, scientific and technical advances by third parties, introduction of competitive products, third party reimbursement and physician training, and other risk factors and matters set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2000 and the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.*



**RADIANCE MEDICAL SYSTEMS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)

	(Unaudited)			
	Three Months Ended June 30,	2000	Six Months Ended June 30,	2000
	2001		2001	2000
<b>Revenue:</b>				
Product sales	\$336	\$623	\$765	\$1,193
License revenue	1,498	1,919	3,094	3,711
<b>Total revenues</b>	<b>1,834</b>	<b>2,542</b>	<b>3,859</b>	<b>4,904</b>
Cost of sales	346	366	653	859
<b>Gross profit</b>	<b>1,488</b>	<b>2,176</b>	<b>3,206</b>	<b>4,045</b>
<b>Operating expenses:</b>				
Research, development and clinical	3,914	2,814	8,242	5,559
Marketing and sales	445	319	839	642
General and administrative	661	750	1,398	1,477
Minority Interest	(6)	(8)	(13)	(9)
<b>Total operating expenses</b>	<b>5,014</b>	<b>3,875</b>	<b>10,466</b>	<b>7,669</b>
<b>Loss from operations</b>	<b>(3,526)</b>	<b>(1,699)</b>	<b>(7,260)</b>	<b>(3,624)</b>
<b>Other income (expense):</b>				
Interest income	356	294	807	587
Gain on disposal of assets	43	234	66	467
Other income (expense)	(24)	-	1	(48)
<b>Total other</b>	<b>375</b>	<b>528</b>	<b>874</b>	<b>1,006</b>
<b>Net loss</b>	<b>(\$3,151)</b>	<b>(\$1,171)</b>	<b>(\$6,386)</b>	<b>(\$2,618)</b>
<b>Basic and diluted net loss per share</b>	<b>(\$0.24)</b>	<b>(\$0.10)</b>	<b>(\$0.49)</b>	<b>(\$0.23)</b>
<b>Shares used in computing basic and diluted net loss per share</b>	<b>13,072</b>	<b>11,352</b>	<b>13,066</b>	<b>11,316</b>

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