

CARDIOVASCULAR SYSTEMS INC

Form 425

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**CARDIOVASCULAR SYSTEMS REPORTS FISCAL SECOND-QUARTER 2009 FINANCIAL RESULTS**

**Revenue Increases 200 Percent from Fiscal Second Quarter 2008**

*Conference call scheduled for today, Wednesday, February 11, 2009 at 4 PM CT (5 PM ET)*

**Second-quarter revenue increases to \$14.0 million in fiscal 2009 from \$4.6 million in fiscal 2008;**

**Current quarter gross margin rises to 70 percent from 53 percent in 2008;**

**Merger expected to close on or about February 25, 2009;**

**Next-generation Diamondback 360° Orbital Atherectomy System launched.**

**St. Paul, Minn., February 11, 2009** Cardiovascular Systems, Inc. (CSI), a medical device company developing and commercializing innovative interventional treatment systems for vascular disease, today reported financial results for its fiscal second quarter ended December 31, 2008. CSI also reported it expects to close its previously announced merger transaction on or about February 25, 2009, in which CSI will combine its business with Replidyne, Inc. (Nasdaq: RDYN) in an all-stock transaction. The combined company will be named Cardiovascular Systems, Inc. and it has applied for listing on the Nasdaq Global Market under the symbol CSII.

CSI's revenue in the second quarter of fiscal 2009 rose to \$14.0 million, a 200 percent increase over revenue of \$4.6 million in the second quarter of fiscal 2008. The second-quarter net loss improved 11 percent to \$(8.7) million from \$(9.8) million in the second quarter of fiscal 2008. Net loss available to common shareholders, which includes the effect of accretion of redeemable convertible preferred stock, was \$(11.7) million compared with \$(10.1) million last year, reflecting an increase in preferred stock accretion of \$2.6 million. Basic and diluted loss per common share was \$(1.51) versus \$(1.56) in last year's second quarter. The number of weighted average common shares increased by 1.2 million from the issuance of restricted stock and exercise of stock options.

David L. Martin, CSI president and chief executive officer, noted: "CSI's fiscal second-quarter revenue was driven by solid increases in both the number of accounts and Diamondback 360° devices sold. Over the last year, our direct sales staff grew to nearly 90 professionals from 20, and we are seeing the results of this investment. To sustain our growth, we have continued to make additional investments in infrastructure and product development.

The number of hospitals using the Diamondback 360° system rose to 400 by the end of the second quarter, up from 283 at the end of the first quarter of fiscal 2009 and 39 at the end of the second quarter of fiscal 2008. Sales of disposable units also showed strong growth with nearly 4,400 units sold in the second quarter this year, up from 3,600 units in first quarter this fiscal year and 1,400 units in the second quarter of fiscal 2008.

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Martin continued, Revenue has grown significantly each quarter since CSI commercially launched the Diamondback 360° system in September 2007 a strong endorsement of our product. The Diamondback 360° system is demonstrating its utility in treating a broad range of plaque types, especially calcified plaque, both above and below the knee. The product's efficacy, safety, ease of use, and procedure speed make it a valuable tool for every peripheral lab in the battle against peripheral arterial disease.

This year's second-quarter gross margin increased to 70 percent from 53 percent in the same period last year, driven by higher disposable volumes and manufacturing efficiencies. Sales, general and administrative expenses rose 55 percent to \$14.9 million, reflecting the increase in the sales organization and infrastructure investments to support growth. CSI continues to emphasize product development and innovation. As a result, research and development rose 16 percent to \$3.5 million.

In the first six months of fiscal 2009, revenue grew to \$25.6 million, more than five times greater than the \$4.6 million in the same period last year, which only had one quarter of revenue due to the timing of FDA clearance to market the initial Diamondback 360° product. The gross margin in the first six months of fiscal 2009 was 69 percent, up from 41 percent in the same period last year, due to higher product volumes and manufacturing efficiencies. In the first half of fiscal 2009, the net loss was \$(22.4) million, compared to \$(17.2) million in the first half of fiscal 2008. The higher net loss was due to significant investments in sales and marketing, and infrastructure to support growth, as well as product development. The net loss available to common shareholders, including accretion of preferred stock, was \$(25.4) million, or \$(3.29) per diluted share, in the first half of fiscal 2009, compared to \$(22.4) million, or \$(3.50) per diluted share, in the comparable period last year.

#### **New Product Introductions**

In December 2008, CSI introduced the next generation of the Diamondback 360° Orbital Atherectomy System, its minimally invasive catheter system for treating peripheral arterial disease (PAD). Major enhancements include a new handle for treating longer lesions without repositioning the device; improved fluid management; a one-click-connect feature to attach tubing and cables; and a convenient saline infusion port.

Martin added, The next-generation system represents great progress in CSI's product development program and reflects our commitment to continuous improvement in the efficacy, speed, safety and ease of use of our product. The system's new features are in direct response to needs voiced by our physician customers. In addition, we introduced two supplemental products that will enhance our sales productivity, and we are actively pursuing additional products to supplement our leadership position in the treatment of PAD. Some of these products are expected to be introduced later this calendar year.

New supplemental products recently introduced include ViperSlide an exclusive lubrication designed to optimize the smooth operation of the Diamondback 360° System; and ViperTrack a radiopaque tape designed to assist in identifying lesion lengths and the best treatment strategy for procedures using fluoroscopic or radiographic imaging.

#### **Fiscal 2009 Guidance**

For the last six months of fiscal year 2009, ending June 30, 2009, CSI expects revenue to range between \$31.0 million and \$33.0 million, bringing the expected full fiscal year's revenue to between \$56.6 million and \$58.6 million. This represents growth of greater than 150 percent over fiscal year 2008 and a 21 percent to 29 percent increase in the second half of fiscal 2009 over the first half of the year. Gross margin is anticipated to be in the range of 70 percent to 73 percent for the six-month period. The company also expects a net loss for the last six months of fiscal year 2009 ranging from \$(17.0) million to \$(19.0) million, compared to \$(22.4) million in the first half of the year. The net loss improvement results from increasing revenue and gross profit, with lower operating expense growth. The improvement is more pronounced on an adjusted EBITDA basis, calculated as loss from operations less depreciation and amortization and stock-based compensation expense. The loss range on an adjusted EBITDA basis is

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expected to be approximately \$(10.0) million to \$(12.0) million in the last half of fiscal 2009, a substantial improvement from the \$(18.8) million negative adjusted EBITDA in the first half of fiscal 2009.

#### **Merger Update**

A joint proxy statement/prospectus relating to the proposed merger has been mailed to the shareholders of CSI and Replidyne, and the special shareholder meetings of both companies to vote on the transaction are scheduled for February 24. If approved, the transaction is expected to close on or about February 25.

Martin added, "This merger is our best opportunity to obtain financing and become listed on a major U.S. stock exchange in exceptionally difficult financial markets, giving our shareholders the potential to realize future value.

Through this transaction, we expect to receive \$35.0 million to \$37.0 million in net assets, primarily cash, which should be sufficient to bridge CSI to profitability and positive cash flow.

Under this agreement, current CSI shareholders will own approximately 83 percent of the combined company (calculated on a fully diluted basis using the treasury method for stock options and warrants). The combined company will be named Cardiovascular Systems, Inc. and has applied for listing on the Nasdaq Global Market under the symbol CSII.

All of CSI's stock, including common and preferred, will be converted into common stock in the combined company. When added to Replidyne's outstanding shares, the combined company's total common shares outstanding are expected to be between 136 million and 142 million, which is expected to be reduced via a reverse split, the ratio for which will be finalized near the closing date.

#### **About the Diamondback 360<sup>o</sup>™ Orbital Atherectomy System and PAD**

CSI's Diamondback 360<sup>o</sup> Orbital Atherectomy System is a minimally invasive catheter system for the treatment of peripheral arterial disease, or PAD, which affects approximately 8 million to 12 million people in the U.S. PAD is caused by the accumulation of plaque in peripheral arteries (commonly the pelvis or leg), reducing blood flow. The plaque deposits range from soft to calcified, with calcified plaque being difficult to treat with traditional interventional procedures. The Diamondback 360<sup>o</sup> is capable of treating a broad range of plaque types both above and below the knee, including calcified vessel lesions, and addresses many of the limitations associated with existing treatment alternatives. In August 2007, the U.S. FDA granted 510(k) clearance for the use of the Diamondback 360<sup>o</sup> as a therapy in patients with PAD, and CSI commenced a commercial introduction of the product in the United States in September 2007.

CSI has conducted three clinical trials involving 207 patients to demonstrate the safety and efficacy of the Diamondback 360<sup>o</sup> in treating PAD. In particular, the pivotal OASIS clinical trial was a prospective 20-center study that enrolled 124 patients with 201 treated lesions and met the study endpoints. CSI was the first, and so far the only, company to conduct a prospective multi-center clinical trial with a prior investigational device exemption, or IDE, in support of a 510(k) clearance for an atherectomy device.

The Diamondback 360<sup>o</sup> provides a platform that can be leveraged across multiple market segments. CSI plans to launch additional products to more efficiently treat lesions in larger vessels and to seek premarket approval (PMA) from the FDA to use the Diamondback 360<sup>o</sup> to treat patients with coronary artery disease.

#### **Conference Call Today at 4 PM CT (5 PM ET)**

Cardiovascular Systems Inc. will host a live conference call and webcast of its fiscal second-quarter 2009 results today, Wednesday, February 11, 2009, at 4 p.m. CT (5 p.m. ET). To access the call dial (888) 713-4213 and enter 80520252. Please dial in at least 10 minutes prior to the call. To listen to the live webcast, go to the investor information section of the company's Web site, [www.csi360.com](http://www.csi360.com), and click on the webcast icon. A webcast replay will be available beginning at 7 p.m. CT the same day.

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For an audio replay of the conference call, dial (888) 286-8010 and enter access number 71792538. The audio replay will be available beginning at 8 p.m. CT on Wednesday, February 11, 2009, through 6 p.m. CT on Monday, February 16, 2009.

**Safe Harbor**

*This press release contains plans, intentions, objectives, estimates and expectations that constitute forward-looking statements about Replidyne and CSI that involve significant risks and uncertainties. Examples of such statements include, but are not limited to, the anticipated closing date of the merger, the expected cash that will be available to CSI at the closing of the merger, the anticipated benefits of the transaction, including the sufficiency of Replidyne's net assets to bridge CSI to profitability and a positive cash flow, the expected ownership of CSI shareholders in the combined company, the number of shares outstanding following the merger, and CSI's expectation for revenues, gross margin, net loss, and adjusted EBITDA for the last six months of the fiscal year ending June 30, 2009. Actual results could differ materially from those discussed in the forward-looking statements due to a number of factors including the outcome of the shareholder vote for the proposed merger; the outcome of Replidyne's efforts to wind up its business including the disposition of its research pipeline programs; Replidyne's actual net assets at the closing of the merger; the number of outstanding shares of CSI and Replidyne immediately prior to the closing of the merger; regulatory developments in the U.S. and foreign countries; the experience of physicians regarding the effectiveness and reliability of the Diamondback 360°; competition from other devices; unanticipated developments affecting CSI's estimates regarding expenses, future revenues and capital requirements; and CSI's ability to obtain and maintain intellectual property protection for product candidates. These and additional risks and uncertainties are described more fully in CSI's registration statement on Form 10 filed with the Securities and Exchange Commission (SEC) on December 17, 2008, Replidyne's Form S-4 filed with the SEC on January 26, 2009, and Replidyne's most recent Form 10-Q filed with the SEC. Copies of filings made with the SEC are available through the SEC's electronic data gathering analysis and retrieval system (EDGAR) at [www.sec.gov](http://www.sec.gov). All forward-looking statements made in the press release are made as of the date hereof and neither Replidyne nor CSI assumes any obligation to update the forward-looking statements in the document.*

**Additional Information About the Merger and Where to Find It**

This communication may be deemed to be solicitation material with respect to the proposed transaction between CSI and Replidyne. In connection with the transaction, Replidyne has filed a registration statement on Form S-4 with the SEC containing a related proxy statement/prospectus. The proxy statement/prospectus has been mailed to the stockholders of Replidyne and CSI. Investors and security holders of Replidyne and CSI are urged to read the proxy statement/prospectus because it contains important information about Replidyne, CSI and the proposed transaction. The proxy statement/prospectus, and any other documents filed by Replidyne or CSI with the SEC, may be obtained free of charge at the SEC web site at [www.sec.gov](http://www.sec.gov). In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Replidyne by contacting Replidyne Investor Relations by email at [ir@replidyne.com](mailto:ir@replidyne.com) or by telephone at (303) 996-5522. Investors and security holders may obtain free copies of the documents filed with the SEC by CSI by contacting CSI by telephone at (651) 259-1000. Investors and security holders are urged to read the proxy statement/prospectus and the other relevant materials before making any voting decision with respect to the proposed transaction.

Replidyne and CSI and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from their shareholders in favor of the proposed transaction. Information about the directors and executive officers of Replidyne and CSI and their respective interests in the proposed transaction is available in the proxy statement/prospectus.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the

securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Additional information about the merger transaction is available online at [www.Replidyne.com](http://www.Replidyne.com) or [www.csi360.com](http://www.csi360.com).

**Use of Non-GAAP Financial Measures**

To supplement CSI's consolidated condensed financial statements prepared in accordance with U.S. generally accepted accounting principles (GAAP), CSI uses certain non-GAAP financial measures in this release. Reconciliations of the non-GAAP financial measures used in this release to the most comparable U.S. GAAP measures for the respective periods can be found in tables later in this release immediately following the consolidated statements of operations.

Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for CSI's financial results prepared in accordance with GAAP.

**About Cardiovascular Systems Inc.**

Cardiovascular Systems Inc. is a medical device company focused on developing and commercializing interventional treatment systems for vascular disease. For more information visit the company's Web site at [www.csi360.com](http://www.csi360.com).

**Contacts:**

**For Cardiovascular Systems Inc.**

Investor Relations

(651) 259-2800

[investorrelations@csi360.com](mailto:investorrelations@csi360.com)

**Padilla Speer Beardsley:**

Marian Briggs

(612) 455-1742

[mbriggs@psbpr.com](mailto:mbriggs@psbpr.com)

Nancy A. Johnson

(612) 455-1745

[njohnson@psbpr.com](mailto:njohnson@psbpr.com)

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**Cardiovascular Systems, Inc.**  
**Consolidated Statements of Operations**  
(Dollars in Thousands, except per share and share amounts)  
(unaudited)

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Revenues	\$ 14,004	\$ 4,631	\$ 25,650	\$ 4,631
Cost of goods sold	4,153	2,193	8,034	2,732
Gross profit	9,851	2,438	9,851	1,899
Selling, general and administrative	14,949	9,629	31,373	13,181
Research and development	3,469	2,996	8,424	6,324
Total expenses	18,418	12,625	39,797	19,505
Loss from operations	(8,567)	(10,187)	(22,181)	(17,606)
<b>Other (expense) income</b>				
Interest expense	(799)		(1,026)	(216)
Interest income	2,867	419	3,009	613
Impairment on investments	(2,233)		(2,233)	
Total other (expense) income	(165)	419	(250)	397
Net loss	(8,732)	(9,768)	(22,431)	(17,209)
Accretion of redeemable convertible preferred stock	(2,997)	(353)	(2,997)	(5,206)
Net loss available to common shareholders	\$ (11,729)	\$ (10,121)	\$ (25,428)	\$ (22,415)
Loss per common share:				
Basic and diluted	\$ (1.51)	\$ (1.56)	\$ (3.29)	\$ (3.50)
Weighted average common shares used in computation:				
Basic and diluted	7,756,147	6,508,541	7,724,197	6,400,027
<b>Stock-based compensation supplemental detail (included in amounts above):</b>				
<b>(Dollars in Thousands) (unaudited)</b>				
Cost of goods sold	\$ 100	\$ 69	\$ 275	\$ 69
Selling, general and administrative	1,340	4,500	2,724	4,777
Research and development	108	27	222	100
Totals	\$ 1,548	\$ 4,596	\$ 3,220	\$ 4,946



**Cardiovascular Systems, Inc.**  
**Consolidated Balance Sheets**  
(Dollars in Thousands)  
(unaudited)

	<b>December 31, 2008</b>	<b>June 30, 2008</b>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 6,370	\$ 7,595
Accounts receivable, net	7,351	4,897
Inventories	3,072	3,776
Prepaid expenses and other current assets	1,757	1,936
<b>Total current assets</b>	<b>18,550</b>	<b>18,204</b>
Auction rate security put option	2,700	
Investments, trading	19,500	
Investments, available for sale		21,733
Property and equipment, net	1,291	1,041
Patents, net	1,163	980
<b>Total assets</b>	<b>\$ 43,204</b>	<b>\$ 41,958</b>
<b>LIABILITIES AND SHAREHOLDERS (DEFICIENCY) EQUITY</b>		
Current liabilities		
Current maturities of long-term debt	\$ 27,821	\$ 11,888
Accounts payable	4,188	5,851
Accrued expenses	5,242	3,467
Deferred revenue		116
<b>Total current liabilities</b>	<b>37,251</b>	<b>21,322</b>
Long-term liabilities		
Long-term debt, net of current maturities	2,100	
Redeemable convertible preferred stock warrants	4,226	3,986
Deferred rent	100	100
<b>Total long-term liabilities</b>	<b>6,426</b>	<b>4,086</b>
<b>Total liabilities</b>	<b>43,677</b>	<b>25,408</b>
Commitments and contingencies		
Redeemable convertible preferred stock	101,239	98,242
Shareholders (deficiency) equity		
Common stock	39,869	35,933
Common stock warrants	2,152	680
Accumulated deficit	(143,733)	(118,305)



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Total shareholders (deficiency) equity	(101,712)	(81,692)
Total liabilities and shareholders (deficiency) equity	\$ 43,204	\$ 41,958

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**Non-GAAP Financial Measures**

To supplement CSI's consolidated condensed financial statements prepared in accordance with GAAP, CSI uses certain non-GAAP financial measures in this release. These non-GAAP financial measures include Supplemental Sales Information, and Adjusted EBITDA.

Reconciliations of the non-GAAP financial measures used in this release to the most comparable U.S. GAAP measures for the respective periods can be found in the tables below. In addition, an explanation of the manner in which CSI's management uses these non-GAAP measures to conduct and evaluate its business, the economic substance behind management's decision to use these non-GAAP measures, the substantive reasons why management believes that these non-GAAP measures provide useful information to investors, the material limitations associated with the use of these non-GAAP measures and the manner in which management compensates for those limitations is included following the reconciliation tables below.

**Cardiovascular Systems, Inc.**  
**Supplemental Sales Information (unaudited)**  
(Dollars in Thousands)

	Q2 2008	Q3 2008	Q4 2008	Q1 2009	Q2 2009
<b>Revenue Components:</b>					
Devices	\$4,157	\$6,867	\$9,000	\$10,664	\$12,853
Other	474	787	892	982	1,151
Total revenue	\$4,631	\$7,654	\$9,892	\$11,646	\$14,004
Device units sold	1,404	2,328	3,063	3,636	4,368
Customers, at quarter end	39	106	183	283	400

**Cardiovascular Systems, Inc.**  
**Adjusted EBITDA (unaudited)**  
(Dollars in Thousands)

	Actual		Actual		Projected Range	
	Three Months Ended	December 31,	Six Months Ended	December 31,	Six Months Ending	June 30, 2009
	2008	2007	2008	2007	High	Low
Loss from operations	\$(8,567)	\$(10,187)	\$(22,181)	\$(17,606)	\$(16,000)	\$(18,000)
Add: Stock-based compensation	1,548	4,596	3,220	4,946	5,700	5,700
Add: Depreciation and amortization	101	85	196	132	300	300
Adjusted EBITDA	\$(6,918)	\$(5,506)	\$(18,765)	\$(12,528)	\$(10,000)	\$(12,000)

**Use and Economic Substance of Non-GAAP Financial Measures Used by CSI and Usefulness of Such Non-GAAP Financial Measures to Investors**

CSI uses the non-GAAP financial measures described above as supplemental measures of performance and believes these measures facilitate operating performance comparisons from period to period and company to company by factoring out potential differences caused by non-recurring, unusual or



infrequent charges not related to CSI's regular, ongoing business, depreciation, non-cash charges and certain large and unpredictable charges. CSI's management uses the non-GAAP financial measures used in this release to analyze the underlying trends in CSI's business, assess the performance of CSI's core operations, establish operational goals and forecasts that are used in allocating resources and evaluate CSI's performance period over period and in relation to its competitors' operating results. Additionally, CSI's management is evaluated on the basis of some of these non-GAAP financial measures when determining achievement of their incentive compensation performance targets.

CSI believes that presenting the non-GAAP financial measures used in this release provides investors greater transparency to the information used by CSI's management for its financial and operational decision-making and allows investors to see CSI's results through the eyes of management. CSI also believes that providing this information better enables CSI's investors to understand CSI's operating performance and evaluate the methodology used by CSI's management to evaluate and measure such performance. CSI's management believes that non-GAAP financial measures are useful to investors to evaluate CSI's performance period over period and in relation to its competitors' operating results.

The following is an explanation of each of the items that management excluded from one or more of the non-GAAP financial measures used in this release and the reasons for excluding each of these individual items:

**Supplemental Sales Information.** In addition to disclosing net sales and growth rates that are determined in accordance with GAAP, CSI's management believes that in order to properly understand underlying business trends in and performance of CSI's business, management has found and investors may find it useful to consider supplemental sales information, including revenue component detail, device units sold, and number of customers.

**Stock-based compensation.** CSI excludes stock-based compensation expense from its non-GAAP financial measures primarily because such expense, while constituting an ongoing and recurring expense, is not an expense that requires cash settlement. CSI's management also believes that excluding this item from CSI's non-GAAP results is useful to investors to understand the application of SFAS 123R and its impact on CSI's operational performance, liquidity and its ability to make additional investments in the company, and it allows for greater transparency to certain line items in CSI's financial statements.

**Depreciation and amortization expense.** CSI excludes depreciation and amortization expense from its non-GAAP financial measures primarily because such expenses, while constituting ongoing and recurring expenses, are not an expense that requires cash settlement and is not used by CSI's management to assess the core profitability of CSI's business operations. CSI's management also believes that excluding these items from CSI's non-GAAP results is useful to investors to understand CSI's operational performance, liquidity and its ability to make additional investments in the company.

**Material Limitations Associated with the Use of Non-GAAP Financial Measures and Manner in which CSI Compensates for these Limitations**

Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for CSI's financial results prepared in accordance with GAAP. Some of the limitations associated with CSI's use of these non-GAAP financial measures are:

Items such as stock-based compensation do not directly affect CSI's cash flow position; however, such items reflect economic costs to CSI and are not reflected in CSI's Adjusted EBITDA and therefore these non-GAAP measures do not reflect the full economic effect of these items.

Non-GAAP financial measures are not based on any comprehensive set of accounting rules or principles and therefore other companies may calculate similarly titled non-GAAP financial measures differently than CSI, limiting the usefulness of those measures for comparative purposes.

CSI's management exercises judgment in determining which types of charges or other items should be excluded from the non-GAAP financial measures CSI uses.

CSI compensates for these limitations by relying primarily upon its GAAP results and using non-GAAP financial measures only supplementally. CSI provides full disclosure of each non-GAAP financial measure CSI uses and detailed reconciliations of each non-GAAP measure to its most directly comparable GAAP measure. CSI encourages investors to review these reconciliations. CSI qualifies its use of non-GAAP financial measures with cautionary statements as set forth above.