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): May 1, 2019

Cardiovascular Systems, Inc.

(Exact name of Registrant as Specified in its Charter)

Delaware	**000-52082**	**41-1698056**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1225 Old Highway 8 Northwest
St. Paul, Minnesota 55112-6416

(Address of Principal Executive Offices and Zip Code)

(651) 259-1600

(Registrant's telephone number, including area code)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 1, 2019, Cardiovascular Systems, Inc. (the "Company") issued a press release regarding the Company's financial results for its third fiscal quarter ended March 31, 2019. A copy of the Company's press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated May 1, 2019.

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.

Date: May 1, 2019

CARDIOVASCULAR SYSTEMS, INC.

By: /s/ Jeffrey S. Points

Jeffrey S. Points
Chief Financial Officer

CARDIOVASCULAR SYSTEMS, INC. REPORTS FISCAL 2019 THIRD-QUARTER FINANCIAL RESULTS

Conference Call Scheduled for Today, May 1, 2019, at 3:30 PM CT (4:30 PM ET)

- **Revenues of $63.3 million increased 13.9% from third quarter last year**
- **Net income was $0.7 million, or $0.02 per diluted share**
- **Company increases fiscal 2019 revenue guidance to upper half of previous range**

St. Paul, Minn., May 1, 2019 – Cardiovascular Systems, Inc. (CSI ®) (NASDAQ: CSII), a medical device company developing and commercializing innovative interventional treatment systems for patients with peripheral and coronary artery disease, today reported financial results for its fiscal third quarter, ended March 31, 2019.

CSI's third-quarter revenues were $63.3 million, an increase of $7.7 million, or 13.9%, from the third quarter of fiscal 2018. Gross profit margin remained healthy at 80.8%.

Selling, general and administrative expenses increased 9.4% to $41.4 million due to increased investments to support international expansion. Research and development expenses increased 26.6% to $9.3 million as a result of planned new product development and patient enrollment costs in the ECLIPSE clinical trial.

Third-quarter net income was $0.7 million, or $0.02 per basic and diluted share, compared favorably to net income of $0.4 million, or $0.01 per basic and diluted share, in the prior-year period. Adjusted EBITDA totaled $4.1 million.

Scott Ward, CSI's Chairman, President and Chief Executive Officer, said, "Our strategy to provide exceptional case support, deliver continuous innovation and produce compelling medical evidence resonates with our customers. Fiscal year-to-date, these efforts are translating into market-leading growth in both peripheral and coronary atherectomy."

CSI Updates Fiscal 2019 Guidance

Ward concluded, "Consistent with our plan, we have successfully accelerated revenue growth this year. During the first nine months of fiscal 2019, revenues increased 13.9% versus 3.9% during the comparable period one year ago. We are driving growth primarily through increased adoption of orbital atherectomy domestically and introducing our technology to new international markets. We remain on track to achieve revenue of $245 million to $247 million, representing the upper half of our fiscal 2019 revenue guidance range."

For fiscal 2019 ending June 30, 2019, CSI anticipates:

- Revenue of $245 million to $247 million, representing 13% to 14% growth compared to fiscal 2018;
- Gross profit as a percentage of revenues of 80%-81%;
- Net loss equal to 0.5% of revenue to breakeven; and
- Positive Adjusted EBITDA.

Conference Call Scheduled for Today at 3:30 p.m. CT (4:30 p.m. ET)
CSI will host a live conference call and webcast of its fiscal third-quarter results today, May 1, 2019, at 3:30 p.m. CT (4:30 p.m. ET). To access the call, dial (833) 241-7255 at least 10 minutes prior to the call and enter the access number 5768999. To access the live webcast, or replay, click on this link
https://investors.csi360.com/events-and-presentations/events-calendar/default.aspx, and then click on the webcast link.

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 Peripheral Artery Disease (PAD)
As many as 18 million Americans, most over age 65, suffer from PAD, which is caused by the accumulation of plaque in peripheral arteries reducing blood flow. Symptoms include leg pain when walking or at rest. Left untreated, PAD can lead to severe pain, immobility, non-healing wounds and eventually limb amputation. With risk factors such as diabetes and obesity on the rise, the prevalence of PAD is growing at double-digit rates.

Millions of patients with PAD may benefit from treatment with orbital atherectomy utilizing the Stealth 360 ® and Diamondback 360 ® Peripheral Orbital Atherectomy Systems, minimally invasive catheter systems developed and manufactured by CSI. These systems use a diamond-coated crown, attached to an orbiting shaft, which sands away plaque while preserving healthy vessel tissue — a critical factor in preventing reoccurrences. Balloon angioplasty and stents have significant shortcomings in treating hard, calcified lesions. Stents are prone to fractures and high recurrence rates, and treatment of hard, calcified lesions often leads to vessel damage and suboptimal results.

About Coronary Artery Disease (CAD)
CAD is a life-threatening condition and a leading cause of death in men and women in the United States. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of CAD increases if a person has one or more of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. According to the American Heart Association, 16.3 million people in the United States have been diagnosed with CAD, the most common form of heart disease. Heart disease claims more than 600,000 lives in the United States each year. According to estimates, significant arterial calcium is present in nearly 40% of patients undergoing a percutaneous coronary intervention (PCI). Significant calcium contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used, including a significantly higher occurrence of death and major adverse cardiac events (MACE).

About Cardiovascular Systems, Inc.
Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The company’s Orbital Atherectomy Systems treat calcified and fibrotic plaque in arterial vessels throughout the leg and heart in a few minutes of treatment time, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The U.S. FDA granted 510(k) clearance for the use of the Diamondback Orbital Atherectomy System in peripheral arteries in August 2007. In October 2013, the company received FDA approval for the use of the Diamondback Orbital

Atherectomy System in coronary arteries. The Stealth 360 ® Peripheral Orbital Atherectomy System (OAS) received CE Mark in October 2014. In March 2017, the company received PMDA approval in Japan for the Diamondback 360 ® Coronary OAS Micro Crown and reimbursement approval effective February 2018. Over 450,000 of CSI's devices have been sold to leading institutions worldwide. For more information, visit the company's website at www.csi360.com.

Safe Harbor
Certain statements in this news release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are provided under the protection of the safe harbor for forward-looking statements provided by that Act. For example, statements in this press release regarding (i) CSI's strategy and growth; and (ii) anticipated revenue, gross profit, net loss and Adjusted EBITDA, are forward-looking statements. These statements involve risks and uncertainties that could cause results to differ materially from those projected, including, but not limited to, regulatory developments, clearances and approvals; approval of our products for distribution in countries outside of the United States; approval of products for reimbursement and the level of reimbursement in the U.S., Japan and other foreign countries; dependence on market growth; agreements with third parties to sell their products; the ability of OrbusNeich to successfully launch CSI products outside of the United States and Japan; our ability to maintain third-party supplier relationships and renew existing purchase agreements; our ability to maintain our relationship with our distribution partner in Japan and with OrbusNeich; the experience of physicians regarding the effectiveness and reliability of the products we sell; the reluctance of physicians, hospitals and other organizations to accept new products; the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; actual clinical trial and study results; the impact of competitive products and pricing; unanticipated developments affecting our estimates regarding expenses, future revenues and capital requirements; the difficulty of successfully managing operating costs; our ability to manage our sales force strategy; our actual research and development efforts and needs; our ability to obtain and maintain intellectual property protection for product candidates; our actual financial resources and our ability to obtain additional financing; fluctuations in results and expenses based on new product introductions, sales mix, unanticipated warranty claims, and the timing of project expenditures; our ability to manage costs; investigations or litigation threatened or initiated against us; court rulings and future actions by the FDA and other regulatory bodies; the effects of hurricanes, flooding, and other natural disasters on our business; issues relating to our saline pump recall; the impact of federal corporate tax reform on our business, operations and financial statements; international trade developments; shutdowns of the U.S. federal government; general economic conditions; and other factors detailed from time to time in CSI's SEC reports, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. CSI encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this release. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, CSI's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this release. The forward-looking statements made in this release are made only as of the date of this release, and CSI undertakes no obligation to update them to reflect subsequent events or circumstances.

Product Disclosures:

Peripheral Products
The Stealth 360 ® PAD System and Diamondback 360 ® PAD System are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. The systems are contraindicated for use in coronary arteries, bypass grafts, stents or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm. See the instructions for use for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information call CSI at 1-877-274-0901 and/or consult CSI's website at www.csi360.com.

Coronary Product
Indications: The Diamondback 360 ® Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to *de novo* , severely calcified coronary artery lesions.

Contraindications: The OAS is contraindicated when the ViperWire ® guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children.

Warnings/Precautions: Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions, A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated. See the instructions for use before performing Diamondback 360 Coronary OAS procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information call CSI at 1-877-274-0901 and/or consult CSI's website at www.csi360.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Cardiovascular Systems, Inc.

Consolidated Statements of Operations

(Dollars in Thousands)

(unaudited)

	Three Months Ended March 31		Nine Months Ended March 31	
	2019	**2018**	**2019**	**2018**
Net revenues	$ 63,311	$ 55,587	$ 179,783	$ 157,891
Cost of goods sold	12,166	9,969	34,218	28,670
Gross profit	51,145	45,618	145,565	129,221
Expenses:				
Selling, general and administrative	41,356	37,796	123,705	110,722
Research and development	9,282	7,333	23,937	20,037
Total expenses	50,638	45,129	147,642	130,759
Income (loss) from operations	507	489	(2,077)	(1,538)
Other (income) and expense, net	(251)	91	(505)	388
Income (loss) before income taxes	758	398	(1,572)	(1,926)
Provision for income taxes	86	33	152	99
Net income (loss)	$ 672	$ 365	$ (1,724)	$ (2,025)
Basic earnings per share	$ 0.02	$ 0.01	$ (0.05)	$ (0.06)
Diluted earnings per share	$ 0.02	$ 0.01	$ (0.05)	$ (0.06)
Basic weighted average shares outstanding	33,600,148	33,237,552	33,510,368	33,105,174
Diluted weighted average shares outstanding	34,241,432	33,641,804	33,510,368	33,105,174

Cardiovascular Systems, Inc.

Consolidated Balance Sheets

(Dollars in Thousands)

(unaudited)

	March 31, 2019	June 30, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 115,280	$ 116,260
Accounts receivable, net	34,970	31,225
Inventories	19,304	16,605
Marketable securities	456	544
Prepaid expenses and other current assets	2,221	2,977
Total current assets	172,231	167,611
Property and equipment, net	27,607	27,744
Patents, net	5,242	5,231
Other assets	6,149	2,766
Total assets	$ 211,229	$ 203,352
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 12,396	$ 10,441
Accrued expenses	26,489	25,776
Deferred revenue	1,612	1,243
Total current liabilities	40,497	37,460
Long-term liabilities		
Finance obligation	21,005	21,064
Deferred revenue	7,230	8,946
Other liabilities	884	1,412
Total liabilities	69,616	68,882
Commitments and contingencies	—	—
Total stockholders' equity	141,613	134,470
Total liabilities and stockholders' equity	$ 211,229	$ 203,352

Non-GAAP Financial Measures
To supplement CSI's consolidated condensed financial statements prepared in accordance with GAAP, CSI uses a non-GAAP financial measure referred to as "Adjusted EBITDA" in this release.

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

Adjusted EBITDA

(Dollars in Thousands)

(unaudited)

	Three Months Ended March 31		Nine Months Ended March 31	
	2019	**2018**	**2019**	**2018**
Net income (loss)	$ 672	$ 365	$ (1,724)	$ (2,025)
Less: Other (income) and expense, net	(251)	91	(505)	388
Less: Provision for income taxes	86	33	152	99
Income (loss) from operations	507	489	(2,077)	(1,538)
Add: Stock-based compensation	2,674	2,140	8,600	7,880
Add: Depreciation and amortization	932	990	2,617	3,080
Adjusted EBITDA	$ 4,113	$ 3,619	$ 9,140	$ 9,422

Use and Economic Substance of Non-GAAP Financial Measures Used by CSI and Usefulness of Such Non-GAAP Financial Measures to Investors
CSI uses Adjusted EBITDA as a supplemental measure of performance and believes this measure facilitates operating performance comparisons from period to period and company to company by factoring out potential differences caused by depreciation and amortization expense and non-cash charges such as stock based compensation. CSI's management uses Adjusted EBITDA 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 to allocate 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 Adjusted EBITDA when determining achievement of their incentive compensation performance targets.

CSI believes that presenting Adjusted EBITDA 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.

The following is an explanation of each of the items that management excluded from Adjusted EBITDA and the reasons for excluding each of these individual items:

-- 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 stock-based compensation guidance 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 expenses that require cash settlement and are 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.

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