# 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): **August 4, 2015**

# SUNSHINE HEART, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **001-35312** | **68-0533453** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**12988 Valley View Road**
**Eden Prairie, Minnesota 55344**
(Address of principal executive offices) (Zip Code)

**(952) 345-4200**
(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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 August 4, 2015, Sunshine Heart, Inc. (the ***"Company"***) issued a press release reporting its financial results for the second quarter ended June 30, 2015. The press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

**(d)**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated August 4, 2015, reporting the Company's financial results for the second quarter ended June 30, 2015. |



**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: August 4, 2015

**SUNSHINE HEART, INC.**

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton

Title: Chief Financial Officer



**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated August 4, 2015, reporting the Company's financial results for the second quarter ended June 30, 2015. |

**Sunshine Heart Announces Second Quarter 2015 Results and Provides Corporate Update**

**Eden Prairie, MN: August 4, 2015:** Sunshine Heart, Inc. (NASDAQ: SSH) announced today its financial results and provided a corporate update for the second quarter of 2015. The Company will host a conference call and webcast at 9:00 AM ET today to discuss its financial results and provide an update on its ongoing clinical studies.

To access the live webcast, please visit the Investors page of the Sunshine Heart website at http://ir.sunshineheart.com. Alternatively, the live conference call can be accessed by dialing (877) 303 -9826 (U.S.) or (224) 357-2194 (international) and using conference ID 88546172. An audio archive of the webcast will be available following the call at http://ir.sunshineheart.com.

“The past quarter was clearly a critical one for the Company, highlighted by the resumption of enrollment in the COUNTER HF™ pivotal study. We are pleased we were able to resolve this matter with the FDA in an expeditious manner and are especially encouraged with the speed in which we are reactivating centers. In addition, we are making substantial progress in other initiatives in both the research and product development areas,” commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

Second Quarter Corporate Highlights:

- Resumption of enrollment in COUNTER HF US pivotal study
- Conducted investigator meeting with 25 participating centers
- 7 sites activated during the second quarter after receiving Investigational Review Board (IRB) approval. To date, a total of 15 of 27 sites have been activated
- The 15th OPTIONS HF EU patient was implanted
- Completed pre-clinical study plans investigating the effect of C-Pulse® with respect to pulmonary artery hypertension with Dr. Mark Slaughter of Jewish Hospital in Louisville Kentucky
- 3 scientific papers were presented covering improved driveline infection rate, C-Pulse efficacy in CRT patients and pre-clinical results from CPII. 2 additional papers have been submitted to AHA on improved hospitalization rates and clinical hemodynamic data demonstrating novel mechanism of action.

Second Quarter Financial Highlights:

- Cash used in operations was $12.8 million in the first six months of 2015 vs. $11.9 million in the first six months of 2014
- Additional $2.0 million term loan from Silicon Valley Bank funded based on FDA approval for interim analysis
- Cash and cash equivalents on hand at June 30, 2015 was $33.4 million vs. $31.3 million at year-end 2014

As previously reported, the COUNTER HF study was temporarily paused this past March after Sunshine Heart communicated to the FDA four deaths in the treatment arm of the study. The deaths were independently adjudicated as not being device or therapy related and, on May 26th, the Company announced that the FDA had approved resumption of patient enrollment into the study. Upon receiving the FDA’s approval, the Company immediately provided participating sites all of the required documentation for IRB submission. To date, 15 of 27 sites have received IRB approval and are activated. Sunshine Heart currently expects the remaining 12 sites to receive approval by the end of August. Also, the Company is pleased to report that the first 3 patients have been enrolled in COUNTER HF shortly

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after sites were activated for a total of 51 enrollments in the study to date. The Company has a growing pipeline of patients that are being evaluated for enrollment in the third quarter of 2015. In addition, Sunshine Heart’s newly formed Physician Subject Selection Committee met to review the profiles of these initial patients and the process was both efficient and expeditious.

A COUNTER HF study investigator meeting was held on May 7-8, 2015 to prepare the study sites for resumption of enrollment. The Company is pleased to report that while the study remained in pause during this timeframe, 25 centers attended. There was a high level of enthusiasm among attending physicians and clinicians and the Company plans to post a video on its website from sessions held at the meeting.

The European based OPTIONS HF study implanted its 15th patient, which was the first referred by Professor Hüseyin Ince. Professor Ince is head of the cardiology department at the Vivantes clinic Friedrichshain and Vivantes clinic Urban in Berlin.

A key development during the second quarter was the Company’s continued work around exploring the breadth and potential of the C-Pulse technology platform. Clinical data was recently obtained from OPTIONS HF patients, in collaboration with Prof. Segers’ lab at University of Ghent, Belgium, to quantify the effects of C-Pulse on arterial stiffness. This is a first of its kind study, employing noninvasive measurements of pressure and flow in the ascending aorta to quantify the unloading effects of C-Pulse which may be mediated by relaxing the muscle in the walls of blood vessels in the peripheral circulation. These unique observations may be due to neuromodulation effects of C-Pulse where compression of the ascending aorta may lead to signals being sent to the brain resulting in alteration of sympathetic nerve activity to the blood vessels, kidney and heart. Additionally, physician initiated studies are being planned and the Company is providing technical support for these studies where the physicians are obtaining clinical data to directly measure sympathetic nerve activity during device ON/OFF phases.

Pre-clinical studies evaluating the effects of C-Pulse for pulmonary artery hypertension are also planned to begin in the third quarter at The University of Louisville. Initial observations have indicated counterpulsation of the pulmonary artery may lead to relaxation of the pulmonary blood vessels. Based on physician feedback, this may be possibly related to release of nitric oxide. The studies will be designed to measure hemodynamic and hormonal mechanisms.

During the quarter, Sunshine Heart also continued to make substantial progress regarding development of its fully implantable system. Chronic animal studies are expected to occur in the latter half of 2015 and the Company is preparing to commence a first-in-human study using the novel transcutaneous energy transmission (TET) system and a new smaller implantable pump in Q3 2016. The study will initially enroll patients at hospitals outside the US, and will target patients suffering from advanced Class III/IV heart failure, similar to the patient population of Sunshine Heart's current ongoing COUNTER HF Study. Feasibility of implant, safety and short term durability will be the primary objectives. Performance and efficacy data will be collected to evaluate patient quality of life, freedom from heart failure symptoms and other standard heart failure measures including the ability to bridge to other therapies.

Finally, Thoratec Corporation, a shareholder of Sunshine Heart, with board observation rights, announced on July 22, 2015 that it has entered into a definitive agreement pursuant to which it will be acquired by St. Jude Medical. If the proposed transaction is consummated, Sunshine Heart expects St. Jude will succeed to the rights of Thoratec Corporation under the terms of the observation rights agreement. There can be no assurance that the proposed transaction will occur, and Sunshine Heart makes no representations regarding the proposed transaction, Thoratec Corporation or St. Jude Medical.

**PRESENTATIONS AND PUBLICATIONS**

During the quarter, there were a number of important presentations and papers submitted including:

- ISHLT (Nice) presentation - C-Pulse System Extra-Aortic Counterpulsation for Heart Failure: Driveline Infections and Management - Presented April 2015: Dr. Mark Slaughter

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- HRS (Boston) presentation - Clinical experience with the C-Pulse Extra Aortic Counterpulsation system in patients previously treated with Optimal Medical Therapy and CRT - Presented May 2015: Dr. William Abraham
- ASAIO (Chicago) presentation - Development and Chronic In-vivo testing of fully implantable extra-aortic counterpulsation device - Presented June 2015: Dr. William Cohn

Two papers were submitted to AHA (Orlando) by Dr. Sanjeev Aggarwal and Dr. Eduardo Rame for presentation:

- Reduced Heart Failure Readmission Rates: Clinical Experience with the C-Pulse® Extra-Aortic Counterpulsation System (Dr. Sanjeev Aggarwal)
- Arterial and Cardiac Hemodynamics in Advanced HF Patients Implanted with the C-Pulse Counterpulsation Device: Implications for Myocardial Recovery (Dr. Eduardo Rame)

**FINANCIALS**

The Company's revenue to date has been generated by sales of the C-Pulse System to hospitals and clinics in conjunction with its U.S. clinical study. The Company did not record any revenue under its U.S. COUNTER HF study during the second quarter of 2015 or 2014. There were no enrollments into the study during the second quarter of 2015 as the Company worked to resume enrollment after the May 2015 FDA approval to resume the study. The Company's results for the six months ended June 30, 2015 include revenue of $59,000, the same amount for the same period in 2014. The Company has obtained reimbursement for some, but not all of its implant procedures, because some private insurance companies and certain governmental institutions have a non-coverage policy for experimental or investigational procedures.

Product costs incurred for the Company's clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Operating expenses in the second quarter of 2015 totaled $6.3 million, compared to $6.7 million in the second quarter of 2014. Equity compensation expense included in operating expenses totaled $0.7 million for the second quarter of 2015 and $0.8 million for the comparable period in 2014. Excluding equity compensation expense, non-GAAP operating expenses totaled $5.6 million and $5.9 million for the three months ended June 30, 2015 and 2014, respectively. The decrease in operating expenses during the second quarter of 2015 is the result of decreased spending in the COUNTER HF pivotal study as a result of the clinical study pause that was announced in March 2015. The Company received FDA approval to resume enrollment in the study in May 2015, and is currently in the process of reactivating its clinical sites and restarting patient enrollment into the study.

Operating expenses for the six months ended June 30 2015 were $13.4 million, compared to $13.1 million in the same period of 2014. Equity compensation expense included in operating expenses during the first half of 2015 totaled $1.6 million, compared to $1.5 million during the same period of 2014. Excluding equity compensation expense, non-GAAP operating expenses totaled $11.8 million and $11.6 million for the six months ended June 30, 2015 and 2014, respectively. The slight increase over the prior year is primarily attributable to increased development expenses associated with the Company's fully-implantable system, offset by decreased clinical research expenses related to the pause of the Company's U.S. pivotal study, which was announced in March 2015.

Net loss in the second quarter of 2015 was $6.4 million, or $0.35 per share, compared to $6.4 million, or $0.38 per share, in the second quarter of 2014. Excluding equity compensation expense, second quarter 2015 and 2014, net non-GAAP losses totaled $5.7 million, or $0.31 per share, and $5.6 million, or $0.33 per share, respectively. Net loss in the six months ended June 30, 2015 was $13.4 million, or $0.75 per share, compared to $12.7 million, or $0.75 per share, in the six months ended June 30, 2014. Excluding equity compensation expense, net non-GAAP losses for the six months ended June 30, 2015 and 2014 totaled $11.9 million, or $0.66 per share, and $11.2 million, or $0.67 per share, respectively.

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Cash used in operating activities totaled $12.8 million for the six months ended June 30, 2015 compared to $11.9 million for the same period of 2014, with the increase driven primarily by higher research and development expenses as well as interest expense on outstanding debt. During the first six months of 2015, the Company received net proceeds from financing activities of $15.1 million, as follows: $7.1 million from the sale of common shares under the Company's existing "at the market" facility, and $8.0 million from borrowings under a $10.0 million debt facility with Silicon Valley Bank. The Company had $33.4 million in cash and cash equivalents on June 30, 2015, compared to $31.3 million at December 31, 2014.

**SUNSHINE HEART, INC. AND SUBSIDIARIES**

***Condensed Consolidated Statements of Operations and Comprehensive Loss***

**(Unaudited)**
(In thousands, except per share amounts)

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| **Net sales** | **$ —** | $ — | $ 59 | $ 59 |
| Operating expenses | | | | |
| Selling, general and administrative | 2,348 | 2,243 | 4,534 | 4,604 |
| Research and development | 3,991 | 4,413 | 8,856 | 8,476 |
| Total operating expenses | 6,339 | 6,656 | 13,390 | 13,080 |
| Loss from operations | (6,339) | (6,656) | (13,331) | (13,021) |
| Other income (expense), net | (151) | 11 | (217) | 44 |
| Loss before income taxes | (6,490) | (6,645) | (13,548) | (12,977) |
| Income tax benefit | (132) | (265) | (127) | (265) |
| **Net loss** | **$ (6,358)** | **$ (6,380)** | **$ (13,421)** | **$ (12,712)** |
| **Basic and diluted loss per share** | **$ (0.35)** | **$ (0.38)** | **$ (0.75)** | **$ (0.75)** |
| Weighted average shares outstanding — basic and diluted | 18,297 | 16,882 | 17,903 | 16,870 |
| **Other comprehensive income:** | | | | |
| Foreign currency translation adjustments | $ (16) | $ (3) | $ (6) | $ (22) |
| **Total comprehensive loss** | **$ (6,374)** | **$ (6,383)** | $ (13,427) | $ (12,734) |

***Condensed Consolidated Balance Sheets***
(Dollars in thousands, except share and per share amounts)

| | June 30, 2015 (unaudited) | December 31, 2014 |
|---|---|---|
| **ASSETS** | | |
| **Current assets** | | |
| Cash and cash equivalents | $ 33,419 | $ 31,293 |
| Accounts receivable | — | 59 |
| Other current assets | 767 | 360 |
| **Total current assets** | 34,186 | 31,712 |
| **Property, plant and equipment, net** | 598 | 661 |
| **Other assets** | 129 | — |
| **TOTAL ASSETS** | $ **34,913** | **$ 32,373** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities** | | |
| Current portion of long-term debt | $ 1,895 | $ — |
| Accounts payable | 1,458 | 2,079 |
| Accrued salaries, wages, and other compensation | 1,235 | 1,079 |
| **Total current liabilities** | 4,588 | 3,158 |
| **Long-term debt, net of discount** | 5,801 | — |
| **Total liabilities** | 10,389 | 3,158 |
| Commitments and contingencies | — | — |
| **Stockholders' equity** | | |
| Series A junior participating preferred stock as of June 30, 2015 and December 31, 2014, par value $0.0001 per share; authorized 30,000 shares, none outstanding | — | — |
| Preferred stock as of June 30, 2015 and December 31, 2014, par value $0.0001 per share; authorized 39,970,000 shares, none outstanding | — | — |
| Common stock as of June 30, 2015 and December 31, 2014, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 18,311,490 and 16,982,642 shares, respectively | 2 | 2 |
| Additional paid-in capital | 163,276 | 154,540 |
| Accumulated other comprehensive income: | | |
| Foreign currency translation adjustment | 1,266 | 1,272 |
| Accumulated deficit | (140,020) | (126,599) |
| **Total stockholders' equity** | 24,524 | 29,215 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | $ **34,913** | **$ 32,373** |

***Condensed Consolidated Statements of Cash Flows***
**(Unaudited)**
(In thousands)

| | Six months ended June 30, | |
|---|---|---|
| | 2015 | 2014 |

| | | |
|---|---|---|
| **Operating Activities:** | | |
| Net loss | **$ (13,421)** | $ (12,712) |
| Adjustments to reconcile net loss to cash flows used in operating activities: | | |
| Depreciation | 158 | 128 |
| Stock-based compensation expense, net | 1,326 | 1,321 |
| Amortization of debt discount | 51 | — |
| Changes in assets and liabilities | | |
| Accounts receivable | 59 | 59 |
| Other current assets | (407) | (319) |
| Other assets | (129) | — |
| Accounts payable and accrued expenses | (446) | (399) |
| **Net cash used in operations** | **(12,809)** | **(11,922)** |
| | | |
| **Investing Activities:** | | |
| Purchases of property and equipment | (95) | (113) |
| **Net cash used in investing activities** | **(95)** | **(113)** |
| | | |
| **Financing Activities:** | | |
| Net proceeds from the sale of common stock | 7,055 | 16 |
| Proceeds from borrowings on long-term debt | 8,000 | — |
| **Net cash provided by financing activities** | **15,055** | **16** |
| | | |
| Effect of exchange rate changes on cash | (25) | 8 |
| Net increase (decrease) in cash and cash equivalents | 2,126 | (12,011) |
| Cash and cash equivalents - beginning of period | 31,293 | 54,136 |
| **Cash and cash equivalents - end of period** | **$ 33,419** | **$ 42,125** |
| | | |
| **Supplement schedule of non-cash activities** | | |
| Stock options and restricted stock units classified as liabilities, net | **$ —** | $ (286) |
| Warrants issued in connection with debt financing | **$ 355** | $ — |

**USE OF NON-GAAP MEASURES**

Management uses non-GAAP measures to establish operational goals and cash flows, and believes that non-GAAP measures may assist investors in analyzing underlying trends in the Company's business over time. Investors should consider these non-GAAP measures in addition to, and not as a substitute for or as superior to, financial reporting measures prepared in accordance with GAAP. In this press release, the Company has reported non-GAAP measures of operating expenses, net loss and loss per share, which exclude equity compensation expenses related to stock options, warrants, restricted stock units and common stock awards, and reconcile to GAAP operating expense, GAAP net loss and GAAP loss per share as follows:

**SUNSHINE HEART, INC. AND SUBSIDIARIES**
***Reconciliation of non-GAAP amounts to GAAP***
**(Unaudited)**
(In thousands, except per share amounts)

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | **2015** | **2014** | **2015** | **2014** |
| **Operating Expenses** | | | | |
| GAAP operating expenses | $ 6,339 | $ 6,656 | $ 13,390 | $ 13,080 |
| Equity compensation expense | (690) | (753) | (1,557) | (1,488) |
| **Non-GAAP operating expenses** | **$ 5,649** | **$ 5,903** | **$ 11,833** | **$ 11,592** |
| | | | | |
| **Net Loss** | | | | |
| GAAP net loss | $ (6,358) | $ (6,380) | $ (13,421) | $ (12,712) |
| Equity compensation expense | 690 | 753 | 1,557 | 1,488 |
| **Non-GAAP net loss** | **$ (5,668)** | **$ (5,627)** | **$ (11,864)** | **$ (11,224)** |
| | | | | |
| **Loss Per Share** | | | | |
| GAAP basic and diluted loss per share | $ (0.35) | $ (0.38) | $ (0.75) | $ (0.75) |
| **Non-GAAP basic and diluted loss per share** | **$ (0.31)** | **$ (0.33)** | **$ (0.66)** | **$ (0.67)** |
| | | | | |
| Weighted average shares outstanding — basic and diluted | 18,297 | 16,882 | 17,903 | 16,870 |

**About the COUNTER HF Study**

COUNTER HF is a prospective, randomized, multi-center clinical study. It is being conducted by heart failure and cardiac surgeon specialists in the United States. It is expected to randomize 388 patients in up to 40 clinical sites. The purpose of the study is to determine whether the C-Pulse System is a safe and effective treatment for heart failure patients who meet the following key study qualifications:

- NYHA Class III or early Class IV heart failure*;
- Ejection fraction ≤ 35% (measure of how well the heart pumps blood);
- Taking appropriate heart failure medications as prescribed by doctor; and

- Have been evaluated for cardiac resynchronization therapy with or without defibrillation (CRT, CRT-D) or implantable cardioverter defibrillator (ICD) therapy.

*New York Heart Class (NYHA) Class III or early Class IV: Very limited in daily activities or unable to do activities without discomfort. Become tired, short of breath, and have heart palpitations during physical activity. Note: Other qualifications apply and study doctors will determine who is eligible for the study.

**About the OPTIONS HF Study**

The OPTIONS HF study is a post-market, multi-center, prospective, open label study that will include 50 patients in up to 15 European centers. The study is designed to observe clinical outcomes of heart failure patients treated with the C-Pulse system. The primary endpoint is comparable to the COUNTER HF study as it evaluates the rate of re-hospitalization due to worsening heart failure and heart failure related death in addition to many other traditional heart failure endpoints.

**About the C-Pulse® Heart Assist System**

The C-Pulse Heart Assist System, or C-Pulse System, an investigational device in the United States, Canada and countries that do not recognize the CE mark approval, utilizes the scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Combined, these potential benefits may help sustain the patient's current condition or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as left ventricular assist devices (LVADs), artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the results from our feasibility study, we also believe that some patients treated with our C-Pulse System may be able to stop using the device due to sustained improvement in their conditions as a result of the therapy.

*Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.*

**About Sunshine® Heart**

Sunshine Heart, Inc. (Nasdaq:SSH) is an early-stage medical device company focused on developing, manufacturing and commercializing the C-Pulse System for treatment of Class III and ambulatory Class IV heart failure. Sunshine Heart has completed an approved U.S. Food and Drug Administration (FDA) feasibility clinical study of the C-Pulse System and presented the results in November 2011. In March 2012, the FDA notified the Company that it could move forward with an investigational device exemption (IDE) application. Sunshine Heart received unconditional approval from the FDA in November 2012 to initiate its pivotal study. In July 2012, Sunshine Heart received CE Mark approval for its C-Pulse System in Europe. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with wholly owned subsidiaries in Australia and Ireland. The Company has been listed on the NASDAQ Capital Market since February 2012.

**Forward-Looking Statements**

Certain statements in this release are forward-looking statements that are based on management's beliefs, assumptions, expectations, and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including, without limitation, our expectations with respect to future clinical study activities and results including patient enrollment in studies. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, the possibility that our clinical studies do not meet their enrollment goals, meet their endpoints or otherwise fail, that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the

possibility that we may be unable to raise the funds necessary for the development and commercialization of our products, that we may not be able to commercialize our products successfully in the EU and the other risk factors described under the caption "Risk Factors" and elsewhere in our filings with the U.S. Securities and Exchange Commission. You should not place undue reliance on forward-looking statements because they speak only as of the date when made and may turn out to be inaccurate. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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For further information, please contact:

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