

**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): **November 3, 2015**

SUNSHINE HEART, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-35312
(Commission File Number)

68-0533453
(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:

- 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))

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2015, Sunshine Heart, Inc. (the "**Company**") issued a press release reporting its financial results for the third quarter ended September 30, 2015. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The information in this Item 2.02 and the attached exhibit shall be considered filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and shall be deemed incorporated by reference in the following registration statements (collectively, the "**Registration Statements**"):

- (1) Registration Statement (Form S-8 No. 333-183924) pertaining to the Sunshine Heart, Inc. Amended and Restated 2002 Stock Plan;
- (2) Registration Statement (Form S-8 No. 333-183925) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan;
- (3) Registration Statement (Form S-8 No. 333-188935) pertaining to the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan;
- (4) Registration Statement (Form S-8 No. 333-190499) pertaining to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan;
- (5) Registration Statement (Form S-8 No. 333-194642) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan, the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan, and the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, as amended;
- (6) Registration Statement (Form S-8 No. 333-202904) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan, the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan, and the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, as amended; and
- (7) Registration Statement (Form S-3 No. 333-194731) of Sunshine Heart, Inc. and in the related base prospectus and sales agreement prospectus.

Item 9.01 Financial Statements and Exhibits.

The attached exhibit shall be considered filed for purposes of Section 18 of the Exchange Act and shall be deemed incorporated by reference in the Registration Statements.

(d)

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 3, 2015, reporting the Company's financial results for the third quarter ended September 30, 2015.

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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: November 3, 2015

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton
Title: Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 3, 2015, reporting the Company's financial results for the third quarter ended September 30, 2015.

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Sunshine Heart Announces Third Quarter 2015 Results and Provides Corporate Update

Eden Prairie, MN: November 3, 2015: Sunshine Heart, Inc. (NASDAQ: SSH) announced today its financial results and provided a corporate update for the third 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 65012954. An audio archive of the webcast will be available following the call at <http://ir.sunshineheart.com>.

“Progress was made in a number of key areas of our business in the third quarter. I am particularly pleased to have our first patient reach the 5 year mark on the C-Pulse® therapy. We achieved positive pre-clinical animal data for pulmonary hypertension, initial echocardiography and neurohormonal clinical data pointing to neuromodulation as a mechanism for potential myocardial recovery, continued site activations in the COUNTER HF™ pivotal study and progress with our next generation fully implantable system,” commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

Third Quarter Corporate Highlights:

- First patient to reach five years on C-Pulse therapy
- U.S. Food and Drug Administration (FDA) approved amendment for stopping rule criteria from “all cause deaths” to “mortality associated with the device, procedure or therapy”
- Initiated protocol development for European post market study to include recovery endpoints
- Positive results from pre-clinical animal testing applying counterpulsation to the pulmonary artery to treat pulmonary hypertension at Jewish Hospital in Louisville, Kentucky
- Initial echocardiography and neurohormonal data from the OPTIONS HF European post market study and optimization data from the COUNTER HF study point to neuromodulation as a mechanism for potential myocardial recovery
- Chronic animal studies initiated at Texas Heart Institute for C-Pulse fully implantable system; studies remain ongoing
- Sixteen sites activated during the third quarter for a total of 23, and subsequent to quarter end, an additional four sites were activated, bringing total activated sites to 27
- Seven patients enrolled in the COUNTER HF study during the quarter, and five additional patients enrolled after quarter end
- Two abstracts have been accepted for presentation at the American Heart Association (AHA) meeting in Orlando
- Oral and poster presentations at the Transcatheter Cardiovascular Therapeutics (TCT) Conference

Third Quarter Financial Highlights:

- Cash used in operations was \$18.2 million in the first nine months of 2015 vs. \$17.4 million in the first nine months of 2014
- Cash and cash equivalents on hand at September 30, 2015 was \$27.9 million vs. \$31.3 million at year-end 2014

CORPORATE UPDATE

The first patient to reach five years on C-Pulse therapy occurred this past quarter, which represents a major milestone for the device. During this quarter, the Company also collected initial echocardiography and neurohormonal data from the OPTIONS European post market study and optimization data from the COUNTER HF study that appears to point to neuromodulation as a mechanism for potential myocardial recovery. This mechanism of action is not seen in other pump related technologies such as left ventricular assist devices (LVADs) and, if confirmed, would position the C-Pulse therapy as the only mechanical circulatory assist therapy that has the potential to offer a mechanical unloading and neuromodulation effects.

Based on the potential impact of this new data, the Company decided to initiate discussions on a protocol for a modified European post market study that incorporates many of the OPTIONS HF endpoints but also includes patient recovery/weaning endpoints.

In October 2015, the Company submitted an application for an NUB to the InEk, the German Institute for Hospital Remuneration System, to obtain reimbursement for this important market. A decision is expected the first week of February 2016.

With respect to the COUNTER HF study, on August 31, 2015, the Company announced that the FDA approved an amendment to the stopping rule criteria for the study. The Agency agreed to change the protocol from “all cause deaths” to “mortality associated with the device, procedure or therapy.” Sunshine Heart previously communicated that it expected to have all sites reactivated by end of August 2015. Due to site related delays, the Company finished the quarter with 23 sites activated, with eight sites being reactivated in the last few weeks of the quarter. Despite the limited number of sites, Sunshine Heart enrolled seven patients during the third quarter, and five patients have been enrolled so far in the fourth quarter. As of the quarter ended September 30, 2015, an aggregate of 55 patients have been enrolled, of which 30 have been randomized into the COUNTER HF study. Subsequent to quarter end, the Company activated an additional four sites and now has 27 activated centers with another 13 in process. In total, twenty centers have been activated since the end of the second quarter.

An important accomplishment during the quarter was the continued development work for the C-Pulse technology platform. The Company conducted a pre-clinical pulmonary artery hypertension study at Jewish Hospital in Louisville, Kentucky under the guidance of Dr. Mark Slaughter. This acute animal study demonstrated a profound impact in reducing pulmonary hypertension in the animals. Additional pre-clinical studies are planned in the fourth quarter of 2015.

Sunshine Heart furthered the development of its fully implantable system in the third quarter. As previously communicated, chronic animal studies were launched at Texas Heart Institute and are progressing well. The Company plans to initiate discussions with the FDA in the fourth quarter regarding the Expedited Access Pathway (EAP) approach to market. If approved, this could potentially expedite the process for obtaining U.S. approval and have significant implications for the Company's growth strategy.

As part of the Company's on-going effort to evaluate C-Pulse's current development strategy and potential, the Company hosted a U.S. advisory board meeting on October 21, 2015 comprised of key thought leaders in the cardiovascular space. Key topics discussed at the forum included a review of the COUNTER HF study, European recovery study design, applications such as pulmonary hypertension, business development opportunities and the fully implantable system.

PRESENTATIONS AND PUBLICATIONS

Sunshine Heart conducted oral and poster presentations at the Transcatheter Cardiovascular Therapeutics (TCT) Conference held in San Francisco, California on October 11 to 15, 2015. During the quarter, the Company submitted a number of important presentations and papers, including two abstracts that were accepted for presentation at the upcoming AHA meeting in Orlando:

- Reduced Heart Failure Readmission Rates: Clinical Experience with the C-Pulse® Extra-Aortic Counterpulsation System to be presented by Dr. Sanjeev Aggarwal, Mid-America Heart and Vascular, Kansas City MO.
- Arterial and Cardiac Hemodynamics In Advanced HF Patients Implanted with A Para-Aortic Counterpulsation Device Assessed by Pulse Wave Analysis to be presented by Dr. Eduardo Rame, Hospital of University of Pennsylvania, Philadelphia PA.

FINANCIALS

The Company's revenue to date has been generated by implants of the C-Pulse System at hospitals and clinics in conjunction with its U.S. COUNTER HF clinical study. The Company did not record any revenue during the third quarter of 2015 as there were no implants performed during this period that qualified for reimbursement. The Company recognized \$59,000 in revenue during the third quarter of 2014. Results for the nine months ended September 30, 2015 and 2014 include revenue of \$59,000 and \$118,000, respectively. The Company has obtained reimbursement for some, but not all of its implants, 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 third quarter of 2015 totaled \$6.3 million, compared to \$6.2 million in the third quarter of 2014. Equity compensation expense included in operating expenses totaled \$0.5 million for the third quarter of 2015 and \$0.7 million for the comparable period in 2014. Excluding equity compensation expense, non-GAAP operating expenses totaled \$5.7 million and \$5.5 million for the three months ended September 30, 2015 and 2014, respectively. Operating expenses for the quarter reflect lower spending resulting from the consolidation of certain management positions, offset by increased investments in clinical infrastructure.

Operating expenses for the nine months ended September 30, 2015 were \$19.7 million, compared to \$19.2 million in the same period of 2014. Equity compensation expense included in operating expenses during the first nine months of 2015 totaled \$2.1 million, compared to \$2.2 million during the same period of 2014. Excluding equity compensation expense, non-GAAP operating expenses totaled \$17.6 million and \$17.1 million for the nine months ended September 30, 2015 and 2014, respectively. The increase over the prior year is primarily attributable to increased development expenses associated with the Company's fully-implantable system, along with increased investments in clinical infrastructure.

Net loss in the third quarter of 2015 was \$6.6 million, or \$0.36 per share, compared to \$6.1 million, or \$0.36 per share, in the third quarter of 2014. Excluding equity compensation expense, third quarter 2015 and 2014 net non-GAAP losses totaled \$6.0 million, or \$0.33 per share, and \$5.4 million, or \$0.32 per share, respectively. Net loss in the nine months ended September 30, 2015 was \$20.0 million, or \$1.11 per share, compared to \$18.8 million, or \$1.12 per share, in the nine months ended September 30, 2014. Excluding equity compensation expense, net non-GAAP losses for the nine months ended September 30, 2015 and 2014 totaled \$17.9 million, or \$0.99 per share, and \$16.7 million, or \$0.99 per share, respectively.

Cash used in operating activities totaled \$18.2 million for the nine months ended September 30, 2015 compared to \$17.4 million for the same period of 2014, with the increase driven primarily by higher research, clinical, and development expenses as well as interest expense on outstanding debt. During the first nine 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 \$27.9 million in cash and cash equivalents on September 30, 2015, compared to \$31.3 million at December 31, 2014.

With regards to the Company's loan facility and the required equity raise by March of 2016, the Company is exploring alternative structures with a goal of achieving increased financing flexibility. The Company cannot comment on the specifics of these alternatives or assess the likelihood of success as these discussions are ongoing.

SUNSHINE HEART, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net sales	\$ —	\$ 59	\$ 59	\$ 118

Operating expenses				
Selling, general and administrative	1,725	2,361	6,259	6,965
Research and development	4,548	3,808	13,404	12,284
Total operating expenses	6,273	6,169	19,663	19,249
Loss from operations	(6,273)	(6,110)	(19,604)	(19,131)
Other income (expense), net	(282)	(22)	(499)	22
Loss before income taxes	(6,555)	(6,132)	(20,103)	(19,109)
Income tax (benefit) expense	3	—	(124)	(265)
Net loss	\$ (6,558)	\$ (6,132)	\$ (19,979)	\$ (18,844)
Basic and diluted loss per share	\$ (0.36)	\$ (0.36)	\$ (1.11)	\$ (1.12)
Weighted average shares outstanding — basic and diluted	18,330	16,903	18,045	16,881
Other comprehensive income:				
Foreign currency translation adjustments	\$ (16)	\$ 17	\$ (22)	\$ (5)
Total comprehensive loss	\$ (6,574)	\$ (6,115)	\$ (20,001)	\$ (18,849)

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

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets		
Cash and cash equivalents	\$ 27,899	\$ 31,293
Accounts receivable	—	59
Other current assets	765	360
Total current assets	28,664	31,712
Property, plant and equipment, net	595	661
Other assets	108	—
TOTAL ASSETS	\$ 29,367	\$ 32,373
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt	\$ 2,867	\$ —
Accounts payable and accrued expenses	2,329	2,079
Accrued salaries, wages, and other compensation	856	1,079
Total current liabilities	6,052	3,158
Long-term debt, net of discount	4,880	—
Total liabilities	10,932	3,158
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of September 30, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of September 30, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of September 30, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 100,000,000 shares; issued and outstanding 18,337,683 and 16,982,642 shares, respectively	2	2
Additional paid-in capital	163,761	154,540
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,250	1,272
Accumulated deficit	(146,578)	(126,599)
Total stockholders' equity	18,435	29,215
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 29,367	\$ 32,373

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

	Nine months ended September 30,	
	2015	2014
Operating Activities:		
Net loss	\$ (19,979)	\$ (18,844)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	241	198
Stock-based compensation expense, net	1,811	1,924
Amortization of debt discount	102	—

Changes in operating assets and liabilities		
Accounts receivable	59	—
Other current assets	(406)	(207)
Other assets	(108)	—
Accounts payable and accrued expenses	48	(429)
Net cash used in operations	(18,232)	(17,358)
Investing Activities:		
Purchases of property and equipment	(175)	(205)
Net cash used in investing activities	(175)	(205)
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	(42)	(14)
Net decrease in cash and cash equivalents	(3,394)	(17,561)
Cash and cash equivalents - beginning of period	31,293	54,136
Cash and cash equivalents - end of period	\$ 27,899	\$ 36,575
Supplement schedule of non-cash activities		
Stock options and restricted stock units classified as liabilities, net	\$ —	\$ (337)
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 September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Operating Expenses				
GAAP operating expenses	\$ 6,273	\$ 6,169	\$ 19,663	\$ 19,249
Equity compensation expense	(537)	(700)	(2,094)	(2,188)
Non-GAAP operating expenses	\$ 5,736	\$ 5,469	\$ 17,569	\$ 17,061
Net Loss				
GAAP net loss	\$ (6,558)	\$ (6,132)	\$ (19,979)	\$ (18,844)
Equity compensation expense	537	700	2,094	2,188
Non-GAAP net loss	\$ (6,021)	\$ (5,432)	\$ (17,885)	\$ (16,656)
Loss Per Share				
GAAP basic and diluted loss per share	\$ (0.36)	\$ (0.36)	\$ (1.11)	\$ (1.12)
Non-GAAP basic and diluted loss per share	\$ (0.33)	\$ (0.32)	\$ (0.99)	\$ (0.99)
Weighted average shares outstanding — basic and diluted	18,330	16,903	18,045	16,881

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 \leq 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 product development and commercialization efforts, clinical and pre-clinical studies activities and results, design and development of future studies, site activations, patient enrollment in studies, timing of regulatory filings and approvals, regulatory acceptance of our filings, research and development activities, ultimate clinical outcomes and benefits of our products to patients, market and physician acceptance of our products, intellectual property protection, and potentially competitive product offerings. The risk factors described in our filings with the SEC could cause actual events to adversely differ from the expectations indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. Sunshine Heart does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Sunshine Heart 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. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC. 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.

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