# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

# **FORM 10-Q**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38238

# **Restoration Robotics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware** (State or other jurisdiction of incorporation or organization) 06-1681204 (I.R.S. Employer Identification No.)

128 Baytech Drive San Jose, CA (Address of principal executive offices)

95134 (Zip Code)

Registrant's telephone number, including area code: (408) 883-6888

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 🛛 No 🗌

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes 🗵 No 🗌

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer	
Non-accelerated filer	$\boxtimes$	Smaller reporting company	$\boxtimes$
Emerging growth company	$\boxtimes$		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 🗌 No 🗵

As of October 23, 2018, the registrant had 40,676,012 shares of common stock, \$0.0001 par value per share, outstanding.

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# PART I

# ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

# **RESTORATION ROBOTICS, INC.**

# Condensed Consolidated Balance Sheets (Unaudited)

# (in thousands, except share and per share data)

		September 30, 2018		1 7		December 31, 2017	
ASSETS							
CURRENT ASSETS:							
Cash and cash equivalents	\$	23,609	\$	23,545			
Accounts receivable, net of allowance of \$839 and \$229 as of September 30, 2018 and December 31, 2017,							
respectively		6,441		3,864			
Inventory		4,446		2,761			
Prepaid expenses and other current assets		1,502		1,562			
Total current assets		35,998		31,732			
Property and equipment, net		1,556		1,138			
Restricted cash		83		100			
Other assets		100					
TOTAL ASSETS	\$	37,737	\$	32,970			
LIABILITIES AND STOCKHOLDERS' EQUITY							
CURRENT LIABILITIES:							
Accounts payable	\$	3,947	\$	2,044			
Accrued compensation		1,423		1,630			
Other accrued liabilities		1,671		1,125			
Deferred revenue		1,449		1,517			
Current portion of long-term debt, net of discount of \$270 as of December 31, 2017		_		7,730			
Total current liabilities		8,490		14,046			
Other long-term liabilities		558		459			
ong-term debt, net of discount of \$1,454 and \$29 as of September 30, 2018 and December 31, 2017		19,376		5,271			
TOTAL LIABILITIES		28,424		19,776			
Commitments and Contingencies (Note 6)							
Convertible preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding as							
of September 30, 2018 and December 31, 2017		_		—			
STOCKHOLDERS' EQUITY:							
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of September 30, 2018 and December 31, 2017;							
10,676,012 and 28,940,282 shares issued and outstanding as of September 30, 2018 and December 31, 2017		4		3			
Additional paid-in capital		194,586		177,757			
Accumulated other comprehensive loss		(46)		(79)			
Accumulated deficit		(185,231)		(164,487)			
TOTAL STOCKHOLDERS' EQUITY		9,313		13,194			
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	37,737	\$	32,970			

The accompanying notes are an integral part of these condensed consolidated financial statements.

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# **Condensed Consolidated Statements of Operations**

# (Unaudited) (in thousands, except share and per share data)

	Three Months Ended September 30,			Nine Months September				
		2018		2017		2018		2017
Revenue	\$	4,818	\$	4,177	\$	15,298	\$	15,441
Cost of revenue		2,663		2,474		8,362		9,053
Gross profit		2,155		1,703		6,936		6,388
Operating expenses:								
Sales and marketing		4,398		3,433		13,147		10,736
Research and development		2,008		1,737		6,286		5,579
General and administrative		2,191		1,139		6,159		3,549
Total operating expenses		8,597		6,309		25,592		19,864
Loss from operations	_	(6,442)		(4,606)		(18,656)		(13,476)
Other expense, net:								
Interest expense		(631)		(492)		(1,489)		(1,607)
Other income (expense), net		12		(1,473)		(567)		(1,646)
Total other expense, net	_	(619)		(1,965)		(2,056)		(3,253)
Net loss before provision for income taxes		(7,061)		(6,571)	_	(20,712)		(16,729)
Provision for income taxes		8		25		32		50
Net loss attributable to common stockholders	\$	(7,069)	\$	(6,596)	\$	(20,744)	\$	(16,779)
Net loss per share attributable to common stockholders, basic and diluted	\$	(0.20)	\$	(4.07)	\$	(0.67)	\$	(10.36)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	_	35,007,299	_	1,620,691	_	31,054,837		1,620,016

The accompanying notes are an integral part of these condensed consolidated financial statements.

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# **Condensed Consolidated Statements of Comprehensive Loss**

(Unaudited) (in thousands, except share and per share data)

	 Three Months Ended September 30,				Nine Months Ended September 30,			
	 2018		2017		2018		2017	
Net loss	\$ (7,069)	\$	(6,596)	\$	(20,744)	\$	(16,779)	
Other comprehensive income (loss):								
Cumulative translation adjustment	(9)		26		33		(22)	
Comprehensive loss	\$ (7,078)	\$	(6,570)	\$	(20,711)	\$	(16,801)	

The accompanying notes are an integral part of these condensed consolidated financial statements.

# Condensed Consolidated Statement of Stockholders' Equity

# (Unaudited) (in thousands, except share and per share data)

	<u> </u>	on Stock An	nount	P	ditional aid-in Capital	Con	cumulated Other ıprehensive ome (Loss)	cumulated Deficit	Total kholders' Equity
Balance — December 31, 2017	28,940,282	\$	3	\$	177,757	\$	(79)	\$ (164,487)	\$ 13,194
Issuance of common stock pursuant to stock option exercises of vested options	235,730		_		392		_	_	392
Stock-based compensation	_		_		419		_	_	419
Issuance of common stock warrants pursuant to debt financing	_		_		404		_	_	404
Issuance of common stock in connection with our follow-on offering, net of underwriters' commission and offering costs of									
\$1,635	11,500,000		1		15,614		_	_	15,615
Other comprehensive gain	_		_		_		33	_	33
Net loss	—		—		—		—	(20,744)	(20,744)
Balance — September 30, 2018	40,676,012	\$	4	\$	194,586	\$	(46)	\$ (185,231)	\$ 9,313

The accompanying notes are an integral part of these condensed consolidated financial statements.

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# **Condensed Consolidated Statements of Cash Flows**

(Unaudited)

# (in thousands, except share and per share data)

		ed		
		Septem 2018		2017
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	\$	(20,744)	\$	(16,779)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		539		452
Amortization of debt issuance costs		318		440
Non-cash loss on extinguishment of debt		178		
Stock-based compensation		419		349
Changes in fair value of preferred stock warrant liabilities				1,618
Provision for bad debt		839		—
Changes in excess and obsolete inventory		(55)		
Loss on disposal of property and equipment		41		34
Changes in operating assets and liabilities:				
Accounts receivable		(3,417)		(741)
Inventory		(1,631)		65
Prepaid expenses and other assets		(40)		(2,272)
Accounts payable		1,956		1,194
Accrued and other liabilities		253		1,249
Deferred revenue		118		15
Net cash used in operating activities		(21,226)		(14,376)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property and equipment		(1,051)		(215)
Net cash used in investing activities		(1,051)		(215)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from convertible notes, net		—		5,000
Proceeds from issuance of Series C convertible preferred stock, net		—		10,209
Proceeds from exercised stock options		392		16
Payment of deferred offering costs		_		(749)
Proceeds from follow-on offering, net		15,615		_
Proceeds from long-term debt, net		19,584		_
Principal payments on long-term debt		(13,300)		(6,000)
Net cash provided by financing activities		22,291		8,476
Effect of exchange rate changes on cash, cash equivalents and restricted cash		33		(22)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH		47		(6,137)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH — Beginning of period		23,645		11,906
CASH, CASH EQUIVALENTS AND RESTRICTED CASH — End of period	\$	23,692	\$	5,769
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:	-	,		
Cash paid for income taxes	\$	35	\$	4
•				
Interest paid during the period	\$	1,240	\$	1,185
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:				
Purchase of property and equipment included in accounts payable	\$	4	\$	
Discounts and issuance costs in connection with long-term debt	\$	1,246	\$	—
Issuance of warrants in connection with long-term debt	\$	404	\$	
Deferred offering costs included in accounts payable and accrued liabilities	\$	121	\$	1,474
	÷	161	÷	1,174

The accompanying notes are an integral part of these condensed consolidated financial statements.

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#### Notes to Condensed Consolidated Financial Statements (Unaudited) (in thousands, except share, per share data and percentage)

#### **1. NATURE OF OPERATIONS**

Restoration Robotics, Inc. is a medical technology company incorporated in the state of Delaware on November 22, 2002 and headquartered in San Jose, California. The Company develops an image-guided robotic system that enables follicular unit extraction (FUE) for use in the field of hair transplantation and markets the ARTAS<sup>®</sup> Robotic System in the United States and other countries. In these notes to the unaudited condensed consolidated financial statements, the "Company," "Restoration Robotics," "we," "us," and "our" refers to Restoration Robotics, Inc. and its subsidiaries on a consolidated basis.

# **Initial Public Offering**

On October 11, 2017, the Company's Registration Statement on Form S-1 (File No. 333-220303) relating to the initial public offering (IPO) of its common stock was declared effective by the Securities and Exchange Commission (SEC). Pursuant to such Registration Statement, the Company completed its IPO of 3,897,910 shares of its common stock (inclusive of 322,910 shares of common stock from the subsequent exercise of the over-allotment option granted to the underwriters) at a price of \$7.00 per share for aggregate cash proceeds of approximately \$22,114, after deducting underwriting discounts and commissions, and offering costs totaling \$5,171.

Immediately prior to the closing of the IPO, all outstanding shares of convertible preferred stock converted into 22,671,601 shares of common stock and all the outstanding convertible preferred stock warrants converted into common stock warrants resulting in the reclassification of our preferred stock warrant liabilities to additional paid-in capital. In addition, the principal and accrued interest on the outstanding Convertible Notes converted into 718,184 shares of common stock. The IPO closed on October 16, 2017.

#### **Follow-on Public Offering**

On August 16, 2018, the Company closed its follow-on public offering of 10,000,000 shares of its common stock, plus 1,500,000 shares of common stock from the subsequent exercise of the over-allotment option granted to the underwriters. The public offering price of the shares sold was \$1.50 per share. The Company received aggregate proceeds of approximately \$15.6 million from the follow-on offering, after deducting underwriting discounts and commissions and offering costs totaling \$1.6 million. The Company intends to use the net proceeds from this offering (including net proceeds from the underwriters' exercise of their option to purchase additional shares of common stock) to fund expanded commercialization activities in connection with our recently launched ARTAS<sup>®</sup> iX System and for working capital and general corporate purposes.

#### **Reverse Stock Split**

On September 15, 2017, the Company effected a 1-for-10 reverse stock split of its common stock. Upon the effectiveness of the reverse stock split, (i) every 10 shares of outstanding common stock were combined into one share of common stock, (ii) the number of shares of common stock for which each outstanding option to purchase common stock is exercisable was proportionately decreased on a 1-for-10 basis, (iii) the exercise price of each outstanding preferred stock which is convertible into our common stock was proportionately reduced on a 1-for-10 basis. All of the outstanding common stock share numbers (including shares of common stock into which our outstanding convertible preferred stock shares are convertible), share prices, exercise prices and per share amounts have been adjusted in these consolidated statements, on a retroactive basis, to reflect this 1-for-10 reverse stock split for all periods presented. The par value per share and the authorized number of shares of common stock and convertible preferred stock were not adjusted because of the reverse stock split.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Liquidity

These condensed consolidated financial statements are prepared on a going concern basis that contemplates the realization of assets and extinguishment of liabilities in the normal course of business. The Company has incurred net operating losses and negative cash flows from operations since inception. As of September 30, 2018, and December 31, 2017, the Company has an accumulated deficit of \$185,231 and \$164,487 and, as of such dates, and through the date of this filing, does not have sufficient capital to fund its planned operations. Because of the Company's recurring losses from operations and negative cash flows, the Company's independent registered public accounting firm included an explanatory paragraph in its report on the Company's consolidated financial statements as of, and for the year ended, December 31, 2017 that such factors raise substantial doubt about the Company's ability to continue as a going concern. To continue its operations, the Company must achieve profitable operations and/or obtain additional financing. Until the Company generates revenue at a level to support its cost structure, the Company expects to continue to incur substantial operating losses and net cash outflows. The Company may never become profitable and even if it does attain profitable operations, it may not be able to sustain profitability or positive cash flows on a recurring basis.

The Company will need to raise further capital in the future to service its debt or fund its operations until the time it can sustain positive cash flows. There can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, it may be compelled to reduce the scope of its operations and planned capital expenditures or sell certain assets, including intellectual property assets.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and, as such, the condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

#### **Basis of Presentation**

The condensed consolidated balance sheet as of September 30, 2018, the condensed consolidated statements of operations and condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and the condensed consolidated statement of stockholders' equity for the nine months ended September 30, 2018 are unaudited. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) and in the opinion of management, reflect all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed consolidated financial statements related to the three- and nine-month periods are also unaudited. The condensed consolidated results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, or for any other future annual or interim period. The consolidated balance sheet as of December 31, 2017 included herein was derived from the audited consolidated financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in its Annual Report filed on Form 10-K for the year ended December 31, 2017, with the SEC on March 5, 2018.

#### Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Restoration Robotics, Inc. and its wholly owned subsidiaries, which are organized in the United States, United Kingdom, Spain, Hong Kong and South Korea. All significant intercompany accounts and transactions have been eliminated in consolidation.

#### Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited to revenue recognition, the fair value of common stock, and the recoverability of the Company's net deferred tax assets and related valuation allowance. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

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#### Reclassification

Accrued compensation, which were previously included in other accrued liabilities in the prior year's condensed consolidated balance sheet have been reclassified to conform to the current period's presentation. The reclassification had no impact on the previously reported consolidated financial statements for the year ended December 31, 2017.

# **Concentration of Customers**

For the three and nine months ended September 30, 2018, no customers accounted for more than 10% of the Company's revenue. For the three months ended September 30, 2017, two customers accounted for 11% and 12% of the Company's revenues and no customers accounted for more than 10% of the Company's revenue for the nine months ended September 30, 2017. As of September 30, 2018, no customers accounted for more than 10% of the Company's accounts receivable. As of December 31, 2017, two customers accounted for 10% and 11% of the Company's accounts receivable.

#### JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these condensed consolidated financial statements may not be companies that comply with the new or revised accounting pronouncements as of public company effective dates.

### **Recently Issued Accounting Standards Not Yet Adopted**

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), as amended by ASU No. 2015-14, ASU No. 2016-08, ASU No. 2016-10, ASU No. 2016-12, and ASU No. 2016-20, collectively, ASU 2014-09. ASU 2014-09 establishes a principle for recognizing revenue upon the transfer of promised goods or services to customers in an amount that reflects the expected consideration received in exchange for those goods or services and provides guidance on the recognition of costs related to obtaining and fulfilling customer contracts. For public entities, this standard is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. For all other entities, this standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. Early adoption is permitted. ASU 2014-09 may be adopted either retrospectively to each prior period presented (full retrospective method) or with the cumulative effect recognized as of the date of initial application (modified retrospective method). The Company expects to adopt this standard effective January 1, 2019 using the modified retrospective adoption method. The Company's preliminary assessment of areas to be impacted by the new standard identified possible impact to the deferral of costs to obtain a contract, which are primarily commission expense directly incurred because of sales of products and related support, and the allocation of revenue between products and support and maintenance for certain arrangements, taking into account performance obligations that may be immaterial in the contract under Topic 606. While the Company continues to assess the potential impact of the new standard, including the areas described above, it has not yet quantified the impact the new standard may have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02, which requires lessees to record most leases on their balance sheets but recognize the expenses on their income statements in a manner similar to current practice. Under ASU 2016-02, a lessee would recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying asset for the lease term. For public entities, this standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period. For all other entities, this standard is effective for annual reporting periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the standard and its impact on the condensed consolidated financial statements. However, the Company does expect a material change in its consolidated assets and liabilities upon adoption of this standard.



#### 3. NET LOSS PER SHARE

#### **Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, preferred stock warrants and stock options are common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following outstanding shares of common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	As of September 30,			
	2018	2017		
Options to purchase common stock	2,026,889	1,912,644		
Convertible preferred stock		22,671,601		
Warrants for preferred stock	—	385,126		
Warrants for common stock	468,181	—		
Total potential dilutive shares	2,495,070	24,969,371		

#### 4. FAIR VALUE MEASUREMENTS

Cash and cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued liabilities approximate fair market value because of the short-term nature of those instruments. The Company's lease obligation, term loan and Convertible Notes have fair values that approximate their carrying value.

U.S. GAAP establishes a framework for measuring fair value and a fair value hierarchy based on the inputs used to measure fair value. This framework maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. It applies to both items recognized and reported at fair value in the condensed consolidated financial statements and items disclosed at fair value in the notes to the condensed consolidated financial statements.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. Unobservable inputs reflect assumptions that market participants would use in pricing the asset or liability based on the best information available in the circumstances. The hierarchy is broken down into three levels based on the transparency of inputs as follows:

*Level 1* - Quoted prices are available in active markets for identical assets or liabilities as of the report date. A quoted price for an identical asset or liability in an active market provides the most reliable fair value measurement because it is directly observable to the market.

*Level 2* - Pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the report date. The nature of these securities includes investments for which quoted prices are available but traded less frequently and investments that are fair valued using other securities, the parameters of which can be directly observed.

*Level 3* - Securities that have little to no pricing observability as of the report date. These securities are measured using management's best estimate of fair value, where the inputs into the determination of fair value are not observable and require significant management judgment or estimation.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. However, the determination of what constitutes "observable" requires significant judgment by the Company. The categorization of a financial instrument within the hierarchy is based upon the pricing transparency of the instrument and does not necessarily correspond to the Company's perceived risk of that instrument.



The following tables summarize the levels of fair value measurements of the Company's cash equivalents:

		Fair Value N	feasurements as of Sep	tember 30, 2018	
	Quoted in Act Mark using Id Asse (Leve	tive Sig tets C entical Obs ets I	ervable Unob nputs In	iificant servable puts evel 3)	Total
Assets					
Cash Equivalents:					
Money market account	\$	21,940 \$	— \$	— \$	21,940
Restricted cash:					
Money market account		83			83
Total assets	\$	22,023 \$	— \$	— \$	22,023
	Quoted in Act Mark using Id	Prices tive Sig cets (		cember 31, 2017 nificant servable	
	Asse	ets I		puts	Total
Assets	(Leve	<u> </u>	evel 2) (Le	evel 3)	10141
Cash Equivalents: (1)					
Money market account	\$	18,728 \$	— \$	— \$	18,728
Restricted cash:					
Money market account		100			100
Total assets	\$	18,828 \$	— \$	— \$	18,828

(1) The Company incorrectly overstated its cash equivalents by \$4,817 in its annual report on Form 10-K for the year ended December 31, 2017. Cash equivalents were \$18,728, while cash was \$4,817. The error in disclosure had no impact on previously reported cash and cash equivalents in the consolidated balance sheet as of December 31, 2017 or consolidated statement of operations for the year ended December 31, 2017.

#### 5. BALANCE SHEET COMPONENTS

#### Inventory

Inventory consists of the following:

	Se	ptember 30,	Dec	ember 31,
		2018		2017
Finished goods	\$	3,593	\$	2,761
Work in process		38		—
Raw materials		815		
Total inventory	\$	4,446	\$	2,761

Inventory as of September 30, 2018, includes work in process and raw materials related to the Company's next generation ARTAS iX System which was launched and manufactured by the Company starting in the third quarter of 2018.

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#### Property and Equipment, Net

Property and equipment, net consist of the following:

	Sep	tember 30, 2018	December 31, 2017		
Equipment	\$	3,625	\$	2,929	
Computer hardware and software		786		721	
Leasehold improvements		874		869	
Furniture and fixtures		453		270	
Total property and equipment		5,738		4,789	
Less: Accumulated depreciation and amortization		(4,182)		(3,651)	
Total property and equipment, net	\$	1,556	\$	1,138	

Depreciation and amortization expense were \$268 and \$539 for three and nine months ended September 30, 2018. Depreciation and amortization expense were \$139 and \$452 for the three and nine months ended September 30, 2017.

#### 6. COMMITMENTS AND CONTINGENCIES

#### **Operating Leases**

The Company has various operating leases including 23,000 square feet of office space in San Jose, California, which expires in April 2022.

Aggregate future minimum lease payments required under the Company's operating leases as of September 30, 2018 are as follows:

Years Ending December 31,	
2018 (remaining 3 months)	\$ 128
2019	518
2020	534
2021	550
2022	188
Thereafter	_
Total future minimum lease payments	\$ 1,918

Total rent expense was \$163 and \$401 for three and nine months ended September 30, 2018. Total rent expense was \$103 and \$310 for the three and nine months ended September 30, 2017.

#### Commitments

The Company has two master agreements and a component pricing agreement with Evolve Manufacturing Technologies, Inc. (Evolve) for the supply of the ARTAS® System and consumable products. The terms of these master agreements are substantially similar. The master agreement for the sale of ARTAS® Systems was effective beginning on April 1, 2016 and the master agreement for the sale of kits used with the ARTAS System was effective beginning on March 1, 2016. Both agreements are effective for an initial term of two years and will continue to automatically renew for additional twelve-month periods, subject to either party's right to terminate the agreement upon 180 days advance notice during the initial term, if our quarterly forecasted demand falls below 75% of our historical forecasted demand for the same period in the previous year or upon 120 days' advance notice after the initial term. Under the agreements, the Company has future purchase commitments up to \$330 as of September 30, 2018.

In March 2018, the Company received U.S. FDA 510(k) clearance to expand the ARTAS® System technology to include an implantation functionality, referred to as ARTAS® iX. Based on manufacturing changes associated with the ARTAS® iX System, the Company determined that certain components procured or expected to be procured by Evolve, will be in excess of expected demand or usage based on the advance notice the Company provided to Evolve under the term of the agreement mentioned above. Although the Company will be taking steps to minimize the adverse impact on the Company's business, based on information available as of September 30, 2018, the Company's management recorded a loss contingency accrual of \$384 which is reported in "Cost of revenue" in the condensed consolidated statements of operations for the nine-months ended September 30, 2018 and included in "Other accrued liabilities" on the condensed consolidated balance sheets as of September

30, 2018. During the three-months ended September 30, 2018, the Company reduced the loss contingency estimate by \$300 based on recent facts and circumstances available during the period.

### **Licensing Agreements**

In July 2006, the Company entered into a license agreement with Rassman Licensing, LLC (Rassman) for non-exclusive, royalty bearing, nontransferable, perpetual, world-wide rights for use on approved fields relating to robotically controlled hair removal and implantation procedures. In consideration for this license, the Company paid Rassman a one-time payment of \$1,000. The agreement terminates on May 9, 2020. In February 2012, the Company amended its license agreement with Rassman. In exchange for a one-time \$400 payment to Rassman, the Company now has a fully paid royalty-free perpetual license to a patent subject to this license agreement.

In July 2006, the Company entered into a license agreement with HSC Development, LLC for exclusive non-transferable, royalty-free worldwide rights for use in approved fields relating to a computer-controlled system in which a device is carried on a mechanized arm for extraction or implantation of a follicular unit without manual manipulation. In consideration for this license, the Company paid HSC Development, LLC a one-time payment of \$25 and issued 2,500 shares of the Company's common stock. The agreement terminates on July 27, 2024.

### Legal Proceedings

From time to time the Company is involved in litigation arising out of claims in the normal course of business. Based on the information presently available, management believes that there are no claims or actions pending or threatened against us, the ultimate resolution of which will have a material effect on our financial position, liquidity or results of operations, although the results of litigation are inherently uncertain.

### Purported Shareholder Class Action

On May 23, 2018, a putative shareholder class action complaint was filed in Superior Court of the State of California, County of San Mateo (the "Superior Court"), captioned Wong v. Restoration Robotics, Inc., et al., No. 18CIV02609. On June 21, 2018 and June 28, 2018, two putative class action complaints were filed in the United States District Court for the Northern District of California, captioned Guerrini v. Restoration Robotics, Inc., et al., No. 5:18-cv-03883-BLF, respectively. On July 24, 2018, the U.S. Northern District Court related the Guerrini and Yzeiraj actions and reassigned the Yzeiraj action to Judge Edward J. Davila. The Wong and Guerrini complaints name the Company as defendants, and certain of its current and former executive officers and directors, certain of its current and former executive officers and directors. The Wong complaint asserts claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, or the Securities Act. The Guerrini and Yzeiraj complaints assert claims under Sections 11, 2017 and the Prospectus filed with the SEC on October 13, 2017 in connection with the Company's IPO were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading and omitted to state material facts required to be stated therein. The complaints seek unspecified monetary damages, other equitable relief and attorneys' fees and costs.

On August 8, 2018, the Company, along with certain of its current and former executive officers and directors, filed a motion to dismiss the Wong complaint based on the forum selection clause designating the federal district courts as the exclusive forum for claims arising under the Securities Act contained in the Company's Amended and Restated Certificate of Incorporation, and which asked the court in the alternative to stay the Wong action. Also, on August 8, 2018, the venture capital investor and underwriters' defendants in the Wong action filed demurrers to the Wong complaint, and the Company, along with certain of its current and former executive officers and directors, joined in the venture capital investor defendants' demurrer. A hearing on the Company's motion to dismiss and the demurrers to the Wong complaint was held on October 24, 2018. The Company is unable to predict the date on which the Superior Court will issue any decision at this time.

On October 2, 2018, the U.S. Northern District Court granted a Motion for Consolidation of Related Actions, Appointment as Lead Plaintiff and Approval of Lead Counsel filed by Plaintiff Edgardo Guerrini, which consolidated the Guerrini and Yzeiraj actions under the caption In re Restoration Robotics, Inc. Securities Litigation, Case No. 5:18-cv-03712-EJD. The U.S. Northern District Court has set an initial hearing for January 24, 2019.

The Company believes that these lawsuits are without merit and management intends to vigorously defend against these claims.



#### 7. LONG-TERM DEBT

#### Loan and Security Agreement

In May 2018, the Company entered into a Loan and Security Agreement (the Solar Agreement) with Solar Capital Ltd. (Solar) and certain other lenders thereunder (together with Solar, the Lenders), and Solar, as the Collateral Agent. The Solar Agreement consists of a four-year term loan for an aggregate principal amount of \$20,000 (the Borrowings), for working capital, to fund the Company's general business requirements and to repay indebtedness of the Company to Oxford Finance LLC (the Oxford Agreement). The Company used \$10,085 of the loan proceeds to repay the outstanding principal of \$8,667, a final payment fee of \$1,300 plus accrued interest and prepayment fees of \$118 under the Oxford Agreement. The Borrowings under the Solar Agreement bear interest through maturity at a rate equal to the U.S. Dollar LIBOR rate plus 7.95% per annum (the Interest Rate). The outstanding balance on the loan was \$20,000 and accrued interest totaled \$168 as of September 30, 2018. The Interest Rate was 10.1% at September 30, 2018.

Pursuant to the terms of the Solar Agreement, the Company shall make interest only payments until December 1, 2019 (the Interest Only Period). The Interest Only Period may be extended up to three additional months, if the Company achieves certain revenue and capital fundraising thresholds. Following cessation of the Interest Only Period, the Company shall make equal monthly payments on the outstanding principal balance of the Borrowings and any unpaid and accrued interest such that the Borrowings shall be fully repaid on May 1, 2022.

In addition, pursuant to the Solar Agreement, the Company issued the Lenders warrants (the Warrants) to purchase an aggregate of 161,725 shares of the Company's common stock, \$0.0001 par value per share, at an exercise price of \$3.71 per share. The Warrants were immediately exercisable upon issuance, and excluding certain mergers or acquisitions, will expire on the ten-year anniversary of the date of issuance. The fair value of the Warrants issued was determined to be \$404 using a Black-Scholes valuation model with the following assumptions: common stock price at issuance of \$3.71 per share; exercise price of \$3.71; risk-free interest rate of 2.97% based upon observed risk-free interest rates; expected volatility of 55.50% based on the Company's implied volatility; expected term of ten years, which is the contractual life of the Warrants; and a dividend yield of 0%. The fair value of the Warrants was recorded as a debt discount within notes payable and an increase to additional paid-in capital on the Company's balance sheet. The debt discount is being amortized as interest expense over the term of the Solar Agreement, using the effective interest method.

The third-party transaction costs (not paid directly to the lenders) related to the debt of \$404 are accounted for as a debt discount and classified within notes payable on the Company's balance sheet and amortized as interest expense over the term of the loan using the effective interest method. Unamortized debt discounts related to the Oxford Agreement and all fees paid directly to Solar and Oxford totaling \$505 in connection with the debt financing in May 2018 were written off to "Other income (expense), net" in the consolidated statements of operations.

The obligations under the Solar Agreement are secured by a lien on substantially all the Company's property, excluding intellectual property. The Solar Agreement contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, require the Company and its subsidiary to satisfy certain financial covenants including covenants requiring the Company to satisfy certain revenue and liquidity thresholds, and restricts the ability of the Company and its subsidiary's ability to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, engage in asset sales or sale and leaseback transactions, and declare dividends or redeem or repurchase capital stock. A failure to comply with these covenants could permit the Lenders under the Solar Agreement to declare the Borrowings, together with accrued but unpaid interest and certain Prepayment Fees, to be immediately due and payable. On November 2, 2018, the Solar Agreement was amended to modify the compliance requirement for certain revenue and liquidity threshold. As part of this amendment, the Company paid a fee of \$50 to the Lenders and cancelled 161,725 Warrants (originally issued in May 2018, as mentioned above) and issued 161,725 new warrants of the Company's common stock, \$0.0001 par value per share, at an exercise price of \$1.76 per share. All other terms of the Warrants were unchanged. As of September 30, 2018, the Company was in compliance with all covenants under the Solar Agreement, as amended.

The Company is also required to make mandatory prepayments of the Borrowings, subject to specified exceptions, upon defaulting on any payments of principal or interest on the Borrowings, the occurrence of certain specified defaults of the covenants in the Solar Agreement, the occurrence of a material adverse change in the business, operations or conditions of the Company and specified other events (each, an Event of Default). Upon the occurrence and continuation of an Event of Default, the Borrowings shall accrue at the Interest Rate plus 4.0%.

If all or any of the Borrowings are prepaid or required to be prepaid under the Solar Agreement, then the Company shall pay, in addition to such prepayment, a prepayment premium (the Prepayment Premium) equal to (i) with respect to any such prepayment paid on or prior to May 1, 2019, 3.0% of the principal amount of the Borrowings being prepaid, (ii) with respect to



any prepayments paid after May 1, 2019 but on or prior to May 1, 2020, 2.0% of the principal amount of the Borrowings being prepaid and (iii) with respect to any prepayments paid after May 1, 2020 but on or prior to May 1, 2021, 1.0% of the principal amount of the Borrowings being prepaid. Notwithstanding the foregoing, if the Lenders each participate in a refinancing of the Borrowings, then the Prepayment Premium shall be 0%.

The scheduled principal payments on the outstanding borrowings as of September 30, 2018 are as follows:

	As of September 30, 2018
2018 (remaining 3 months)	\$
2019	667
2020	8,000
2021	8,000
2022	4,163
Total	20,830
Less debt discount	(1,454)
Non-current portion	\$ 19,376

#### 8. COMMON STOCK RESERVED FOR ISSUANCE

The Company is required to reserve and keep available out of its authorized but unissued shares of common stock a number of shares sufficient to affect the conversion of all outstanding shares of convertible preferred stock, of which, there are none, plus options granted and available for grant under the incentive plans.

	September 30, 2018	December 31, 2017
Outstanding common stock warrants	468,181	306,456
Outstanding and issued stock options	2,026,889	1,930,752
Shares reserved for future option grants 1	2,800,358	2,162,037
Total common stock reserved for issuance	5,295,428	4,399,245

(1) The Company incorrectly understated its shares reserved for future option grants by 1,890,547 in its annual report on Form 10-K for the year ended December 31, 2017. The Company disclosed 271,490 shares reserved for future option grants at December 31, 2017, instead of 2,162,037 shares reserved for future option grants (as shown in the table above). The error in disclosure had no impact on previously reported consolidated financial statements as of and for the year ended December 31, 2017.

# 9. STOCK OPTION PLAN

# 2005 and 2015 Plans

The Company granted incentive stock options (ISOs) and non-statutory stock options (NSOs) pursuant to its 2005 Stock Option Plan (the 2005 Plan) until the Board of Directors approved the 2015 Stock Option Plan (the 2015 Plan), and all remaining shares available for future award under the 2005 Plan were transferred to the 2015 Plan and the 2005 Plan was terminated. The Company granted ISOs and NSOs pursuant to its 2015 Plan until the 2017 Equity Incentive Plan (the 2017 Plan) was approved by the Board of Directors and became effective on October 11, 2017. As a result of the 2017 Plan becoming effective, all remaining shares available for future award under the 2015 Plan were transferred to the 2017 Plan, the 2015 Plan was terminated, and no further grants will be made under the Company's 2005 Plan and the 2015 Plan and the applicable stock award agreements, until such outstanding stock awards that are stock options are exercised or until they terminate or expire by their terms, or until such stock awards are fully settled, terminated or forfeited.

#### 2017 Plan

The Company's 2017 Plan provides for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other forms of equity compensation to employees, directors and consultants. In addition, the Company's 2017 Plan provides for the grant of performance cash awards to employees, directors and consultants.

The Company recognized stock-based compensation expense for its employees and non-employees in the accompanying consolidated statements of operations as follows:

	 Three Mor Septem		 Nine Mon Septem	ths Ended iber 30,			
	2018	2017	2018		2017		
Cost of revenue	\$ 6	\$ 3	\$ 14	\$	8		
Sales and marketing	31	25	77		60		
Research and development	11	18	39		69		
General and administrative	119	72	289		212		
Total stock-based compensation	\$ 167	\$ 118	\$ 419	\$	349		

#### **Determination of Fair Value**

The estimated grant-date fair value of all of the Company's stock-based awards was calculated using the Black-Scholes-Merton option pricing model, based on the following assumptions:

	Three Mor Septem			ths Ended Iber 30,
	2018	2017 *	2018	2017
Expected term (years)	6.0	—	5.37 - 6.10	4.95 - 7.50
Risk-free interest rate	2.82%	—	2.40 - 2.82%	1.77 - 2.13%
Expected volatility	53.87%	—	53.72 - 55.49%	51.62 - 53.58%
Dividend yield	0%	—	0%	0%

\*No stock options were issued during the three months ended September 30, 2017

The following table summarizes stock option activity under the Company's stock option plan:

	Number of Shares	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding — December 31, 2017	1,930,752	\$ 1.90	7.9	\$ 5,322
Options granted	539,207	3.77		
Options exercised	(235,730)	1.66		
Options cancelled	(207,340)	2.02		
Outstanding — September 30, 2018	2,026,889	\$ 2.39	8.0	\$ 1,804
Vested and expected to vest — September 30, 2018	1,906,322	\$ 2.36	7.9	\$ 1,724
Exercisable — September 30, 2018	945,639	\$ 1.83	7.1	\$ 1,053

The weighted-average grant date fair value of options granted was \$2.01 per share for nine months ended September 30, 2018.

The total intrinsic value of options exercised was \$92.0 and \$413.0 for the three and nine months September 30, 2018, and \$0 for three and nine months ended September 30, 2017, respectively.

Unamortized stock-based compensation was \$1,300 as of September 30, 2018, which is expected to be recognized over a weighted-average period of approximately 3.50 years.

#### **10. INCOME TAXES**

The Company generated a loss for the three and nine months ended September 30, 2018 and incurred \$8 and \$32 of tax expense for the three and nine months ended September 30, 2018, respectively. The Company's effective tax rate is (0.12)% and (0.18)% for income tax for the three and nine months ended September 30, 2018 and the Company expects that its effective tax rate for the full year 2018 will be (0.42)%. Based on available evidence, including cumulative losses since inception and expected future losses, the Company has determined that it is more likely than not that the Company's U.S. federal, U.S. state and Korea deferred tax assets will not be realized and therefore a valuation allowance has been provided on these net deferred tax assets.

The Company has substantial net operating loss carry forwards available to offset future taxable income for U.S. federal and state income tax purposes. The Company's ability to utilize its net operating losses may be limited due to changes in its ownership as defined by Section 382 of the Internal Revenue Code (the Code). Under the provisions of Sections 382 and 383 of the Code, a change of control, as defined in the Code, may impose an annual limitation on the amount of the Company's net operating loss and tax credit carryforwards, and other tax attributes that can be used to reduce future tax liabilities.

The Company files tax returns for U.S. federal and state tax returns along with tax returns in the United Kingdom, Hong Kong, Spain and South Korea. The Company is not currently subject to any income tax examinations. Since the Company's inception, the Company had incurred losses from its U.S. operations, which generally allows all tax years to remain open.

Beginning in first quarter of 2018, the Company is subject to new provisions of the tax law, including provisions related to Global Low Taxed Intangible Income (GILTI), Foreign Derived Intangible Income deductions (FDII), and other changes. However, due to the Company's losses and full valuation allowance in the U.S., these were determined to have no material impact to the Estimated Annual Effective Tax Rate due to the full Valuation Allowance in the U.S.

#### **Uncertain Tax Positions**

Effective January 1, 2009, the Company adopted ASC 740-10, which requires that the Company recognize the financial statement effects of a tax position when it becomes more likely than not, based upon the technical merits, that the position will be sustained upon examination. The gross amount of unrecognized tax benefits as of September 30, 2018 is approximately \$1,420 and related to the reserve on R&D credits, none of which will affect the effective tax rate if recognized due to the valuation allowance. The Company does not expect any material changes in the next 12 months in unrecognized tax benefits.

The Company recognizes interest and/or penalties related to uncertain tax positions. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected in the period that such determination is made. The interest and penalties are recognized as other expense and not tax expense. The Company currently has no interest and penalties related to uncertain tax positions.

# **11. SEGMENT AND GEOGRAPHIC INFORMATION**

The Company has determined that it operates in a single operating segment and has one reportable segment, as its Chief Executive Officer, reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. The Company does not assess the performance of individual product line on measures of profit or loss, or asset-based metrics. Therefore, the information below is presented only for revenues by geography.

The following table reflects revenue by geographic area by customer location:

	Three Mor Septem	 	 Nine Mon Septen		
	 2018	 2017	 2018		2017
United States	\$ 3,856	\$ 1,429	\$ 8,712	\$	6,242
Europe and Middle East	362	1,205	2,323		4,333
Asia Pacific	553	874	3,213		3,192
Rest of World	47	669	1,050		1,674
Total revenue	\$ 4,818	\$ 4,177	\$ 15,298	\$	15,441

As of September 30, 2018, and December 31, 2017, all long-lived assets were located within the United States.

#### **12. SUBSEQUENT EVENT**

The Company's Board of Directors appointed Keith Sullivan, a current Board member of the Company, as interim Chief Commercial Officer, effective November 1, 2018, and for a period up to one year. Under the terms of the arrangement, Mr. Sullivan was granted 360,000 restricted stock awards, which shall vest in quarterly installments equal to 25% of the shares starting with the first vest date on January 15, 2019 so long as Mr. Sullivan is providing services.

#### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto in the Company's Annual Report filed on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission ("SEC") and other filings we have made with the SEC.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Form 10-Q and in our other SEC filings, including the Prospectus. You should review the risk factors for a more complete understanding of the risks associated with an investment in our securities. We disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements. Therefore, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q. Our fiscal year end is December 31, and references throughout this Quarterly Report on Form 10-Q to a given fiscal year are to the twelve months ended on that date.

#### Overview

We are a medical technology company developing and commercializing a robotic device, the ARTAS<sup>®</sup> System, which assists physicians in performing many of the repetitive tasks that are a part of a follicular unit extraction, or FUE surgery, a type of hair restoration procedure. We believe the ARTAS<sup>®</sup> System is the first and only physician assisted robotic system that can identify and dissect hair follicular units directly from the scalp, create recipient implant sites and robotically implant the hair follicles into the implant sites. In addition to the ARTAS<sup>®</sup> System, we also offer the ARTAS Hair Studio application, an interactive three-dimensional patient consultation tool that enables a physician to create a simulated hair transplant model for use in patient consultations. We received clearance from the U.S. Food and Drug Administration, or FDA, in April 2011 to market the ARTAS<sup>®</sup> System in the U.S., and we have sold the ARTAS<sup>®</sup> System into 37 other countries. In March 2018, we received 510(k) clearance from the FDA to expand the ARTAS<sup>®</sup> technology to include implantation. In the third quarter of 2018, we commercially launched the next generation ARTAS<sup>®</sup> System, called ARTAS<sup>®</sup> ix System, which incorporates the implantation functionality as well as other functionalities. As of September 30, 2018, the ARTAS<sup>®</sup> System and ARTAS Hair Studio application are protected by over 80 patents in the U.S. and over 110 international patents.

On October 11, 2017, our Registration Statement on Form S-1 (File No. 333-220303) relating to our initial public offering ("IPO") of its common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 3,897,910 shares of its common stock (inclusive of 322,910 shares of common stock from the subsequent exercise of the over-allotment option granted to the underwriters) at a price of \$7.00 per share for aggregate cash proceeds of approximately \$22.1 million after deducting offering costs and commissions of \$5.2 million.

On May 10, 2018, we entered into a Loan and Security Agreement (the Solar Agreement) with Solar Capital Ltd. (Solar) and certain other lenders thereunder (together with Solar, the Lenders). Pursuant to the terms of the Solar Agreement, we borrowed \$20.0 million with an interest rate at U.S. Dollar LIBOR plus 7.95% per annum (the Borrowings). All amounts borrowed under the Solar Agreement are secured by liens over all personal property of the Company, excluding intellectual property. Monthly payments on any amounts drawn shall consist of the interest only payments for the first 18 months, followed by payments of principal and accrued interest monthly thereafter until the four-year anniversary of the date of the Solar Agreement. In connection with the Solar Agreement, we granted the Lenders warrants to purchase an aggregate of 161,725 shares of our common stock exercisable at a price of \$3.71 per share. On November 2, 2018, the Solar Agreement was amended to modify the compliance requirement for certain revenue and liquidity threshold. As part of this amendment, we paid a fee of \$50 to the Lenders and cancelled 161,725 Warrants (originally issued in May 2018, as mentioned above) and issued 161,725 new warrants of the Company's common stock, \$0.0001 par value per share, at an exercise price of \$1.76 per share. All other terms of the Warrants were unchanged.

We used approximately \$10.1 million of the net proceeds from the Solar Agreement loan to repay the entire outstanding principal balance and accrued interest under our existing loan agreement with Oxford Finance, LLC (Oxford) and terminated our loan agreement with Oxford.

In August 2018, we closed our public follow-on offering of 10,000,000 shares of our common stock, plus 1,500,000 shares of common stock from the subsequent exercise of the over-allotment option granted to the underwriters. The public offering price of the shares sold was \$1.50 per share. We received aggregate proceeds of approximately \$15.6 million from our follow-on offering and the subsequent exercise of the over-allotment option, after deducting underwriting discounts and commissions, and offering

costs totaling \$1.6 million. We intend to use the net proceeds from this offering to fund expanded commercialization activities and the launch of our ARTAS<sup>®</sup> iX System and for working capital and general corporate purposes.

We have funded our operations to date primarily from the issuance and sale of our common stock in our IPO as well as our follow-on offering, private placements of our equity securities and, to a lesser extent, through debt financings, exercises of our common stock warrants and payments from our customers. As of September 30, 2018, we had cash and cash equivalents of \$23.6 million.

#### **Factors Affecting our Results of Operations**

We believe there are several important factors that have impacted, and that we expect will impact, our results of operations.

#### Adoption of the ARTAS<sup>®</sup> System

The growth of our business depends on our ability to gain broader acceptance of the ARTAS® System and, in particular, the latest iteration of our ARTAS System, ARTAS® iX, as well as the ARTAS procedure by successfully marketing and distributing the ARTAS® System and the ARTAS procedure. If we are unable to successfully commercialize our ARTAS® System and the ARTAS procedure, we may not be able to generate sufficient revenue to achieve or sustain profitability. In the near term, we expect we will continue to operate at a loss and we anticipate we will finance our operations principally through offerings of our capital stock and by incurring debt. If we are unable to raise adequate additional capital, we will be unable to maintain our commercialization efforts and our revenue could decline.

#### Significant Investment in our Sales and Marketing

We have made certain strategic changes to and investments in our U.S. sales and global marketing organizations, which included terminating certain personnel and hiring new personnel and realigning our reporting and leadership structure in the sales organization. For example, throughout 2018 we are increasing the size of our U.S. sales force by hiring sales professionals with experience selling capital equipment and equipment to physicians in the aesthetic market. In addition, we are investing significantly in our sales and marketing efforts related to the launch of the ARTAS® iX System. Strategically, we have been focused on our branding and have consolidated our regional marketing teams to standardize our messaging and focus of our marketing spending with an aim to be more efficient and cost-effective. As a result, we have seen a reduction in and improved efficiency of our marketing spending.

While we increased revenue in 2018 because of increased unit sales, these sales initiatives have also increased our sales and marketing expenses. Furthermore, we anticipate as we continue to advance the commercialization of the ARTAS<sup>®</sup> iX System, our sales and marketing expenses will continue to increase.

#### **Revenue Composition and Trends**

The following table reflects revenue by category:

	Three Mor Septen				ıths Ended ıber 30,			
	2018	2017		 2018		2017		
Systems	\$ 3,040	\$	1,971	\$ 7,571	\$	8,419		
Procedure-based	1,280		1,678	6,150		5,512		
Service related fees	498		528	1,577		1,510		
Total revenue	\$ 4,818	\$	4,177	\$ 15,298	\$	15,441		

We derive our revenue from the sale and service of ARTAS® Systems and procedure-based fees.

- Revenue from systems for the three months ended September 30, 2018 increased as compared to the same period in 2017 due to the launch of the ARTAS® iX Systems in the third quarter of 2018 in the United States. For the nine months ended September 30, 2018, revenue from systems was relatively unchanged due to our ongoing implementation of our new sales strategy, which has not taken full effect given several recent key hires, including our new Vice President of Sales who joined in February 2018, and the weaker than expected performance outside of the United States. We anticipate U.S. revenue from system sold going forward to be primarily from ARTAS iX Systems, while revenue from systems sold outside of the U.S. to be primarily from the existing ARTAS Systems until the time, if and when, we receive regulatory approval for the ARTAS® iX System.
- Revenue from procedure-based fees for the three months end September 30, 2018 decreased as compared to the same period in 2017, while revenue from procedure-based fees for the nine months ended September 30, 2018 increased as



compared to the same period in 2017. Revenue from procedure-based fees for the three months ended September 30, 2018, decreased at least in part due to the timing of prior period purchases of bulk procedures, with customers purchasing bulk procedures in prior periods and using them during in later quarterly periods which we believe resulted in fewer procedures being purchased in the three months ended September 30, 2018. Further, while revenue from procedure-based fees for the nine months ended September 30, 2018 increased, the total number of procedures performed by our customers on their patients did not change proportionally to the growth in our installed base.

• Service-related fees did not change significantly for the three and nine months ended September 30, 2018 as compared to the same periods in 2017.

Historically, the majority of our revenue and our revenue growth has been generated through system sales. While we would expect our procedure-based fees to increase as our installed base of ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems grow worldwide, the total number of procedures has not followed the increase in our installed base of systems sold. For example, our procedure-based revenue decreased for the three months ended September 30, 2018, as compared to the same period in 2017, whereas our installed base has grown from 2017 to 2018. While procedure-based revenue has increased, on from a year-to-date perspective, more than our revenue from system sales on a combined basis, during the aforementioned periods, we believe that revenue from procedure-based fees may not grow proportionally as compared to the increase in our installed base and that it could vary from quarter-to-quarter due to a number of factors, including:

- physician uptake causing a slow ramp-up to utilizing the ARTAS® or ARTAS® iX Systems, which is particularly evident with physicians who are new to hair restoration procedures or physicians who do not operate a solely hair restoration focused practice who are commonly the profile we are targeting;
- capacity limitations with the current installed base of ARTAS® or ARTAS® iX Systems, which can result in procedure-based fees not growing as quickly as system sales, as high performing practitioners are limited in the number of procedures that can be performed in any given period;
- limited or no utilization of the ARTAS® or ARTAS® iX Systems after purchase because of a change in physician preference or practice; and
- the concentration of ARTAS procedures being performed on a limited number of ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems leading to volatility between periods if particular high-volume practitioners perform a smaller number of procedures in a given period.

In order to increase the number of procedures performed per ARTAS® or ARTAS® iX System, and in turn increase revenue from procedure-based fees, we have, in connection with the leadership and sales and marketing changes, initiated programs to assist certain physicians in marketing efforts, patient education and practice optimization to increase utilization of the ARTAS® and ARTAS® iX Systems. If these efforts are successful, we anticipate that the growth in procedure-based fees will increase and that quarterly fluctuations in the number of total procedures performed will be reduced.

#### Revenue from Markets Outside the U.S.

Since launching the ARTAS® System in 2011, we have obtained clearance to sell our products in over 60 countries. In June 2012, we obtained our CE mark to sell our product into the European Economic Area, or EEA. We have sold into 37 countries and sell directly into the U.S., Korea, Hong Kong, Singapore, Spain, Poland, Benelux, Scandinavia, Portugal, the Netherlands and through distributors in the other countries. We obtained clearance to sell in China in September 2016. However, we have not obtained any regulatory approvals or clearances outside of the U.S. for our implantation functionality.

Revenue from markets outside of the U.S accounted for 43% of our total revenue in the first nine months of 2018, compared to 60% from the same period in 2017. Although we will continue to invest resources outside of the U.S., we anticipate that the strategic shift in our sales strategy towards the U.S. market will impact the revenue mix between the U.S. and non-U.S. markets. In particular, in connection with our newly launched ARTAS<sup>®</sup> iX System, which is only cleared for sale in the U.S., our marketing efforts are highly focused on the U.S.

The ARTAS<sup>®</sup> System unit sales declined in the first nine months of 2018 relative to the first nine months of 2017 because of decreased unit sales in Europe, Middle East and Asia Pacific regions, which was partially offset by increased procedure-based fees in these regions. We believe the decline in system sales in the Europe, Middle East and Asia Pacific regions were due in part to potential customers delaying their purchase until the ARTAS<sup>®</sup> iX System is approved or cleared for use in their region.

While we believe our newly launched ARTAS<sup>®</sup> iX System, which incorporates a robotic implantation functionality, could have a positive effect on system sales in the U.S., it may have a negative effect on system sales outside the U.S. as the robotic

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implantation functionality is only approved in the U.S. and potential non-U.S. customers of the ARTAS<sup>®</sup> iX System may delay purchases of ARTAS<sup>®</sup> systems until the implantation functionality is available in their market.

We expect our operating expenses to increase because of increased sales and marketing activity to promote penetration in markets outside the U.S. where we already sell the ARTAS<sup>®</sup> System and geographic expansion into new markets.

#### **Factors Affecting Comparability**

We anticipate that our quarterly results of operations may fluctuate for the foreseeable future due to several factors, including the performance of our direct sales force and international distributors, the launch of our implantation functionality and the ARTAS® iX System, and unanticipated interruptions and expenses related to our operations. In addition, due to the long lead time to finalize ARTAS® and ARTAS® iX-Systems unit sales with our physician customers, and the significant impact each unit sale has on a period's revenue due to the price of each unit, our quarterly revenue may not be comparable from one period to another.

Furthermore, our industry is characterized by seasonally lower demand during the third calendar quarter of the year, when both physicians and prospective patients take summer vacations. A detailed discussion of these and other factors that impact our business is provided in the "Risk Factors" section in this Quarterly Report on Form 10-Q.

#### **Results of Operations**

#### Three and Nine Months Ended September 30, 2018 and 2017:

		Three Mon Septem			Change					Nine Mont Septem			Change			
		2018		2017		\$	%	, .		2018		2017		\$	%	
Revenue	\$	4,818	\$	4,177	\$	641	(dol	<i>lars in t</i> 15%		ands) 15,298	\$	15,441	\$	(143)	(1)%	
Cost of revenue	Ψ	2,663	Ψ	2,474	Ψ	189		8	Ψ	8,362	Ψ	9,053	Ψ	(691)	(8)	
Gross profit		2,155		1,703		452		27		6,936		6,388		548	9	
Gross margin		45%		41%						45%		41%				
Operating expenses:																
Sales and marketing		4,398		3,433		965		28		13,147		10,736		2,411	22	
Research and development		2,008		1,737		271		16		6,286		5,579		707	13	
General and administrative		2,191		1,139		1,052		92		6,159		3,549		2,610	74	
Total operating expenses		8,597		6,309		2,288		36		25,592		19,864		5,728	29	
Loss from operations		(6,442)		(4,606)	_	(1,836)		40	_	(18,656)		(13,476)	_	(5,180)	38	
Other expense, net:																
Interest expense		(631)		(492)		(139)		28		(1,489)		(1,607)		118	(7)	
Other income (expense),																
net		12		(1,473)		1,485	(1	101)		(567)		(1,646)		1,079	(66)	
Total other expense, net		(619)		(1,965)		1,346		(68)		(2,056)		(3,253)		1,197	(37)	
Net loss before provision for																
income taxes		(7,061)		(6,571)		(490)		7		(20,712)		(16,729)		(3,983)	24	
Provision for income taxes		8		25		(17)		(68)		32		50		(18)	(36)	
Net loss	\$	(7,069)	\$	(6,596)	\$	(473)		7%	\$	(20,744)	\$	(16,779)	\$	(3,965)	24%	

*Revenue*. Revenue increased 15% and decreased 1%, for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The change in revenue was primarily due to the changes in volume of system sales for the three and nine months ended September 30, 2018, as compared to the same periods in 2017. We placed 11 and 30 systems in the three and nine months ended September 30, 2018, respectively, as compared to eight and 35 systems in the three and nine months ended September 30, 2018, the revenue increase was partially offset by a decrease of \$0.4 million from procedures-based fees and service-related fees, on a combined basis, as compared to same periods in 2017. For the nine months ended September 30, 2018, the revenue decrease was partially offset by an increase of \$0.7 million from procedures-based fees and service-related fees was due to a significant number of ARTAS procedures being purchased prior to July 1, 2018 and being performed after that date, which we believe resulted in fewer procedures being purchased in the three months ended September 30, 2018.

*Gross Margin*. Gross margin typically fluctuates with product mix, selling prices, material costs and revenue level. Gross margin for the three and nine months ended September 30, 2018 increased by four percentage points compared to the same periods in 2017. The increase for the three months ended September 30, 2018 was primarily driven by certain cost efficiencies and a change in our loss

contingency accrual, which was reported in cost of revenue, which were partially offset by higher initial manufacturing costs associated with our ARTAS iX System that was launched in the third quarter of 2018 and a lower percentage of revenue being generated from procedure-based fees which generally carry a higher gross margin profile. For the nine months ended September 30, 2018, the increase was primarily driven by cost efficiencies and a higher percentage of revenue being generated from procedure-base fees, which were partially offset by a charge related to a loss contingency accrual of \$0.3 million and by higher initial costs associated with the ARTAS® iX System. The loss contingency charge was related to certain excess inventory components procured for our ARTAS® System by our third-party manufacturer, which we determined would be in excess of expected demand due to manufacturing changes associated with the ARTAS® System as a result of the approval of the implantation functionality. We initially anticipate higher manufacturing, warranty, and service costs associated with the ARTAS® iX System which will result in a lower gross margin moving forward.

*Sales and Marketing.* Sales and marketing expenses increased 28% and 22%, for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The increase was primarily due to the growth in employee headcount to support our overall sales and marketing activities, including the ongoing commercialization efforts for the ARTAS® System and ARTAS® iX System and the timing of expenditures for certain tradeshows in first nine months of 2018, which historically were held later in the calendar year.

*Research and Development*. Research and development expense increased 16% and 13%, for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The increase was primarily due to incremental outside services and consulting costs associated with the development of the ARTAS<sup>®</sup> iX System, which was commercially launched in July 2018.

*General and Administrative*. General and administrative expenses increased 92% and 74%, for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The increase was primarily the result of an increase in our allowance for doubtful accounts for certain customers outside of the United States, in addition to professional service costs, consisting of accounting, consulting, legal and other professional fees incurred in connection with our status as a public company following our IPO in October 2017.

*Interest expense.* Interest expense increased 28% and decreased 7% for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The increase in interest expense between the three-month periods was related to a higher average principal balance of our outstanding long-term-debt obligations as we refinanced our debt obligations with Solar in May 2018, which had a higher outstanding balance than the loan with Oxford which we repaid during this period. The change in the interest expense between the nine-month periods was not significant.

*Other income (expense), Net.* Other income (expense), net increased by \$1.5 million and decreased by \$1.1 million for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. For the three-month period, the increase was attributable to the change in the fair value of our convertible preferred stock warrant liability of \$1.5 million for the three months ended September 30, 2017, with no change being recognized in 2018. For the nine-month period, the increase mentioned for the convertible preferred stock warrant liability was partially offset by the unamortized debt issuance and debt discounts written off by us and fees paid directly to Oxford and Solar in connection with the extinguishment of the Oxford loan and the new Solar loan in May 2018.

*Provision for income tax:* Our effective tax rate is (0.12%) and (0.18%) for income tax for the three and nine months ended September 30, 2018, respectively, and we expect that our effective tax rate for the full year 2018 will be (0.42%). Based on available evidence, including cumulative losses since inception and expected future losses, we have determined that it is more likely than not that our U.S. federal, U.S. state and Korea deferred tax assets will not be realized and therefore a valuation allowance has been provided on the U.S. federal, U.S. state and Korea net deferred tax assets.

In general, if we experience a greater than 50% aggregate change in ownership over a three-year period, utilization of our pre-change net operating loss, or NOL, and credit carryforwards are subject to an annual limitation under Sections 382 and 383 of the U.S. Internal Revenue Code, or the Code. Generally, U.S. states maintain similar laws or regulations as Sections 382 and 383 of the Code. The annual limitation generally is determined by multiplying the value of our stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL or tax credit carryforwards before utilization.

We file tax returns for U.S. federal and state taxes along with tax returns in the United Kingdom, Hong Kong, Spain and South Korea. We are not currently subject to any income tax examinations. Since our inception, we have incurred losses from our U.S. operations, which generally allows all tax years to remain open.

We recognize the financial statement effects of a tax position when it becomes more likely than not, based upon the technical merits, that the position will be sustained upon examination. We do not expect any material changes in the next 12 months in unrecognized tax benefits.



We recognize interest and/or penalties related to uncertain tax positions. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected in the period that such determination is made. The interest and penalties are recognized as other expense and not tax expense. We currently have no interest and penalties related to uncertain tax positions.

#### Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. Our net loss was \$7.1 million and \$6.6 million for the three months ended September 30, 2018 and 2017, respectively, and \$20.7 million and \$16.8 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$185.2 million. As of September 30, 2018, and December 31, 2017, we had cash and cash equivalents of \$23.6 million and \$23.5 million, respectively. As of the filing date of this Quarterly Report, we believe our current cash and cash equivalents will not be sufficient to fund our operations for the next twelve months. These factors raise substantial doubt about our ability to continue as a going concern.

In connection with our IPO, we sold an aggregate of 3,897,910 shares of our common stock (inclusive of 322,910 shares of common stock from the exercise of the over-allotment option granted to the underwriters) at a price of \$7.00 per share and we received aggregate cash proceeds of approximately \$22.1 million, net of underwriting discounts and commissions, and offering costs. Additionally, in August 2018, we closed our follow-on public offering of 11,500,000 shares of our common stock with an offering price of \$1.50 per share. We received aggregate proceeds of \$15.6 million, net of underwriters' discounts and commissions, and offering \$1.6 million.

#### Debt Obligations

In May 2018, we entered into the Solar Agreement. The Solar Agreement consists of a four-year term loan for an aggregate principal amount of \$20.0 million, for working capital, to fund our general business requirements and to repay our indebtedness under the Oxford Agreement. We used \$10.1 million of the loan proceeds to repay the outstanding principal of \$8.7 million, a final payment fee of \$1.3 million plus accrued interest and prepayment fees of \$0.1 million under the Oxford Agreement. The Borrowings under the Solar Agreement bear interest through maturity at a rate equal to the U.S. Dollar LIBOR rate plus 7.95% per annum. The outstanding balance on the Solar Agreement was \$20.0 million as of September 30, 2018. The Solar Agreement contains various covenants. As of September 30, 2018, we were in compliance with all required covenants under the Solar Agreement, as amended.

#### Capital Resources

We have financed our operations principally through the issuance and sale of our common stock in our IPO, private placements of our capital stock, and to a lesser extent, secured debt financing and payments from customers. We believe that our existing cash and cash equivalents and cash expected to be generated from sales of our products will not be sufficient to fund our planned operations through the next 12 months. However, we will need additional capital to fund our future operations and we intend to obtain such capital through the sale of additional shares of capital stock or related securities. To the extent that we raise additional capital through future equity financings, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. Further, there can be no assurance that we will be able to raise additional funds on favorable terms, or at all. Our failure to raise additional capital would have a negative impact on our financial condition and our ability to execute our business plan.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with the ongoing commercialization of the ARTAS® System, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the revenue we generate from our operations;
- the scope and timing of our investment in our commercial infrastructure and sales-force;
- the costs of commercialization activities including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of the ARTAS® System and the ARTAS procedure;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to implement additional infrastructure and internal systems;
- the research and development activities we intend to undertake in order to expand the approved indications of use for the ARTAS® System;



- the emergence of competing technologies or other adverse market developments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and
- the costs associated with maintaining subsidiaries in foreign jurisdictions.

We cannot assure that we will ever be profitable or generate positive cash flow from operating activities.

#### Cash flows

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,						
	2018 2017						
		(dollars in t	thous	ands)			
Cash used in operating activities	\$	(21,226)	\$	(14,376)			
Cash used in investing activities		(1,051)		(215)			
Cash provided by financing activities		22,291		8,476			
Effect of exchange rate changes on cash, cash equivalents and restricted							
cash		33		(22)			
Net increase (decrease) in cash, cash equivalents and restricted cash	\$	47	\$	(6,137)			

#### **Cash Flows from Operating Activities**

For the nine months ended September 30, 2018, cash used in operating activities of \$21.2 million was attributable to a net loss of \$20.7 million and a decrease from operating assets and liabilities of \$2.8 million, which was partially offset by \$2.3 million in non-cash charges. The non-cash charges consisted primarily of provision for bad debt of \$0.8 million, depreciation and amortization of \$0.5 million, amortization of debt issuance costs of \$0.3 million, stock-based compensation of \$0.4 million and changes in excess and obsolete inventory of \$0.1 million. The net change in operating assets and liabilities was primarily attributable to an increase in accounts payable and accrued other liabilities of \$2.2 million, which was offset by an increase in accounts receivable of \$3.4 million due to the timing of collections from customers in the third quarter of 2018 as well as an increase in inventory of \$1.6 million due to inventory build of ARTAS® systems in 2018.

For the nine months ended September 30, 2017, cash used in operating activities of \$14.4 million was attributable to a net loss of \$16.8 million, which was partially offset by \$2.9 million in non-cash charges and a decrease from operating assets and liabilities of \$0.5 million. The non-cash charges consisted primarily of \$1.6 million related to a change in fair value of preferred stock warrants, depreciation and amortization of \$0.5 million, amortization of debt issuance costs of \$0.4 million, and stock-based compensation of \$0.3 million. The net change in operating assets and liabilities was primarily attributable to an increase in accounts receivable of \$0.7 million, in prepaid expenses and other assets of \$2.3 million, and an increase in accounts payable and accrued and other liabilities of \$2.5 million due to the timing of receipt and payment of vendor invoices.

### **Cash Flows from Investing Activities**

For the nine months ended September 30, 2018 and 2017, cash used in investing activities related to purchases of property and equipment.

#### **Cash Flows from Financing Activities**

For the nine months ended September 30, 2018, cash provided by financing activities was \$22.3 million, consisting of net proceeds from our Solar loan of \$19.6 million, net proceeds from our follow-on offering of \$15.6 million and \$0.4 million of stock option exercises, which was offset by \$13.3 million for the retirement of our Oxford loan.

For the nine months ended September 30, 2017, cash provided by financing activities was \$8.5 million, consisting of \$10.2 million in net proceeds received from the issuance of convertible preferred stock and \$5.0 million from issuance of convertible notes, each of which converted into common stock upon the consummation of our IPO. Cash provided by financing activities was partially offset by



\$6.0 million of principal payments on our outstanding debt obligation with Oxford and \$0.7 million of payments for financing costs related to our IPO.

#### **Contractual Obligations and Other Commitments**

The following table summarizes our contractual obligations as of September 30, 2018, which represent material expected or contractually committed future obligations.

	Payments Due by Period										
	Less	than						More than			
	1 Y	ear	1	to 3 Years	3	to 5 Years		5 Years		Total	
					(dolla	rs in thousands	)				
Debt obligations, including interest (1)	\$	503	\$	12,226	\$	13,008	\$	—	\$	25,737	
Operating leases		128		1,052		738				1,918	
Total contractual obligations	\$	631	\$	13,278	\$	13,746	\$	_	\$	27,655	

(1) Represents our loan with Solar and our anticipated repayment schedule for the loan. Pursuant to our loan agreement with Oxford, the loan will mature in May 2022. The loan with Solar accrues interest at prime plus 7.9% per annum. The outstanding principal balance on the Solar loan was \$20.8 million as of September 30, 2018, which includes a final payment of \$0.8 million to Solar on the maturity of the loan.

In addition to the contractual obligations listed in the table above, in March 2018, we received U.S. FDA 510(k) clearance to expand the ARTAS® System technology to include an implantation functionality. Based on manufacturing changes associated with the ARTAS® System, we determined that certain components procured or expected to be procured by Evolve Manufacturing Technologies, Inc., our single third-party manufacturer, who assemble the ARTAS® Systems, will be in excess of expected demand or usage. As a result, we recorded a loss contingency accrual of \$0.3 million, which is reported in "Cost of revenue" in the condensed consolidated statements of operations for the nine-months ended September 30, 2018 and included in "Other accrued liabilities" on the condensed consolidated balance sheets as of September 30, 2018.

#### **Off-Balance Sheet Arrangements**

We do not currently engage in off-balance sheet financing arrangements. In addition, we do not have any interest in entities referred to as variable interest entities, which includes special purpose entities and other structure finance entities.

#### **Critical Accounting Policies and Estimates**

Our unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. Preparation of these statements requires management to make judgments and estimates. Some accounting policies have a significant impact on amounts reported in these financial statements. A summary of significant accounting policies and a description of accounting policies that are considered critical may be found in our 2017 Annual Report on Form 10-K for the year ended December 31, 2017, in the Notes to the Consolidated Financial Statements (Note 1) and the Critical Accounting Policies and Estimates section in Management's Discussion and Analysis of Financial Condition and Results of Operations. There have been no changes in these significant accounting policies during the three months ended September 30, 2018.

#### **JOBS Act Accounting Election**

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period for the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

### **Recent Accounting Pronouncements**

See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted as of the date of this Quarterly Report on Form 10-Q.



# ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate and currency exchange rate fluctuations.

#### **Interest Rate Risk**

Our cash and cash equivalents are held in cash deposits and money market funds. Due to the short-term nature of these instruments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio because of changes in interest rates. Declines in interest rates, however, would reduce our future interest income.

We are exposed to interest rate risk related to our debt obligations which are subject to variable interest rates. As of September 30, 2018, a 100-basis point increase in interest rates on our debt subject to variable interest rate fluctuations would increase our interest expense \$0.1 million annually.

#### Foreign Currency Risk

Our sales contracts are primarily denominated in U.S. dollars and, therefore, substantially all of our revenue is not subject to foreign currency risk. However, a strengthening of the U.S. Dollar could increase the real cost of our products to our customers outside of the U.S., which could adversely affect our financial condition and operating results. In addition, a portion of our operating expenses are incurred outside the U.S. and are denominated in foreign currencies and are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the British Pound Sterling, Euro, Hong Kong Dollar, and South Korean Won. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statement of operations. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not engaged in any foreign currency hedging transactions.

#### ITEM 4. CONTROLS AND PROCEDURES.

### Evaluation of disclosure controls and procedures.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

#### Changes in internal control over financial reporting.

Our Chief Executive Officer and Chief Financial Officer did not identify any changes in our internal control over financial reporting in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended September 30, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

#### PART II OTHER INFORMATION

#### **ITEM 1. LEGAL PROCEEDINGS**

On May 23, 2018, a putative shareholder class action complaint was filed in Superior Court of the State of California, County of San Mateo (the "Superior Court"), captioned Wong v. Restoration Robotics, Inc., et al., No. 18CIV02609. On June 21, 2018 and June 28, 2018, two putative class action complaints were filed in the United States District Court for the Northern District of California, captioned Guerrini v. Restoration Robotics, Inc., et al., No. 5:18-cv-03712-EJD and Yzeiraj v. Restoration Robotics, Inc., et al., No. 5:18-cv-03883-BLF, respectively. On July 24, 2018, the U.S. Northern District Court related the Guerrini and Yzeiraj actions and reassigned the Yzeiraj action to Judge Edward J. Davila. The Wong and Guerrini complaints name us as defendants, and certain of our current and former executive officers and directors, certain of our venture capital investors and the underwriters in our IPO. The Yzeiraj complaint names us as defendants and certain of our current and former executive officers and directors. The Wong complaint asserts claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, or the Securities Act. The Guerrini and Yzeiraj complaints assert claims under Sections 11 and 15 of the Securities Act. The complaints all allege, among other things, that our Registration Statement filed with the SEC on September 1, 2017 and the Prospectus filed with the SEC on October 13, 2017 in connection with our IPO were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading and omitted to state material facts required to be stated therein. The complaints seek unspecified monetary damages, other equitable relief and attorneys' fees and costs.

On August 8, 2018, we, along with certain of our current and former executive officers and directors, filed a motion to dismiss the Wong complaint based on the forum selection clause designating the federal district courts as the exclusive forum for claims arising under the Securities Act contained in our Amended and Restated Certificate of Incorporation, and which asked the court in the alternative to stay the Wong action. Also, on August 8, 2018, the venture capital investor and underwriters' defendants in the Wong action filed demurrers to the Wong complaint, and we, along with certain of our current and former executive officers and directors, joined in the venture capital investor defendants' demurrer. A hearing on our motion to dismiss and the demurrers to the Wong complaint was held on October 24, 2018. We are unable to predict the date on which the Superior Court will issue any decision at this time.

On October 2, 2018, the U.S. Northern District Court granted a Motion for Consolidation of Related Actions, Appointment as Lead Plaintiff and Approval of Lead Counsel filed by Plaintiff Edgardo Guerrini, which consolidated the Guerrini and Yzeiraj actions under the caption In re Restoration Robotics, Inc. Securities Litigation, Case No. 5:18-cv-03712-EJD. The U.S. Northern District Court has set an initial hearing for January 24, 2019.

We believe that these lawsuits are without merit and we intend to vigorously defend against these claims.

Further, we may from time to time continue to be involved in various legal proceedings of a character normally incident to the ordinary course of our business, which we do not deem to be material to our business and results of operations.

# **ITEM 1A. RISK FACTORS**

Our operations and financial results are subject to various risk and uncertainties, including those described below, any of which could adversely affect our business, results of operations, financial condition and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. You should carefully consider the risk described below and the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

#### **Risks Related to Our Business**

We have limited commercial history and we have incurred significant losses since our inception. We anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

We have a limited commercial history and have focused primarily on research and development, product design and engineering, establishing supply and manufacturing relationships, seeking regulatory clearances and approvals to market the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX System, and selling and marketing. We have incurred losses in each year since our inception in 2002. Our net losses were approximately \$20.7 million for the nine months ended September 30, 2018 and \$17.8 million for the year ended December 31, 2017. As of September 30, 2018, we had an accumulated deficit of \$185.2 million. We will continue to incur significant expenses for the foreseeable future as we expand our sales and marketing, research and development, and clinical and regulatory activities. We may



never generate sufficient revenue to achieve or sustain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. Furthermore, because of our limited operating history and because the market for aesthetic products is rapidly evolving, we have limited insight into the trends or competitive products that may emerge and affect our business. Before investing, you should consider an investment in our common stock considering the risks, uncertainties, and difficulties frequently encountered by early-stage medical technology companies in rapidly evolving markets such as ours. We may not be able to successfully address any or all of these risks, and the failure to adequately do so could cause our business, results of operations, and financial condition to suffer.

#### We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future because of a variety of factors, many of which are outside of our control. These factors include:

- the cost of growing our ongoing commercialization and sales and marketing activities;
- the costs of manufacturing and maintaining sufficient inventories of our products to meet anticipated demand and inventory write-offs related to obsolete products or components;
- the costs of enhancing the existing functionality and development of new functionalities for the ARTAS® and ARTAS® iX System;
- the costs of preparing, filing, prosecuting, defending, and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the variability of ARTAS procedures being performed between periods if particular high-volume practitioners perform a smaller number of procedures in a given period as a result of the concentration of procedures performed by certain practitioners;
- any product liability or other lawsuits and the costs associated with defending them or the results of such lawsuits;
- the costs associated with conducting business and maintaining subsidiaries in foreign jurisdictions;
- customers in jurisdictions where the ARTAS<sup>®</sup> iX System is not approved delaying their purchase, and not purchasing an ARTAS System, until the ARTAS<sup>®</sup> iX System is approved or cleared for use in their market;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning future revenue from ARTAS<sup>®</sup> Systems sales, servicing and procedure-based fees. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfalls in revenue. Accordingly, a significant shortfall in market acceptance or demand for the ARTAS<sup>®</sup> Systems and procedures could have an immediate and material adverse impact on our business and financial condition.

# It is difficult to forecast our future performance and our financial results may fluctuate unpredictably.

Our limited commercial history and the rapid evolution of the markets for medical technologies and aesthetic products make it difficult for us to predict our future performance. Several factors, many of which are outside of our control, may contribute to fluctuations in our financial results, such as:

- physician demand for the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems and procedure usage may vary from quarter to quarter;
- customers in jurisdictions where the ARTAS<sup>®</sup> iX System is not approved delaying their purchase, and not purchasing a ARTAS System, until the ARTAS<sup>®</sup> iX System is approved or cleared for use in their market;
- the inability of physicians to obtain the necessary financing to purchase the ARTAS® System or the ARTAS® iX System;
- changes in the length of our sales process for the ARTAS® and ARTAS® iX Systems;
- performance of new functionalities and system updates, such as the robotic implantation functionality in the new ARTAS® iX System;
- performance of our international distributors;
- positive or negative media coverage of the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System, the procedures or products of our competitors, or our industry generally;

- our ability to maintain our current, or obtain further, regulatory clearances or approvals such as the regulatory clearances and approvals necessary to market the ARTAS® iX System outside the U.S.;
- delays in, or failure of, product and component deliveries by our third-party manufacturers or suppliers;
- seasonal or other variations in patient demand for aesthetic procedures;
- introduction of new aesthetic procedures or products that compete with the ARTAS® System or ARTAS® iX System;
- changes in accounting rules that may cause restatement of our consolidated financial statements or have other adverse effects; and
- adverse changes in the economy that reduce patient demand for elective aesthetic procedures.

# The long sales cycle, low unit volume for sales of the ARTAS<sup>®</sup> System and ARTAS<sup>®</sup> iX System and the historic seasonality of our industry, each may contribute to substantial fluctuations in our operating results and stock price and make it difficult to compare our results of operations to prior periods and predict future financial results.

We sell a relatively small number of ARTAS® and ARTAS® iX Systems at a relatively high price, with each sale of an ARTAS® System or ARTAS® iX System typically involving a significant amount of time. Because of the relatively small number of ARTAS® and ARTAS® iX Systems we expect to sell in any period, each sale of a system could represent a significant percentage of our revenue for a particular period. Furthermore, due to the significant amount of time it can take to finalize the sale of a system, it is likely that a sale could be recognized in a subsequent period which could have a material effect on our results from quarter to quarter and increase the volatility of quarterly results. In addition, our industry is characterized by seasonally lower demand during the third quarter of the calendar year, generally when both physicians and prospective patients take summer vacation. As a result of these factors, future fluctuations in quarterly results could cause our revenue and cash flows to be below analyst and investor expectations, which could cause decline in our stock price. Due to future fluctuations in revenue and costs, as well as other potential fluctuations, you should not rely upon our operating results in any particular period as an indication of future performance. If we do not sell ARTAS® and ARTAS® iX Systems as anticipated, our operating results will vary significantly from our expectations. In addition, selling the ARTAS® and ARTAS® iX System requires significant marketing effort and expenditure in advance of the receipt of revenue and our efforts may not result in a sale.

#### Our recurring losses from operations and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern.

Our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of, and for the year ended, December 31, 2017 that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations. As of the filing date of this Quarterly Report, we believe our current cash and cash equivalents will not be sufficient to fund our operations for the next twelve months. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

# We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization and other operations or efforts.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development and sales and marketing activities. Research and development, clinical trials, product engineering, ongoing product upgrades and other enhancements such as software-updates for the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems and seeking regulatory clearances and approvals to market future products will require substantial funds to complete. As of September 30, 2018, we had capital resources consisting of cash and cash equivalents of \$23.6 million. In connection with our IPO, we raised an additional \$22.1 million of proceeds, net of underwriting discounts and commissions, and offering expenses. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the ongoing commercializing of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX System, increasing our sales and marketing efforts, and continuing research and development and product enhancements activities.

We believe our existing cash and cash equivalents and cash expected to be generated from the sale of our products will not be sufficient for us to fund our planned operations for the next twelve months. Therefore, we will need additional capital to fund our future operations. In addition, our operating plans may change as a result of many factors some of which may be unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, the licensing of rights to our technology or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay or curtail our efforts to develop enhancements to the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems, including any clinical trials that may be required to market such enhancements;
- delay or curtail our plans to increase and expand our sales and marketing efforts; or
- delay or curtail our plans to enhance our customer support and marketing activities.

We are restricted by covenants in the Solar Agreement. These covenants restrict, among other things, our ability to incur additional debt without Solar's consent, which may limit our ability to obtain additional funds. In addition, the Solar Agreement contains certain minimum liquidity and minimum revenue covenants, which, if we fail to maintain or achieve, will result in a default under the agreement and the requirement for us to repay all outstanding principal amounts and accrued interest repay all amounts outstanding

# We are dependent upon the success of the ARTAS® and ARTAS® iX Systems, which has a limited commercial history. If we are unsuccessful in developing the market for robotic hair restoration or the market acceptance for the ARTAS® and ARTAS® iX Systems fails to grow significantly, our business and future prospects will be harmed.

We commenced commercial sales of the ARTAS<sup>®</sup> System for hair follicle dissection in the U.S. in 2011 and expect that the revenue we generate from both system sales and servicing as well as recurring procedure-based fees will account for all of our revenue for the foreseeable future. Accordingly, our success depends on the acceptance among physicians and patients of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems as the preferred system for performing hair restoration surgery. Acceptance of the ARTAS<sup>®</sup> iX Systems by physicians is significantly dependent on our ability to convince physicians of the benefits of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems to their practices and, accordingly, develop the market for robotic-assisted hair restoration surgery. Acceptance of the ARTAS<sup>®</sup> is equally important as patient demand will influence physicians to offer the ARTAS procedure, and the degree of market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems by physicians and patients is unproven. We believe that market acceptance of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems will depend on many factors, including:

- the perceived advantages or disadvantages of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems compared to other hair restoration products and treatments;
- the safety and efficacy of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems relative to other hair restoration products and treatments;
- the price of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems relative to other hair restoration products and treatments;
- our success in expanding our sales and marketing organization;
- the effectiveness of our marketing, advertising, and commercialization initiatives;



- our success in adding new functionalities to the ARTAS® and ARTAS® iX Systems and enhancing existing functions; and
- our ability to obtain regulatory clearance to market the ARTAS® and ARTAS® iX Systems for additional treatment indications in the U.S.

Further, the ARTAS<sup>®</sup> iX System, which was launched in June 2018, includes our recently approved robotic implantation functionality. As this functionality is new, it is possible that it could include defaults, "bugs" or present other technical issues which could prompt potential physician customers to delay their purchase of the ARTAS iX System or could prompt physicians that have purchased the ARTAS iX System to either return or not utilize the system.

We cannot assure you that the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System will achieve broad market acceptance among physicians and patients. Because we expect to derive substantially all of our revenue for the foreseeable future from ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems sales, servicing and procedure-based fees, any failure of this product to satisfy physician or patient demand or to achieve meaningful market acceptance will harm our business and future prospects.

#### If there is not sufficient patient demand for ARTAS procedures, our financial results and future prospects will be harmed.

The ARTAS procedure is an elective aesthetic procedure, the cost of which must be borne by the patient, and is not covered by or reimbursable through government or private health insurance. The decision to undergo the ARTAS procedure is thus driven by patient demand, which may be influenced by a number of factors, such as:

- the success of our sales and marketing programs;
- the extent to which our physician customers recommend the ARTAS procedures to their patients;
- our success in attracting consumers who have not previously undergone hair restoration treatment;
- the extent to which the ARTAS procedure satisfies patient expectations;
- our ability to properly train our physician customers in the use of the ARTAS® and ARTAS® iX Systems so that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the cost, safety, and effectiveness of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems versus other aesthetic treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and the ARTAS® and ARTAS® iX Systems in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and
- general consumer confidence, which may be impacted by economic and political conditions outside of our control.

Our financial performance will be materially harmed in the event we cannot generate significant patient demand for procedures performed with the ARTAS<sup>®</sup> System.

### Our success depends in part upon patient satisfaction with the effectiveness of the ARTAS® and ARTAS® iX Systems.

In order to generate repeat and referral business, patients must be satisfied with the effectiveness of the ARTAS<sup>®</sup> Systems. If the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System procedure is not done correctly, and or the patient suffers from complications and other adverse effects, the patient may not be satisfied with the benefits of the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System. Furthermore, if the transplanted hair follicles do not grow or survive the transplant, the patient will likely not view the procedure as having a satisfactory outcome. If patients are not satisfied with the aesthetic benefits of the ARTAS<sup>®</sup> System, ARTAS<sup>®</sup> iX System or feel that it is too expensive for the results obtained, our reputation and future sales will suffer.

#### Our success depends on growing physician adoption and use of the ARTAS® System and ARTAS® iX System.

Our ability to increase the number of physicians willing to make a significant capital expenditure to purchase the ARTAS® System, or ARTAS® iX System and make it a significant part of their practices, depends on the success of our sales and marketing programs. We must be able to demonstrate that the cost of the ARTAS® and ARTAS® iX Systems and the revenue that a physician can derive from performing ARTAS procedures are compelling when compared to the costs and revenue associated with alternative aesthetic treatments the physician can offer. In addition, we believe our marketing programs, including clinical and practice development support, will be critical to increasing utilization and awareness of the ARTAS® and ARTAS® iX Systems, but these programs require physician commitment and involvement to succeed. If we are unable to increase physician adoption and use of the ARTAS® System, or ARTAS® iX System our financial performance will be adversely affected.



# Our inability to effectively compete with competitive hair restoration treatments or procedures may prevent us from achieving significant market penetration or improving our operating results.

The medical technology and aesthetic product markets are highly competitive and dynamic, and are characterized by rapid and substantial technological development and product innovations. We designed the ARTAS® System to assist physicians in performing follicular unit extraction surgery. Demand for the ARTAS® Systems and ARTAS procedures could be limited by other products and technologies. Competition to address hair loss comes from various sources, including:

- therapeutic options including Rogaine, which is applied topically, and Propecia, which is ingested, both of which have been approved by the FDA;
- non-surgical options, such as wigs, hair-loss concealer sprays and similar products; and
- other surgical alternatives, including hair transplantation surgery using the strip surgery method or using hand-held devices.

Surgical alternatives to the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems may be able to compete more effectively than the ARTAS procedure in established practices with trained staff and workflows built around performing these surgical alternatives. Practices experienced in offering strip surgery or follicular unit extractions using hand-held devices may be reluctant to incorporate or convert their practices to offer ARTAS procedures due to the effort involved to make such changes.

Many options may be able to provide satisfactory results for male hair loss, generally at a lower cost to the patient than the ARTAS® and ARTAS® iX Systems. As a result, if patients choose these competitive alternatives, our results of operation could be adversely affected.

We also face competition from other aesthetic devices that physicians may consider adding to their practice in lieu of building a hair restoration practice, for instance CoolSculpting, which is utilized for body contouring or cosmetic fat reduction. As a result, if physicians choose these competitive products over building a hair restoration practice with the ARTAS® System or ARTAS® iX System, our results of operation could be adversely affected.

Some of our competitors have a broad range of product offerings, large direct sales forces, and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Our potential physician customers also may need to recoup the cost of expensive products that they have already purchased from our competitors, and thus they may decide to delay purchasing, or not to purchase, the ARTAS® System or ARTAS® iX System.

Many of our competitors are large, experienced companies that have substantially greater resources and brand recognition than we do. Competition could result in price-cutting, reduced profit margins, and limited market share, any of which would harm our business, financial condition, and results of operations.

#### We may not be able to establish or strengthen our brand.

We believe that establishing and strengthening the Restoration Robotics and ARTAS brand is critical to achieving widespread acceptance of the ARTAS® Systems, particularly because of the highly competitive nature of the market for aesthetic treatments and procedures to address male hair loss. Promoting and positioning our brand will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable product to assist them in performing hair restoration surgery. Given the established nature of our competitors, and our limited commercialization in the U.S., it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our ARTAS® Systems may not be accepted by physicians, which would adversely affect our business, results of operations and financial condition.

# We have limited experience with our direct sales and marketing force and any failure to build and manage our direct sales and marketing force effectively could have a material adverse effect on our business.

We rely on a direct sales force to sell the ARTAS<sup>®</sup> Systems in the U.S. and certain markets outside the U.S. In order to meet our anticipated sales objectives, we expect to grow our direct sales and marketing organization significantly over the next several years and intend to opportunistically build a direct sales and marketing force in certain international markets where we do not have a direct sales force. There are significant risks involved in building and managing our sales and marketing organization, including risks related to our ability to:

- hire qualified individuals as needed;
- generate sufficient leads within our target physician group for our sales force;
- provide adequate training for the effective sale and marketing of the ARTAS® System or ARTAS® iX System;
- retain and motivate our direct sales and marketing professionals; and
- effectively oversee geographically dispersed sales and marketing teams.

Our failure to adequately address these risks could have a material adverse effect on our ability to increase sales and use of the ARTAS® and ARTAS® iX Systems, which would cause our revenue to be lower than expected and harm our results of operations.

### To market and sell the ARTAS® System in certain markets outside of the U.S., we depend on third-party distributors.

We depend on third-party distributors to sell, market, and service the ARTAS<sup>®</sup> Systems in certain markets outside of the U.S. and to train our physician customers in such markets. Furthermore, we may need to engage additional third-party distributors to expand into new markets outside of the U.S. where we do not have a direct sales force. We are subject to a number of risks associated with our dependence on these third-parties, including:

- the lack of day-to-day control over the activities of third-party distributors;
- third-party distributors may not commit the necessary resources to market, sell, train, support and service our systems to the level of our expectations;
- third-party distributors may emphasize the sale of third-party products over our products;
- third-party distributors may not be as selective as we would be in choosing physicians to purchase the ARTAS® System or as effective in training physicians in marketing and patient selection;
- third-party distributors may violate applicable laws and regulations which may expose us to potential liability or limit our ability to sell products in certain markets
- third-party distributors may terminate their arrangements with us on limited, or no, notice or may change the terms of these arrangements in a manner unfavorable to us; and
- disagreements with our distributors that could require or result in costly and time-consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar.

If we fail to establish and maintain satisfactory relationships with our third-party distributors, our revenue and market share may not grow as anticipated, and we could be subject to unexpected costs which would harm our results of operations and financial condition.

# To successfully market and sell the ARTAS<sup>®</sup> System in markets outside of the U.S., we must address many international business risks with which we have limited experience.

Sales in markets outside of the U.S. accounted for approximately 58% of our revenue for the year ended December 31, 2017 and 43% and 60% of our revenue for the nine months ended September 30, 2018 and 2017, respectively. We believe that a significant percentage of our business will continue to come from sales in markets outside of the U.S. through increased penetration in countries where we market and sell the ARTAS® System, and with expansion into new international markets. However, international sales are subject to a number of risks, including:

- difficulties in staffing and managing our international operations;
- increased competition as a result of more products and procedures receiving regulatory approval or otherwise free to market in international markets;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;



- reduced or varied protection for intellectual property rights in some countries;
- export restrictions, trade regulations, and foreign tax laws;
- fluctuations in currency exchange rates;
- foreign certification and regulatory clearance or approval requirements, including receiving regulatory approval and clearance for the robotic implantation functionality included in our ARTAS® iX System;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- customs clearance and shipping delays;
- political, social, and economic instability abroad, terrorist attacks, and security concerns in general;
- preference for locally produced products;
- potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of foreign laws and different legal standards; and
- increased financial accounting and reporting burdens and complexities.

If one or more of these risks were realized, our results of operations and financial condition could be adversely affected.

We expect that our revenue from international markets may decrease in the near term as we have received regulatory approval or clearance for the implantation function outside of the U.S., which may result in purchasing delays in international markets as customers await the availability of that function. In addition, the number of ARTAS® systems previously sold to distributors that have not yet been placed with an end user has increased in recent periods, which, in combination with the launch of ARTAS® iX, System may further exaggerate delays in international system sales.

# While traditional hair transplantation surgery has been available for many years, the ARTAS® System has only been commercially available since 2011. As a result, we have a limited track record compared to traditional hair transplantation surgery and the safety and efficacy of the ARTAS® System is not yet supported by long-term clinical data, which could limit sales, and the ARTAS® System could prove to be less safe or effective than initially thought.

The ARTAS® System that we market in the U.S. is regulated as a medical device by the U.S. Food and Drug Administration, or the FDA, and has received premarket clearance under Section 510(k) of the U.S. Federal Food, Drug and Cosmetic Act, or FDCA. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved premarket approval, or PMA, application and later down-classified, or a 510(k)-exempt device. This process is typically shorter and generally requires the submission of less supporting documentation than the FDA's PMA process and does not always require long-term clinical studies.

Hair transplantation surgery has been a treatment option for hair restoration for many years, while we only began commercializing the ARTAS® System in 2011. Consequently, we lack the breadth of published long-term clinical data supporting the safety and efficacy of the ARTAS® System and the benefits it offers that might have been generated in connection with other hair restoration techniques. As a result, physicians may be slow to adopt the ARTAS® System, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Furthermore, future patient studies or clinical experience may indicate that treatment with the ARTAS® System does not improve patient outcomes compared to other hair restoration techniques. Such results would slow the adoption of the ARTAS® System by physicians, would significantly reduce our ability to achieve expected sales and could prevent us from achieving and maintaining profitability.

We have limited complication or patient success rate data with respect to treatment using the ARTAS® System. If future patient studies or clinical testing do not support our belief that our system offers a more advantageous treatment for hair restoration, market acceptance of the ARTAS® System could fail to increase or could decrease and our business could be harmed. Moreover, if future results and experience indicate that our implant products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA or other governmental clearance or approval or, CE Certificates of Conformity, significant legal liability or harm to our business reputation. Furthermore, if patients that receive traditional hair transplantation surgery, such as strip surgery, were to experience unexpected or serious complications or other unforeseen effects, the market for the ARTAS® System may be adversely affected, even if such effects are not applicable to the ARTAS® System.

If we choose to, or are required to, conduct additional studies, such studies or experience could, slow the market adoption of the ARTAS<sup>®</sup> System by physicians, significantly reduce our ability to achieve expected revenue and prevent us from becoming profitable.

#### We were the subject of purported class action lawsuits, and additional litigation may be brought against us in the future.

In May and June 2018, a number of purported stockholder class action complaints were filed against us, the members of our board of directors (and affiliated venture funds), as well as certain of our current and former officers and the underwriters in our IPO. The complaints all allege, among other things, that our Registration Statement filed with the SEC on September 1, 2017 and the Prospectus filed with the SEC on October 13, 2017 in connection with our IPO were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading and omitted to state material facts required to be stated therein. The complaints seek unspecified money damages, other equitable relief and attorneys' fees and costs. While we believe these claims to be without merit, we cannot assure you that additional claims alleging the same or similar facts will not be filed. Any litigation could result in substantial costs and a diversion of management's attention and resources.

#### We rely on a single third-party manufacturer for the manufacturing of the ARTAS® System.

Evolve Manufacturing Technologies, Inc., or Evolve, assembles the ARTAS® System, and produces reusable procedure kits, disposable procedure kits, upgrade kits and spare kits used with the ARTAS® System. If the operations of Evolve are interrupted or if it is unable or unwilling to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill new customer orders, to provide kits required for use with existing ARTAS® Systems and to repair equipment at current customer sites. Any change to another contract manufacturer would likely entail significant delay, require us to devote substantial time and resources, and could involve a period in which our products could not be produced in a timely or consistently high-quality manner, any of which could harm our reputation and results of operations.

We have two master agreements and a component pricing agreement with Evolve for the supply of the ARTAS® System and consumable products, including reusable procedure kits, disposable procedure kits, upgrade kits and spare kits used with the ARTAS® System, pursuant to both of which we make purchases on a purchase order basis. The terms of these master agreements are substantially similar. The master agreement for the sale of ARTAS® Systems was effective beginning on April 1, 2016 and the master agreement for the sale of kits used with the ARTAS® System was effective beginning on March 1, 2016. Both agreements are effective for an initial term of two years and will continue to automatically renew for additional twelve-month periods, subject to either party's right to terminate the agreement upon 180 days advance notice during the initial term if our quarterly forecasted demand falls below 75% of our historical forecasted demand for the same period in the previous year or upon 120 days' advance notice after the initial term. We have an agreement with Evolve for the pricing of certain components at certain quantities, which requires a minimum purchase from us. Otherwise, without this agreement, Evolve is not required and may not be able or willing, to meet our future requirements at current prices, or at all. We recently amended this agreement to extend the maturity date until August 2018.

Additionally, while we do have agreements with some of our component suppliers, many of our component suppliers contract directly with Evolve and we have limited control over the components they supply or the timeliness by which they supply them. Evolve may be unable to acquire components at the quantities and prices at which we need them.

In addition, our reliance on Evolve involves a number of other risks, including, among other things, that:

- our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain compliance with regulatory requirements, which could negatively affect the safety or efficacy of our products, cause delays in shipments of our products, or require us to recall products previously delivered to customers;
- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;
- we may be subject to price fluctuations when a supply contract is renegotiated or if our existing contract is not renewed;
- Evolve may wish to discontinue manufacturing and supplying products to us for risk management reasons; and
- Evolve may encounter financial or other hardships unrelated to our demand for products, which could inhibit its ability to fulfill our orders and meet our requirements.

If any of these risks materialize, it could significantly increase our costs, our ability to generate net sales would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products, which could have a materially adverse effect on our business, financial condition and results of operations.



Furthermore, if we are required to change the manufacturer of a critical component of the ARTAS<sup>®</sup> System, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture the ARTAS<sup>®</sup> System in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of the ARTAS<sup>®</sup> System or could require that we modify the design of those systems. If the change in manufacturer results in a significant change to any product, a new 510(k) clearance from the FDA or similar international regulatory authorization may be necessary before we implement the change, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner.

We cannot assure you that we will be able to secure alternative equipment and materials and utilize such equipment and materials without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and components we require for the ARTAS® System, our reputation, business, financial condition and results of operations could be negatively impacted.

## If Evolve is unable to manufacture the ARTAS<sup>®</sup> System in high-quality commercial quantities successfully and consistently to meet demand, our growth will be limited.

To manufacture our ARTAS<sup>®</sup> System in the quantities that we believe will be required to meet anticipated market demand, Evolve will need to increase manufacturing capacity, which will involve significant challenges. In addition, the development of commercial-scale manufacturing capabilities will require us and Evolve to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturer may successfully complete any required increase to existing manufacturing processes in a timely manner, or at all.

If Evolve is unable to produce the ARTAS® System, reusable procedure kits, disposable procedure kits, upgrade kits and spare kits in sufficient quantities to meet anticipated customer demand, our revenue, business, and financial prospects would be harmed. The limited experience Evolve has in producing larger quantities of the ARTAS® System and kits may also result in quality issues, and possibly result in product recalls. Manufacturing delays related to quality control could harm our reputation and decrease our revenue. Any recall could be expensive and generate negative publicity, which could impair our ability to market the ARTAS® System and procedures and further affect our results of operations.

## If we are unable to manufacture our next generation ARTAS<sup>®</sup> System, called the ARTAS<sup>®</sup> iX System in high-quality commercial quantities successfully and consistently to meet demand, our growth will be limited, and our reputation could be harmed.

To manufacture our ARTAS<sup>®</sup> iX System in the quantities that we believe will be required to meet anticipated market demand, we will need to develop and maintain sufficient manufacturing capacity, which will involve significant challenges. Historically, we have not manufactured any of our other products (e.g. ARTAS<sup>®</sup> System) in-house or without the contract manufacturer involvement. We have not determined whether our ARTAS<sup>®</sup> iX System will be solely manufactured by us or by a third-party manufacturer. The development of commercial-scale manufacturing capabilities will require us or our contract manufacturer for ARTAS<sup>®</sup> iX System to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturer may successfully complete any required increase to existing manufacturing processes in a timely manner, or at all.

If we or our contract manufacturer are unable to produce the ARTAS® iX System, reusable procedure kits, disposable procedure kits, upgrade kits and spare kits in sufficient quantities to meet anticipated customer demand, our revenue, business, financial prospects, and reputation would be harmed. The limited experience we or our third-party manufacturer in producing the ARTAS® iX System and kits may also result in quality issues, and possibly result in product recalls. Manufacturing delays related to quality control could harm our reputation and decrease our revenue. Any recall could be expensive and generate negative publicity, which could impair our ability to market the ARTAS® iX System and procedures and further affect our results of operations.



## Evolve's manufacturing operations are dependent upon third-party suppliers and, in some cases, sole suppliers, for the majority of our components, subassemblies and materials, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

Evolve relies on several sole source suppliers, including Stäubli Corporation, FLIR Integrated Imaging Solutions Inc. and Preproduction Plastics Inc., for certain components of the ARTAS<sup>®</sup> System, reusable procedure kits, disposable procedure kits, upgrade kits, and spare kits. These sole suppliers, and any of our other suppliers, may be unwilling or unable to supply components of these systems to Evolve reliably and at the levels we anticipate or are required by the market. For us to be successful, our third-party manufacturer and its suppliers must be able to provide products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. An interruption in our commercial operations could occur if we or Evolve encounter delays or difficulties in securing these components, and if we cannot then obtain an acceptable substitute. If we are required to transition to new third-party suppliers for certain components of the ARTAS<sup>®</sup> System, we believe that there are only a few such suppliers that can supply the necessary components. A supply interruption, price fluctuation or an increase in demand beyond our current suppliers' capabilities could harm Evolve's ability to manufacture the ARTAS<sup>®</sup> System until new sources of supply are identified and qualified. In addition, the use of components or materials furnished by these alternative suppliers could require us to alter our operations.

Our reliance on these suppliers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

Where practicable, we are seeking, or intending to seek, second-source manufacturers for certain of our components. However, we cannot provide assurance that we will be successful in establishing second-source manufacturers or that the second-source manufacturers will be able to satisfy commercial demand for the ARTAS<sup>®</sup> System.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted. If we are unable to satisfy commercial demand for the ARTAS<sup>®</sup> System in a timely manner, our ability to generate revenue would be impaired and market acceptance of our products could be adversely affected.

## We forecast sales to determine requirements for components and materials used in the ARTAS® and ARTAS® iX System, reusable procedure kits, disposable procedure kits, upgrade kits and spare kits and if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.

We keep limited finished products on hand. To manage our operations, we forecast anticipated product orders and material requirements to predict our inventory needs and enter purchase orders based on these requirements. Several components of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems require significant order lead time. Our limited historical commercial experience and anticipated growth may not provide us with enough data to consistently and accurately predict future demand. If our business expands and our demand for components and materials increases beyond our estimates, our manufacturers and suppliers may be unable to meet our demand. In addition, if we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay, or prevent delivery of the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System and related products to our customers. In contrast, if we overestimate our requirements, we may have excess inventory, which would increase use of our working capital. Any of these occurrences would negatively affect our financial condition and the level of satisfaction our physician customers have with our business.

## Even though the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems are marketed to physicians, there exists a potential for misuse by the operator of the ARTAS<sup>®</sup> systems by physicians, non-physicians or individuals who are not sufficiently trained, which could harm our reputation and our business.

We and our independent distributors market and sell the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems to physicians. Under state law in the U.S., our physician customers can generally allow nurse practitioners, technicians, and other non-physicians to perform the ARTAS procedures under their direct supervision. Similarly, in markets outside of the U.S., physicians can allow non-physicians to perform the ARTAS procedures under their supervision. Although we and our distributors provide training on the use of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems, we do not supervise the procedures performed with the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems, nor can we be assured that direct physician supervision of procedures occurs according to our recommendations. The potential misuse of the ARTAS<sup>®</sup> iX System by physicians and non- physicians may result in adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

We and our distributors offer product training sessions, but neither we nor our distributors require purchasers or operators of our products to attend training sessions. The lack of required training for operators of our product and the use of our products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

### Product liability suits could be brought against us for defective design, labeling, material, or workmanship, or misuse of the ARTAS® or ARTAS® iX System, and could result in expensive and time-consuming litigation, payment of substantial damages, an increase in our insurance rates and substantial harm to our reputation.

If the ARTAS® System or ARTAS® iX System are defectively designed, manufactured, or labeled, contains defective components, or is misused, we may become subject to substantial and costly litigation by our physician customers or their patients. Misuse of the ARTAS® System or ARTAS® iX System or failure to adhere to operating guidelines can cause skin damage and underlying tissue damage and, if our operating guidelines are found to be inadequate, we may be subject to liability. Furthermore, if a patient is injured in an unexpected manner or suffers unanticipated adverse events after undergoing the ARTAS procedure, even if the procedure was performed in accordance with our operating guidelines, we may be subject to product liability claims. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems, or any future products;
- damage to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to physician customers, patients or clinical trial participants;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any future products.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could inhibit commercialization of the ARTAS® and ARTAS® iX Systems. As of September 30, 2018, we carry product liability insurance in the amount of \$4.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is more than the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

## Our ability to market the ARTAS® and ARTAS® iX Systems in the U.S. is limited to hair follicle dissection in males that have black or brown straight hair, and if we want to expand our marketing claims, we will need to obtain additional FDA clearances or approvals, which may not be granted.

We have FDA clearance to market the ARTAS® and ARTAS® iX Systems in the U.S. for dissecting hair follicles only from the scalp in men diagnosed with androgenic alopecia (AGA), also referred to as male pattern baldness, who have black or brown straight hair. This clearance restricts our ability to market or advertise the ARTAS® and ARTAS® iX Systems treatment for women or men who do not have black or brown straight hair, which could limit physician and patient adoption of the ARTAS® System. Developing and promoting new treatment indications and protocols for the ARTAS® and ARTAS® iX Systems are elements of our growth strategy, but we cannot predict when or if we will receive the clearances required to so implement those elements. In addition, we may be required to conduct additional clinical trials or studies to support our applications, which may be time-consuming and expensive, and may produce results that do not result in FDA clearances. If we do not obtain additional FDA clearances, our ability to promote the ARTAS® and ARTAS® iX Systems in the U.S. may be limited. Because we anticipate that sales in the U.S. will continue to be a significant portion of our business for the foreseeable future, ongoing restrictions on our ability to market the ARTAS® and ARTAS® iX Systems in the U.S. could harm our business and limit our revenue growth.

## The clinical trial process required to obtain regulatory clearances or approvals is lengthy and expensive with uncertain outcomes and could result in delays in new product introductions.

In order to obtain 510(k) clearance for the ARTAS® System, we were required to conduct a clinical trial, and we expect to conduct clinical trials in support of marketing authorization for future products and product enhancements. Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical trial process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. We, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks.

Successful results of pre-clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of our products. The data we collect from our pre-clinical studies and clinical trials may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance or approval to market our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the obtainment of the right to affix the CE Mark in the European Union; the submission to the FDA of an investigational device exemption, or IDE, application to commence a pivotal clinical trial for a new product; the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients in a timely manner or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed or terminated for a number of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product for use in clinical trials;
- obtaining institutional review board, or IRB, or ethics committees approval to conduct a clinical trial at each prospective site;

- recruiting and enrolling patients and maintaining their participation in clinical trials;
- having clinical sites observe trial protocol or continue to participate in a trial;
- addressing any patient safety concerns that arise during the course of a clinical trial;
- addressing any conflicts with new or existing laws or regulations; and
- adding a sufficient number of clinical trial sites.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be cleared or approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or suffer adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

We could also encounter delays if the FDA concluded that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of our marketing application by the FDA. Any such delay or rejection could prevent us from commercializing any of our products in development.

Furthermore, clinical trials may also be delayed because of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, the Data Safety Monitoring Board for such trial, any of our clinical trial sites with respect to that site, or other regulatory authorities due to several factors, including:

- failure to conduct the clinical trial in accordance with applicable regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- inability of a clinical investigator or clinical trial site to continue to participate in the clinical trial;
- unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using the product; and
- lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our products may be harmed and our ability to generate product revenue from these products will be delayed or not realized at all. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of the subject product.



## Our business could be adversely affected if we are unable to extend the cleared uses of the ARTAS® and ARTAS® iX Systems or successfully pursue the development, regulatory clearance or approval and commercialization of future products.

The ARTAS<sup>®</sup> System for hair follicle dissection, which has been cleared for use in the U.S. only for dissecting hair follicles from the scalp in men diagnosed with AGA who have black or brown straight hair, recipient site making for the follicle transplantation sites, in our ARTAS<sup>®</sup> iX System, and robotic implantation in which hair follicles are robotically transplanted, which recently has been approved for commercial marketing in the U.S., are our only products. Our business could be adversely affected if we are unable to extend the cleared uses of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems or successfully pursue the development, regulatory clearance or approval and commercialization of future products. In the future, we may also become dependent on other products that we may develop or acquire. The clinical and commercial success of our products will depend on several factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our nonclinical studies and clinical trials, which may be significantly slower or cost more than we anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the clearance or approval and commercialization of any future indications or products;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of any future indications or products;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our future approved products, if any;
- the timely receipt of necessary marketing approvals or clearances from the FDA and foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to any future products or additional approved indications, if any;
- acceptance by physicians and patients of the benefits, safety and efficacy of any future products, if approved or cleared, including relative to alternative and competing treatments;
- our ability to establish and enforce intellectual property rights in and to our products or any future indications or products; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

Even if regulatory approvals or clearances are obtained, we may never be able to successfully commercialize any future indications or products. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of any future products to continue our business.

#### Our loan and security agreement contains restrictions that limit our flexibility in operating our business.

In May 2018, we entered into a loan and security agreement with Solar Capital Ltd. and other lenders. We borrowed \$20.0 million under the loan and security agreement with Solar, the Solar Agreement. The Solar Agreement also contains various covenants that limit our ability to engage in specified types of transactions. Subject to limited exceptions, these covenants limit our ability, without Solar's consent, to, among other things:

- sell, lease, transfer, exclusively license or dispose of our assets;
- create, incur, assume or permit to exist additional indebtedness or liens, which may limit our ability to raise additional capital;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our capital stock;
- pay any cash dividend or make any other cash distribution or payment in respect of our capital stock more than \$150,000 in aggregate per calendar year;
- make specified investments (including loans and advances);
- make changes to certain key personnel including our President and Chief Executive Officer;
- merge, consolidate or liquidate; and
- enter into certain transactions with our affiliates.



In addition, the Solar Agreement contains certain covenants that require us to achieve certain revenue and liquidity thresholds. These covenants under the agreement require us to meet certain minimum liquidity and minimum revenue covenants, which, if we fail to maintain or achieve, will result in a default and require us to repay all outstanding principal amounts and accrued interest repay all amounts outstanding. In the event of a default, if we are unable to repay all outstanding amounts Solar may foreclose on the collateral granted to it to collateralize such indebtedness and will significantly affect our ability to operate our business.

### We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of September 30, 2018, we had 108 employees, with 49 employees in sales and marketing, 18 employees in customer support, 22 employees in research and development, including clinical, regulatory and certain quality control functions, five employees in manufacturing operations and 14 employees in general management and administration. We will need to continue to expand our sales, marketing, managerial, operational, finance and administrative resources for the ongoing commercialization of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems and continue our development activities of any future products.

Our existing management, personnel, systems and facilities may not be adequate to support our future growth. Our need to effectively execute our growth strategy requires that we:

- identify, recruit, retain, incentivize and integrate additional employees, including sales personnel;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

### If we fail to attract and retain senior management and key personnel, we may be unable to successfully grow our business.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and other personnel. We are highly dependent upon our senior management, particularly our President and Chief Executive Officer, our management team and other key personnel. The loss of services of any of these individuals could delay or prevent enhancement of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems, the expansion of the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems to new indications, or the development of any future products. Although we have entered into employment agreements with our senior management team, these agreements do not provide for a fixed term of service.

Competition for qualified personnel in the medical device field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel and we may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

## Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our consolidated financial statements may not be directly comparable to other public companies.

Pursuant to the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. Because we have elected to take advantage of this provision of the JOBS Act, our consolidated financial statements and the reported results of operations contained therein may not be directly comparable to other public companies.

# We incur significant costs because of operating as a public company, and our management devotes substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Market and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will continue to increase our legal and financial compliance costs and will make some activities

more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, our independent registered public accounting firm will be engaged to provide an attestation report on the effectiveness of our internal control over financial reporting. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior September 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three- year period.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the market price of our stock to decline. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, as amended. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm to our business and cause the market price of our common stock to decline.

### Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. In particular, the ARTAS procedures will not receive coverage and reimbursement and, as a result, demand for this product will be tied to discretionary spending levels of our targeted patient population. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including weakened demand for the ARTAS® and ARTAS® iX Systems, ARTAS procedures or any future products, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the economic climate and financial market conditions could adversely impact our business.

## We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in San Jose, California, which in the past has experienced both severe earthquakes and floods. We do not carry earthquake or flood insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our ARTAS enterprise system, enterprise financial systems and records, manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses because of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake or flood insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

## Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a few third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

# Our employees and independent contractors, including consultants, manufacturers, distributors, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including consultants, manufacturers, distributors, commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or



government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### **Risks Related to Intellectual Property**

# We may in the future become involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.

Our success depends in part on not infringing the patents or violating the other proprietary rights of others. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical industry. Whether merited or not, it is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, sell, and/or export our products. Our competitors may have one or more patents for which they can threaten and/or initiate patent infringement actions against us and/or any of our third-party suppliers. Our ability to defend ourselves and/or our third-party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. Furthermore, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages, and/or attorneys' fees. From time to time and in the ordinary course of business, we may develop noninfringement and/or invalidity positions with respect to third-party patents, which may or not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

We may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in several patent infringement actions, the outcomes of which may not be known for prolonged periods of time.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved, and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- find non-infringing substitute products, which could be costly and create significant delay due to the need for FDA regulatory clearance;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; and/or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.



From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Furthermore, as the number of participants in the robotic hair restoration surgery market grows, the possibility of intellectual property infringement claims against us increases.

In addition, we may indemnify our customers, suppliers and international distributors against claims relating to the infringement of the intellectual property rights of third parties relating to our products, methods, and/or manufacturing processes. Third parties may assert infringement claims against our customers, suppliers, or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, suppliers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers, or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, or our suppliers may be forced to stop providing us with products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the United Stated Patent and Trademark Office, or USPTO, or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

### Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the U.S. patent system from a "first- to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, such as *Association for Molecular Pathology v. Myriad Genetics, Inc.* (Myriad I), *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

## Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or like our own, which would have a material adverse effect on our business.

### We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, furthermore, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or like our products, and our competitive position in the international market would be harmed.

## We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our products.

We are dependent on licenses from HSC Development LLC and James A. Harris, M.D. for some of our key technologies. We do not own the patents that underlie these licenses. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of those licenses. In some cases, we do not control the prosecution, maintenance, or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties. These patents and patent applications are not written by us or our attorneys, and we did not have control over the drafting and prosecution. Our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

## Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.



## We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or functionalities that are essential to our products, if such technologies or functionalities are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

## If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We hold various trademarks for our products and services. Many of these trademarks are registered with the USPTO and corresponding government agencies in numerous other countries, and we hold trademark applications for these marks in a number of foreign countries, although the laws of many countries may not protect our trademark rights to the same extent as the laws of the U.S. Actions taken by us to establish and protect our trademarks might not prevent imitation of our products or services, infringement of our trademark rights by unauthorized parties or other challenges to our ownership or validity of our trademarks. If any of these events occur, we may not be able to protect and enforce our rights in these trademarks, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, unauthorized third-parties may have registered trademarks similar and identical to our trademarks in foreign jurisdictions or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use such trademarks to market our products and services in those countries. If we are unable to register our trademarks, enforce our trademarks, or bar a third-party from registering or using a trademark, our ability to establish name recognition based on our trademarks and compete effectively in our markets of interest may be adversely affected.

### If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our consultants and vendors, or our former or current employees. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to enforce trade secret protection.

Furthermore, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technology. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.



### **Risks Related to Government Regulation**

## The ARTAS® and ARTAS® iX Systems and our operations are subject to extensive government regulation and oversight both in the U.S. and abroad, and our failure to comply with applicable requirements could harm our business.

The ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems and related products and services are regulated as medical devices subject to extensive regulation in the U.S. and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- premarket clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

In the U.S., before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (preamendments device), a device that was originally on the U.S. market pursuant to an approved premarket approval, or PMA, application and later downclassified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance.

Both the PMA approval and the 510(k)-clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k)-clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires, and the 510(k)-clearance process sometimes requires, the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business.



In the U.S., we have obtained 510(k) premarket clearance from the FDA to market the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX System for harvesting hair follicles from the scalp in men diagnosed with AGA who have black or brown straight hair. An element of our strategy is to continue to add new functionalities and enhance existing functionalities to the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems. We expect that certain modifications we may make to the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation, but its ultimate implementation remains unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may fail to obtain any marketing clearances or approvals, lose any marketing clearance or approval that we may have obtained, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of several Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies including the FDA, requiring that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency must identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The failure to comply with applicable regulations could jeopardize our ability to sell the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems, and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;



- total or partial suspension of production;
- refusal to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our product or products; and
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and results of operations.

## We are subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer.

We must maintain regulatory approval in foreign jurisdictions in which we plan to market and sell the ARTAS® System.

In the European Economic Area or EEA, manufacturers of medical devices need to comply with the Essential Requirements laid down in Annex II to the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE mark to medical devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark, manufacturers of medical devices must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessment procedure, the Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure to affix the CE mark to its medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. With respect to active implantable medical devices or Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation.



The Medical Devices Regulation will however only become applicable three years after publication. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an impact on the way we conduct our business in the EEA.

## We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and, in the European Union (EU) and shortly in the European Economic Area (EEA), Regulation 2016/679, known as the General Data Protection Regulation, or GDPR. New global privacy rules are being enacted and existing ones are being updated and strengthened. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, whether by us, one of our business associates or another third-party, could have a material adverse effect on our business, reputation, financial condition and results of operations, including but not limited to: material fines and penalties; damages; litigation; consent orders; and injunctive relief.

Furthermore, these rules are constantly changing; for example, the GDPR came into effect in May this year reforming the European regime. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the higher of 20,000,000 Euros or up to 4% of our total worldwide annual turnover in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could have material adverse effect on our reputation and business.

We are also subject to evolving European laws on data export and electronic marketing. The rules on data export will apply when we transfer personal data to group companies or third parties outside of the EEA. For example, in 2015, the Court of Justice of the EU ruled that the U.S.-EU Safe Harbor framework, one compliance method by which companies could transfer personal data regarding citizens of the EU to the United States, was invalid and could no longer be relied upon. The U.S.-EU Safe Harbor framework was replaced with the U.S.-EU Privacy Shield framework, which is now under review and there is currently litigation challenging another EU mechanism for adequate data transfers, the standard contractual clauses. It is uncertain whether the Privacy Shield framework and/or the standard contractual clauses will be similarly invalidated by the European courts. These changes may require us to find alternative bases for the compliant transfer of personal data from the EEA to the U.S and we are monitoring developments in this area. The EU is also in the process of replacing the e-Privacy Directive with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each European member state, without the need for further enactment. The current draft of the e-Privacy Regulation retains strict op-in for electronic marketing and the penalties for contravention have significantly increased with fining powers to the same levels as GDPR (i.e. the greater of 20,000,000 Euros or 4% of total global annual revenue).



# Modifications to the ARTAS® System or ARTAS® iX System and any future products that receive 510(k) clearances may require new 510(k) clearances or PMA approvals, and if we make such modifications without seeking new clearances or approvals, the FDA may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

The ARTAS® and ARTAS® iX Systems have received 510(k) clearances from the FDA. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to the ARTAS® System in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make similar modifications or add additional functionalities in the future that we believe do not require a new 510(k) clearance or approval of a PMA. The FDA has issued a guidance document intended to assist manufacturers in determining whether modifications to cleared devices require the submission of a new 510(k), and such guidance has come under scrutiny in recent years, the practical impact of which is unclear. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to or previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, which could require us to redesign our products, conduct clinical trials to support any modifications, and pay significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required clearances or approvals would adversely affect our abil

## We are subject to restrictions on the indications for which we are permitted to market our products, and any violation of those restrictions, or marketing of the ARTAS® System or ARTAS® iX System for off-label uses, could subject us to regulatory enforcement action.

The FDA's 510(k) clearance for the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems specifies the cleared indication for use of the product is dissecting hair follicles from the scalp in men diagnosed with AGA who have black or brown straight hair. The ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems are intended to assist physicians in identifying and extracting hair follicular units from the scalp during hair transplantation.

We train our marketing and direct sales force to not promote the ARTAS® System or ARTAS® iX System for uses outside of the FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a physician from using the ARTAS® System or ARTAS® iX System off-label when, in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use the ARTAS® System or ARTAS® iX System off-label. Furthermore, the use of the ARTAS® System or ARTAS® iX System for indications other than those cleared by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including, among other things, the issuance or imposition of an untitled letter, a warning letter, injunction, seizure, refusal to issue new 510(k)s or PMAs, withdrawal of existing 510(k)s or PMAs, refusal to grant export approvals, and civil fines or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

# The ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System, or a recall of the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations. The FDA's medical device reporting regulations require us to report to the FDA when we receive or become aware of information that reasonably suggests that the ARTAS® System or ARTAS® iX System may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable

adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the ARTAS® System ARTAS® iX System, as the case may be. If we fail to comply with our reporting obligations, the FDA could act, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or if a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur because of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. We cannot assure you that product defects or other errors will not occur in the future. Recalls involving the ARTAS® System or ARTAS® iX System could be particularly harmful to our business, financial condition and results of operations because it is our only product.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

## If we or our distributors do not obtain and maintain international regulatory registrations or approvals for the ARTAS® System, our ability to market and sell the ARTAS® System outside of the U.S. will be diminished.

Sale of the ARTAS<sup>®</sup> System outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the U.S. While the regulations of some countries may not impose barriers to marketing and selling the ARTAS<sup>®</sup> System or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals in each country in which we plan to market the ARTAS<sup>®</sup> System or that we will be able to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations, clearances, or approvals may significantly differ from FDA requirements. If we modify the ARTAS<sup>®</sup> System, we or our distributors may need to apply for additional regulatory approvals or other authorizations before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country, which could harm our business.

Regulatory clearance or approval by the FDA does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

## We must manufacture our products in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of the ARTAS® and ARTAS® iX Systems and related products must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. The ARTAS® and ARTAS® iX Systems are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

We cannot guarantee that we or any subcontractors will take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with the ARTAS<sup>®</sup> System or ARTAS<sup>®</sup> iX System, or manufacturing processes could result in, among other things:

- warning letters or untitled letters;
- fines, injunctions or civil penalties;
- suspension or withdrawal of approvals or clearances;
- seizures or recalls of our products;
- total or partial suspension of production or distribution;
- administrative or judicially imposed sanctions;
- the FDA's refusal to grant pending or future clearances or approvals for our products;
- clinical holds;
- refusal to permit the import or export of our products; and
- criminal prosecution to us or our employees.

Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

## We may be subject to various federal and state laws pertaining to healthcare fraud and abuse, and any violations by us of such laws could result in fines or other penalties.

While procedures utilizing the ARTAS<sup>®</sup> and ARTAS<sup>®</sup> iX Systems are not currently covered or reimbursed by any third-party payor, our commercial, research and other financial relationships with healthcare providers and others may be subject to various federal and state laws intended to prevent healthcare fraud and abuse. Such laws include the U.S. federal Anti-Kickback Statute and similar laws that apply to state healthcare programs, private payors and self-pay patients; the U.S. federal civil and criminal false claims laws, such as the civil False Claims Act, and civil monetary penalties laws; state and federal data privacy and security laws and regulations; state and federal physician payment transparency laws; and state and federal consumer protection and unfair competition laws. Further, these laws may impact any sales, marketing and education programs we currently have or may develop in the future and the way we implement any of those programs. Penalties for violations of these laws can include exclusion from federal healthcare programs and substantial civil and criminal penalties.

### Recently enacted and future legislation may increase the difficulty and cost for us to sell our products.

In the U.S. and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, restrict or regulate post-approval activities and affect our ability to profitably sell our products. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted. The Affordable Care Act, imposed, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the U.S., which, due to subsequent legislative amendments, has been suspended from January 1, 2016 to December 31, 2017, and, absent further legislative action, will be reinstated starting January 1, 2018. It is uncertain the extent to which any challenges, amendments and attempts to repeal and replace the Affordable Care Act in the future may impact

our business or financial condition. We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may potentially increase our costs to sell our product and decrease our profitability.

## Recent U.S. tax legislation and future changes to applicable U.S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

We are subject to income and other taxes in the U.S. and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a more generally territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

### **Risks Related to Our Common Stock**

### Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The market price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section and others such as:

- the continued growth in demand for the ARTAS® Systems and ARTAS procedures;
- our commercialization, marketing and manufacturing capabilities;
- the continuing productivity and effectiveness of our commercial infrastructure and salesforce;
- our financial performance;
- our intentions and our ability to establish collaborations and/or partnerships;
- the timing or likelihood of regulatory filings and approvals for the ARTAS<sup>®</sup> Systems for expanded indications and functionality;
- our commercialization, marketing and manufacturing capabilities;
- our expectations regarding the potential market size and the size of the patient populations for the ARTAS® Systems;
- the effective pricing of the ARTAS® Systems, services and procedures;
- the implementation of our business model and strategic plans for our business and technology;
- the scope of protection we can establish and maintain for intellectual property rights covering the ARTAS® Systems, along with any product enhancements;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance; and
- developments and projections relating to our competitors and our industry, including competing therapies and procedures.

In addition, the stock markets in general, and the markets for medical device and aesthetic stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the market price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. Recently, several securities class action complaints have been filed against us, certain of our current and former executive officers and directors, certain of our investors and certain underwriters in our IPO. These complaints allege violations of Sections 11, 12(a)(2) and 15 of the Securities Act due to allegedly false and misleading statements made in connection with our IPO. While we believe that these lawsuits are without merit and we intend to vigorously defend against these claims, we could incur substantial costs in defending these lawsuits and the attention of our management could be diverted from the operation of our business. Further, if more of our stockholders were to bring additional lawsuits on similar or unrelated grounds, we could incur substantial costs defending these additional lawsuits and the attention of our business.

### An active market for our common stock may not be maintained.

Prior to our IPO, there had been no public market for shares of our common stock. Our stock only recently began trading on The Nasdaq Global Market, but we can provide no assurance that we will be able to maintain an active trading market on The Nasdaq Global Market or any other exchange in the future. If an active market for our common stock does not develop or is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

### If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have very limited research coverage by securities and industry analysts. If no additional securities or industry analysts commence coverage of us, the market price or trading volume of our stock could be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

### We are an "emerging growth company" and because of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, stockholder approval of any golden parachute payments not previously approved and delayed adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior September 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

### If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

## Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the number of shares outstanding as of September 30, 2018, as adjusted for the consummation of our IPO in October 2017, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 37.8% of our voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

### Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as



amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future and/or subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

## Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to act, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be
  acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the
  acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

## Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to

the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that
  person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right
  to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

# Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

### We do not intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not intend to pay any cash dividends on our common stock for the foreseeable future. We intend to invest our future earnings, if any, to fund our growth. Furthermore, pursuant to the loan and the security agreement between us and Solar, we are not permitted to pay cash dividends more than \$150,000 in aggregate per fiscal year without its prior written consent. Therefore, our stockholders are not likely to receive any dividends on their common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our stockholders have purchased it.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

### Unregistered Sales of Equity Securities

There were no unregistered securities issued and sold during the quarter ended September 30, 2018.

### Use of Proceeds

On August 16, 2018, we closed our public follow-on offering, in which we sold 11,500,000 shares of our common stock at a price to the public of \$1.50 per share. The aggregate proceeds for the offering was approximately \$17.2 million. The offer and sale of all the shares in the follow-on offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-226598). After deducting underwriting discounts and commissions of approximately \$1.2 million and other offering expenses of approximately \$0.4 million, the net proceeds from the offering was approximately \$15.6 million. There has been no material change in the planned use of proceeds from the follow-on offering as described in the final prospectus filed with the SEC on August 13, 2018 pursuant to Rule 424(b) under the Securities Act of 1933, as amended.



On October 11, 2017, our Registration Statement on Form S-1 (File No. 333-220303) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we completed our IPO of 3,897,910 shares of our common stock (inclusive of 322,910 shares of common stock from the subsequent exercise of the underwriters' over-allotment option) at a price of \$7.00 per share. After deducing underwriting discounts and commissions of approximately \$1.9 million and offering expenses of approximately \$3.3 million, the net proceeds from the IPO was approximately \$22.1 million. There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus dated October 11, 2017 and filed with the SEC on October 13, 2017 pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC on October 13, 2017 pursuant to Rule 424(b).

Issuer Purchases of Equity Securities

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES** 

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

### **ITEM 5. OTHER INFORMATION**

None.

### **ITEM 6. EXHIBITS**

Exhibit Number	Description	Form	Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation	8-K	10-17-17	3.1	
		-			
3.2	Amended and Restated Bylaws	8-K	10-17-17	3.2	
4.1	Reference is made to exhibits <u>3.1</u> through <u>3.2</u> .				
4.2	Form of Common Stock Certificate	S-1/A	9-18-17	4.2	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a)				Х
	and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted				
	Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a)				Х
	and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted				
	Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C.				Х
	Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley				
	<u>Act of 2002.</u>				
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section				Х
	1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of				
	<u>2002.</u>				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				
			E 10.01		

The certification attached as Exhibit 32.1 and Exhibit 32.2 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Restoration Robotics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

### 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 thereunto duly authorized.

Date: November 5, 2018

Date: November 5, 2018

Company Name

By: /s/ RYAN RHODES
Ryan Rhodes
President, Chief Executive Officer

By: /s/ MARK L. HAIR Mark L. Hair Chief Financial Officer

### CERTIFICATION OF PRESIDENT AND CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan Rhodes, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Restoration Robotics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2018

By:

/s/ RYAN RHODES

Name: Ryan Rhodes President, Chief Executive Officer (Principal Executive Officer)

### CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark L. Hair, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Restoration Robotics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2018

By:

/s/ MARK L. HAIR

Name: Mark L. Hair Chief Financial Officer (Principal Financial Officer)

### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Restoration Robotics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 5, 2018

Ву:

/s/ RYAN RHODES Name: Ryan Rhodes President, Chief Executive Officer (Principal Executive Officer)

### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Restoration Robotics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 5, 2018

Ву:

/s/ MARK L. HAIR Name: Mark L. Hair Chief Financial Officer (Principal Financial Officer)