UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2020

o **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 000-28440

ENDOLOGIX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**68-0328265**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

2 Musick, Irvine, California 92618
(Address of principal executive offices)
(949) 595-7200
(Registrant's telephone number, including area code)

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 x No o

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 x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a 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	o	Accelerated filer	x
Non-accelerated filer	o	Smaller reporting company	x
		Emerging growth company	o

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. o

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ELGX	The Nasdaq Stock Market, LLC

On May 18, 2020, there were 19,171,650 shares outstanding of the registrant's only class of common stock.

ENDOLOGIX, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE THREE MONTHS ENDED MARCH 31, 2020

TABLE OF CONTENTS

Items 2 through 5 of Part II have been omitted because they are not applicable with respect to the Company and/or the current reporting period.

Part I. Financial Information

ENDOLOGIX, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and par value amounts)
(Unaudited)

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 40,854	$ 41,560
Restricted cash	1,381	1,200
Accounts receivable, net of allowance for doubtful accounts of $1,596 and $1,317, respectively	18,951	22,392
Other receivables	298	282
Inventories	24,486	26,405
Prepaid expenses and other current assets	2,548	1,864
Total current assets	$ 88,518	$ 93,703
Property and equipment, net	12,473	13,152
Goodwill	120,783	120,814
Other intangible assets, net	72,086	72,603
Deposits and other assets	786	1,124
Operating lease right-of-use assets	5,707	5,768
Total assets	$ 300,353	$ 307,164
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,464	$ 14,024
Accrued payroll	21,870	18,232
Accrued expenses and other current liabilities	16,443	12,931
Current portion of debt	167,861	10,606
Revolving line of credit	10,519	—
Total current liabilities	$ 229,157	$ 55,793
Deferred income taxes	150	150
Operating lease liabilities	11,376	11,621
Derivative liabilities	—	940
Other liabilities	1,866	2,244
Contingently issuable common stock	200	500
Debt	4,281	172,060
Total liabilities	$ 247,030	$ 243,308
Commitments and contingencies		
Stockholders' equity:		
Series DF-1 convertible preferred stock, $0.001 par value, 1,150,000 shares authorized, 14,649 shares issued and outstanding	—	—
Common stock, $0.001 par value, 170,000,000 shares authorized, 19,215,059 and 18,190,054 shares issued, respectively, and 19,097,506 and 18,098,464 shares outstanding, respectively	19	18
Treasury stock, at cost, 117,553 and 91,590 shares, respectively	(4,271)	(4,235)
Additional paid-in capital	737,599	730,729
Accumulated deficit	(682,588)	(664,472)
Accumulated other comprehensive income	2,564	1,816
Total stockholders' equity	$ 53,323	$ 63,856
Total liabilities and stockholders' equity	$ 300,353	$ 307,164

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

ENDOLOGIX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2020	2019
Revenue	$ 28,510	$ 35,606
Cost of goods sold	13,378	12,407
Gross profit	15,132	23,199
Operating expenses:		
Research and development	3,536	4,787
Clinical and regulatory affairs	3,165	3,785
Marketing and sales	14,496	16,786
General and administrative	10,119	9,416
Restructuring costs	—	419
Total operating expenses	31,316	35,193
Loss from operations	(16,184)	(11,994)
Other income (expense):		
Interest expense	(10,527)	(8,490)
Other income (expense), net	(1,122)	318
Change in fair value of contingent consideration related to acquisition	300	200
Change in fair value of derivative liabilities	10,175	(2,023)
Loss on debt extinguishment	(730)	—
Total other expense, net	(1,904)	(9,995)
Net loss before income taxes	(18,088)	(21,989)
Income tax expense	(28)	(39)
Net loss	$ (18,116)	$ (22,028)
Comprehensive loss, net of taxes:		
Net loss	(18,116)	(22,028)
Other comprehensive income (loss) foreign currency translation	748	(598)
Comprehensive loss	$ (17,368)	$ (22,626)
Basic and diluted net loss per share	$ (0.90)	$ (2.12)
Shares used in computing basic and diluted net loss per share	20,067	10,374

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

ENDOLOGIX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (18,116)	$ (22,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bad debt expense	438	(126)
Depreciation and amortization	1,192	1,735
Stock-based compensation	1,733	2,361
Change in fair value of derivative liabilities	(10,175)	2,023
Change in fair value of contingent consideration related to acquisition	(300)	(200)
Accretion of interest and amortization of deferred financing costs	5,202	3,554
Payable in kind interest expense on term loan facility	2,040	1,943
Non-cash foreign exchange loss	1,141	(400)
Loss on debt extinguishment	730	—
Non-cash lease expense	48	53
Changes in operating assets and liabilities:		
Accounts receivable and other receivables	2,860	(5,253)
Inventories	1,826	112
Prepaid expenses and other current assets	(409)	(2,367)
Accounts payable	(1,440)	5,378
Accrued payroll	3,676	(1,438)
Accrued expenses and other liabilities	232	995
Net cash used in operating activities	(9,322)	(13,658)
Cash flows from investing activities:		
Purchases of property and equipment	(100)	(107)
Net cash used in investing activities	(100)	(107)
Cash flows from financing activities:		
Deferred financing costs	(1,379)	—
Net proceeds from revolving line of credit	10,519	—
Minimum tax withholding paid on behalf of employees for stock-based compensation	(36)	(2)
Net cash provided by financing activities	$ 9,104	$ (2)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(207)	(68)
Net increase (decrease) in cash, cash equivalents and restricted cash	(525)	(13,835)
Cash, cash equivalents and restricted cash, beginning of period	42,760	24,731
Total cash, cash equivalents and restricted cash, end of period	$ 42,235	$ 10,896
Reconciliation of cash, cash equivalents and restricted cash to the Condensed Consolidated Balance Sheets:		
Cash and cash equivalents	$ 40,854	$ 9,696
Restricted cash	1,381	1,200
Total cash, cash equivalents and restricted cash	$ 42,235	$ 10,896

ENDOLOGIX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,361	$ 2,065
Cash paid for income taxes	94	88
Cash paid for amounts included in the measurement of operating lease liabilities	$ 874	$ 849
Non-cash investing and financing activities:		
Acquisition of property and equipment included in accounts payable	$ —	$ 59
Fair value of embedded derivative issued in connection with loan agreements (Note 6)	$ 12,016	$ —
Fair value of common and preferred stock issued in connection with loan agreements	$ 2,000	$ —

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

ENDOLOGIX, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

(Unaudited)

Three Months Ended March 31, 2020

	Series DF-1 Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Issued Shares	Par Value	Issued Shares	Par Value					
Balance at December 31, 2019	—	—	**18,190**	**$ 18**	**$ 730,729**	**$ (664,472)**	**$ (4,235)**	**$ 1,816**	**$ 63,856**
Treasury shares purchased	—	—	26	—	—	—	(36)	—	(36)
Deerfield warrants	—	—	—	—	(375)	—	—	—	(375)
Equity conversion option	—	—	—	—	3,566	—	—	—	3,566
Stock-based compensation expense	—	—	—	—	969	—	—	—	969
Issuance of restricted stock	—	—	49	—	—	—	—	—	—
Restricted stock expense	—	—	—	—	764	—	—	—	764
Issuance of common stock	—	—	950	1	786	—	—	—	787
Issuance of Series DF-1 Preferred Stock	15	—	—	—	1,213	—	—	—	1,213
Debt issuance costs allocated to equity	—	—	—	—	(53)	—	—	—	(53)
Net loss	—	—	—	—	—	(18,116)	—	—	(18,116)
Other comprehensive income	—	—	—	—	—	—	—	748	748
Balance at March 31, 2020	**15**	**—**	**19,215**	**$ 19**	**$ 737,599**	**$ (682,588)**	**$ (4,271)**	**$ 2,564**	**$ 53,323**

Three Months Ended March 31, 2019

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Issued Shares	Par Value					
Balance at December 31, 2018	**10,388**	**$ 10**	**$ 640,789**	**$ (599,715)**	**$ (4,026)**	**$ 2,588**	**$ 39,646**
Treasury stock purchased	—	—	—	—	(1)	—	(1)
Stock-based compensation expense	—	—	1,512	—	—	—	1,512
Issuance of restricted stock	3	—	—	—	—	—	—
Restricted stock expense	—	—	849	—	—	—	849
Net loss	—	—	—	(22,028)	—	—	(22,028)
Other comprehensive income	—	—	—	—	—	(598)	(598)
Balance at March 31, 2019	**10,391**	**$ 10**	**$ 643,150**	**$ (621,743)**	**$ (4,027)**	**$ 1,990**	**$ 19,380**

1. Description of Business, Basis of Presentation, and Operating Segment

(a) Description of Business

Endologix®, Inc. (the "Company") is a Delaware corporation with corporate headquarters located in Irvine, California and production facilities located in Irvine, California and Santa Rosa, California. The Company develops, manufactures, markets and sells innovative medical devices for the treatment of aortic disorders. The Company's products are intended for the minimally-invasive endovascular treatment of abdominal aortic aneurysms ("AAA"). The Company's AAA products are built on one of two platforms: (i) traditional minimally-invasive endovascular aneurysm repair ("EVAR"); or (ii) endovascular aneurysm sealing ("EVAS"), the Company's innovative solution for sealing the aneurysm sac while maintaining blood flow. The Company's current EVAR products include the AFX® Endovascular AAA System, the VELA® Proximal Endograft and the Ovation® Abdominal Stent Graft System. The Company's current EVAS product is the Nellix® Endovascular Aneurysm Sealing System (the "Nellix EVAS System"). The Company derives all of its reported revenue from sales of its EVAR and EVAS products (including extensions and accessories) to hospitals and third party distributors.

(b) Basis of Presentation

The accompanying Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") and with the rules and regulations of the United States Securities and Exchange Commission ("SEC"). These financial statements include the financial position, results of operations and cash flows of the Company, including its subsidiaries, all of which are wholly-owned. All inter-company accounts and transactions have been eliminated in consolidation. For the three months ended March 31, 2020 and 2019, there were no related party transactions.

The Company adopted Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, Presentation of Financial Statements - (Subtopic 205-40) effective December 31, 2016, which requires the Company to make certain disclosures if it concludes that there is substantial doubt about the entity's ability to continue as a going concern within 12 months from the date of the issuance of these financial statements. The Company has a history of recurring losses from operations, recurring cash flow losses, and a net capital deficiency. Further, during the three months ended March 31, 2020, the COVID-19 pandemic had a negative impact on the Company's financial results and business operations, and the Company expects that financial results and business operations will continue to be negatively impacted by the pandemic. As a result, the Company believes that its existing liquidity will not be sufficient to meet anticipated cash needs for at least the next 12 months from the issuance date of these financial statements, thereby raising substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements included herein have been prepared on a going concern basis, which contemplates continuity of operations and the realization of assets and the repayment of liabilities in the ordinary course of business. The Company has not made any adjustments to the accompanying consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its business plan. If the Company is unable to generate sufficient revenue from its existing business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern, the Company is in default under the Facility Agreement and Credit Agreement with its lender, Deerfield. We have entered into forbearance agreements with Deerfield which provide that Deerfield will not exercise its default rights under the Facility Agreements until June 15, 2020 or earlier upon certain conditions. If Deerfield were to exercise its default rights, such default would result in a cross default under the Company's 5.00% Notes and 2020 5.00% Voluntary Notes. If Deerfield were to exercise its default rights, other lenders may then declare a default and the Company may be unable to repay the amounts owed without raising additional capital. If the Company is unable to repay the amounts owed, it may be forced to declare bankruptcy. Therefore, the entire amount of borrowings of $135.6 million from Deerfield and the $32.1 million 5% Notes and 2020 5.00% Voluntary Notes as at March 31, 2020 have been classified as current in these financial statements. Further, the Company would be required to pay exit fees totaling $11.1 million under the Facility Agreement and the remaining $0.1 million commitment fee under the Credit Agreement. Deerfield has not declared a default.

The interim financial data as of March 31, 2020 is unaudited and is not necessarily indicative of the results for a full year. In the opinion of the Company's management, the interim data includes normal and recurring adjustments necessary for a fair presentation of the Company's financial results for the three months ended March 31, 2020. Certain information and disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements.

The accompanying Condensed Consolidated Financial Statements should be read in conjunction with the Company's audited Consolidated Financial Statements and Notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 11, 2020 (the "Annual Report").

(c) Operating Segment

The Company has one operating and reporting segment that is focused exclusively on the development, manufacture, marketing and sale of EVAR and EVAS products for the treatment of aortic disorders. For the three months ended March 31, 2020, all of the Company's revenue and related expenses were solely attributable to these activities. Substantially all of the Company's long-lived assets are located in the United States.

2. Use of Estimates and Summary of Significant Accounting Policies

(a) Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenue and expenses, and the related disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the periods presented. Management evaluates its estimates on an ongoing basis, including those related to: (i) collectibility of customer accounts; (ii) whether the cost of inventories can be recovered; (iii) the value of goodwill and intangible assets; (iv) realization of tax assets and estimates of tax liabilities; (v) likelihood of payment and the value of contingent liabilities; and (vi) the potential outcome of litigation. Such estimates are based on management's judgment which takes into account historical experience and various assumptions. Nonetheless, actual results may differ from management's estimates.

(b) Summary of Significant Accounting Policies

For a complete summary of the Company's significant accounting policies, please refer to Note 2, "Summary of Significant Accounting Policies," in Part II, Item 8, of the Annual Report. Except as discussed below, there have been no other material changes to the Company's significant accounting policies during the three months ended March 31, 2020.

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

3. Balance Sheet Account Detail

(a) Property and Equipment

Property and equipment consisted of the following:

	March 31, 2020	December 31, 2019
Production equipment, molds and office furniture	$ 10,919	$ 10,844
Computer hardware and software	7,895	7,897
Leasehold improvements	15,594	15,594
Construction in progress (software and related implementation, production equipment and leasehold improvements)	694	795
Property and equipment, at cost	35,102	35,130
Accumulated depreciation	(22,629)	(21,978)
Property and equipment, net	$ 12,473	$ 13,152

Depreciation expense for property and equipment for the three months ended March 31, 2020 and 2019 was $0.7 million and $0.9 million, respectively.

(b) Inventories

Inventories consisted of the following:

	March 31, 2020	December 31, 2019
Raw materials	$ 5,165	$ 5,362
Work-in-process	4,463	4,132
Finished goods	14,858	16,911
Total Inventories	$ 24,486	$ 26,405

(c) Goodwill and Other Intangible Assets

The change in the carrying amount of goodwill for the three months ended March 31, 2020 was as follows:

Balance at December 31, 2019	$ 120,814
Foreign currency translation adjustment	(31)
Balance at March 31, 2020	$ 120,783

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

Other intangible assets consisted of the following:

	March 31, 2020			December 31, 2019		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Indefinite-lived intangible assets:						
Trademarks and trade names	$ 2,708	N/A	$ 2,708	$ 2,708	N/A	$ 2,708
In-process research and development	$ 11,200	N/A	11,200	11,200	N/A	11,200
Total indefinite-lived intangible assets	13,908		13,908	13,908		13,908
Finite-lived intangible assets:						
Developed technology	67,600	(13,797)	53,803	67,600	(13,467)	54,133
Customer relationships	7,500	(3,125)	4,375	7,500	(2,938)	4,562
Total finite-lived intangible assets	75,100	(16,922)	58,178	75,100	(16,405)	58,695
Other intangible assets, net	$ 89,008	$ (16,922)	$ 72,086	$ 89,008	$ (16,405)	$ 72,603

Amortization expense for intangible assets for the three months ended March 31, 2020 and 2019 was $0.5 million and $0.9 million, respectively.

Estimated amortization expense for the 5 succeeding years and thereafter is as follows:

Remainder of 2020	$ 2,444
2021	3,276
2022	3,320
2023	3,379
2024	3,499
2025	3,726
Thereafter	38,534
Total	$ 58,178

(d) Fair Value Measurements

The following fair value hierarchy table presents information about each major category of the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2020 and December 31, 2019:

		March 31, 2020				December 31, 2019			
		Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Financial liabilities:									
Contingently issuable common stock	(a)	$ —	$ —	$ 200	$ 200	$ —	$ —	$ 500	$ 500
Derivative liabilities	(b)	$ —	$ —	2,330	2,330	—	—	940	940
Total financial liabilities		$ —	$ —	$ 2,530	$ 2,530	$ —	$ —	$ 1,440	$ 1,440

(a) See Note 9 for additional details.

(b) See Note 6 for additional details.

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

Changes in the fair value of the Company's Level 3 liabilities were as follows:

	Contingently issuable common stock (a)	Derivative liabilities (b)
Balance at December 31, 2019	$ 500	$ 940
Retirement due to debt extinguishment	—	(1,351)
Additions	—	12,916
Fair value adjustment	(300)	(10,175)
Balance at March 31, 2020	$ 200	$ 2,330

(a) See Note 9 for additional details.

(b) See Note 6 for additional details.

There were no transfers of financial assets or liabilities into or out of Level 3 during the three months ended March 31, 2020. The derivative liabilities as of March 31, 2020 is classified within accrued expenses and other current liabilities on the Company's Condensed Consolidated Balance Sheet.

Financial Instruments Not Recorded at Fair Value on a Recurring Basis

The table below summarizes the carrying and fair values of the Company's debt:

	March 31, 2020		December 31, 2019	
	Carrying value	Fair value	Carrying value	Fair value
Term loan facility	$ 135,627	$ 132,969	$ 141,274	$ 131,892
Convertible notes	32,234	27,771	37,111	24,548
Other debt	4,281	1,259	4,281	1,416
	$ 172,142	$ 161,999	$ 182,666	$ 157,856

The fair values of the Company's debt are determined using Level 3 inputs, with the exception of the 3.25% Senior Notes, which are determined using Level 2 inputs. See Note 6 for further details. The carrying value of the Company's Revolving loan facility approximates fair value.

The following table provides quantitative information about Level 3 inputs for fair value measurement of derivative liabilities and term loan facility as of March 31, 2020 and December 31, 2019. Significant increases or decreases in these inputs in isolation could result in a significant impact on our fair value measurement:

		March 31, 2020	December 31, 2019
Simulation Input			
Volatility	(a)	93%	50%
Yield	(b)	27%	24%

(a) Based on weighted average of implied and historical volatility, used to forecast variability of Company's future stock price.
(b) Based on yields from market comparables, adjusted for each instrument's seniority, for discounting future cash flows.

4. Stock-Based Compensation

The table below summarizes the impact of recording stock-based compensation expense in the Condensed Consolidated Statements of Operations and Comprehensive Loss during the three months ended March 31, 2020 and 2019:

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

	Three Months Ended March 31,	
	2020	2019
Cost of goods sold	$ 164	$ 227
Operating expenses:		
Research and development	181	332
Clinical and regulatory affairs	166	186
Marketing and sales	299	709
General and administrative	923	907
Total operating expenses	1,569	2,134
Total	$ 1,733	$ 2,361

5. Net Loss Per Share

The Company computes earnings per share of its common stock and convertible preferred stock using the two-class method required for participating securities. The convertible preferred stock is considered a participating security because any dividends declared will be distributed among the holders of common stock and convertible preferred stock on a pro rata basis based on the number of shares of common stock held by each holder as of the dividend record date. The number of shares of common stock held by each holder will be determined on an as-converted to common stock basis, based on the then-effective Preferred Exchange Rate and without giving effect to the Ownership Cap (see Note 6). Further, the convertible preferred stock does not have a contractual obligation to share in the losses of the Company therefore its impact is excluded from the calculation of earnings per share in periods of net losses.

Because of the net losses in the three months ended March 31, 2020 and 2019, the following outstanding Company securities, using the treasury stock method, were excluded from the calculations of net loss per share because the effect would have been anti-dilutive:

	Three Months Ended March 31,	
	2020	2019
Restricted stock awards	2,916	2,690
Restricted stock units	101,492	6,578
Warrants	1,522,002	—
Total	1,626,410	9,268

For purposes of calculating the maximum dilutive impact, it is presumed that the convertible notes will be settled in common stock, all conversion features within the term loan facility will be exercised and the convertible preferred stock will be converted into its common stock equivalent with the resulting potential common shares included in diluted earnings per share if the effect is more dilutive. The effect of the conversion of the convertible senior notes, term loan facility and convertible preferred stock is excluded from the calculation of diluted loss per share because the impact of these securities would be anti-dilutive.

The potential dilutive effect of these securities is shown in the table below:

	Three Months Ended March 31,	
	2020	2019
Convertible notes	13,049,893	755,695
Conversion features under term loan facility	31,430,001	—
Convertible preferred stock	1,464,900	—

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

The effect of the contingently issuable common stock (see Note 9) and Nellix Exchanges under the term loan facility (see Note 6) are excluded from the calculation of basic net loss per share until all necessary conditions for issuance have been satisfied.

6. Credit Facilities

Debt consisted of the following:

	March 31, 2020	December 31, 2019
Term loan facility	$ 169,895	$ 167,858
Revolving loan facility	10,519	—
Convertible notes	73,277	73,165
Other debt	4,281	4,281
Debt discounts and deferred financing costs	(75,311)	(62,638)
Long-term debt, including current portion	182,661	182,666
Less current portion	(178,380)	(10,606)
Long-term debt	$ 4,281	$ 172,060

Deerfield Facility Agreement, as Amended

On April 3, 2017 (the "Original Agreement Date"), the Company entered into a facility agreement with affiliates of Deerfield Management Company, L.P. (collectively, "Deerfield"), pursuant to which Deerfield agreed to loan to the Company up to $120.0 million (the "Term Loan"), subject to the terms and conditions set forth in the facility agreement (the "Original Facility Agreement"). The Company drew the entire principal amount of the Term Loan on the Original Agreement Date. The Company will be required to pay Deerfield on each of April 2, 2021, April 2, 2022 and April 2, 2023 (the "Maturity Date"), an amortization payment equal to 33.33% of the Term Loan outstanding on such date (or, if on the Maturity Date, the remaining outstanding principal amount of the Term Loan).

On August 9, 2018 (the "Restated Agreement Date"), the Company entered into an Amended and Restated Facility Agreement (the "Restated Facility Agreement") with Deerfield, pursuant to which Deerfield and the Company canceled and extinguished the $40.5 million principal amount of 3.25% Convertible Senior Notes due 2020 (the "3.25% Senior Notes") held by Deerfield in exchange for an additional $40.5 million of Term Loan indebtedness under the Restated Facility Agreement (as a last-out waterfall tranche under the Restated Facility Agreement), the "Last Out Waterfall Notes"). Such amounts are being amortized 50% on April 2, 2022 and the remaining 50% on April 2, 2023.

On November 18, 2018, the Company and Deerfield amended the Restated Facility Agreement pursuant to that certain First Amendment to Amended and Restated Facility Agreement, dated November 20, 2018 (the "First Facility Amendment"), which amendment permitted the Company to incur debt pursuant to its subordinated promissory note (the "JLL Note") with Japan Lifeline Co., Ltd. ("JLL"), subject to certain conditions.

On March 31, 2019, the Company and Deerfield entered into a Second Amendment to Amended and Restated Facility Agreement (the "Second Facility Amendment"). On April 3, 2019, the terms of the Second Facility Amendment became effective.

The Second Facility Amendment provided for, among other things, the reduction in the Company's global excess liquidity covenant from $22.5 million to $17.5 million and the reduction of the Company's minimum net revenue financial covenants. In addition, the percentage of the $120.0 million of first out waterfall notes (the "First Out Waterfall Notes") due on April 2, 2021 decreased from 33.33% to 16.67% of the First Out Waterfall Notes outstanding on such date, while the percentage of the remainder of the First Out Waterfall Notes due on April 2, 2022 remained at 50% of the First Out Waterfall Notes outstanding on such date.

The Second Facility Amendment provided for the exchange of the existing notes representing the First Out Waterfall Loans for amended notes (the "First Out Waterfall Notes") that provide that in the event that, in any calendar month beginning April 1, 2019 and ending June 30, 2020 (the "Mandatory Conversion Period"), if (A)(i) the arithmetic mean of the volume weighted average prices of the Company's common stock (the "VWAP") on the five (5) consecutive trading days ending on the 15th calendar day (or, if not a trading day, the first trading day thereafter) (the "Mandatory Conversion Measurement Date") and (ii) the closing price for the Company's common stock on the Mandatory Conversion Measurement Date, both exceed $6.625 (as may be adjusted to reflect certain events) (the "Fixed Conversion Price") and (B)(i) the VWAP on the five (5) consecutive trading days ending on (and including) the third (3rd) trading day immediately prior to the Mandatory Conversion Measurement Date (the "Initial Mandatory Conversion Measurement Date") and (ii) the closing price for the Company's common stock on the Initial Mandatory Conversion Measurement Date both exceed the Fixed Conversion Price, Deerfield shall be obligated to convert $1,666,666 of the principal amount of the loan into shares of common stock at the Fixed Conversion Price (each, a "Deerfield Mandatory Conversion"), up to a maximum aggregate amount of $25.0 million over the Mandatory Conversion Period (the "Mandatory Conversion Feature").

Further, the Second Facility Amendment also provided for an increase of $5.0 million, from $6.1 million to $11.1 million, in the amounts payable to Deerfield as a fee upon termination (or reduction, or required reduction of the outstanding amounts under the First Out Waterfall Notes to less than $10,000,000) of the facility agreements and to reimburse Deerfield for all expenses incurred by Deerfield in connection with the negotiation and documentation of the Second Facility Amendment.

The terms of the Second Facility Amendment became effective on April 3, 2019 upon satisfaction of certain conditions precedent, including consummation of the purchase and sale of an aggregate of 7,889,552 shares of the Company's common stock (the "Equity Shares") to select institutional investors and certain other parties at a price per share of $6.61 (the "Equity Offering Price"), for an aggregate cash purchase price of approximately $52.15 million. The Company has issued the Deerfield Warrants and the First Out Waterfall Notes contemplated by the Second Facility Amendment.

On February 24, 2020, the Company and Deerfield entered into a February 2020 Exchange Agreement and Fourth Amendment (the "Fourth Facility Amendment") to Amended and Restated Facility Agreement and Amendment to First Out Waterfall Notes (as amended to date, the "Fourth Facility Agreement") and collectively with the Restated Facility Agreement, First Facility Amendment and Second Facility Amendment, the "Deerfield Facility Agreements"). The Fourth Facility Amendment provides for, among other things, the conversion of certain portions of the outstanding convertible debt upon the achievement of certain milestones. In addition, 16.67% of the First Out Waterfall Notes currently due on the first amortization date of April 2, 2021 (the "First Amortization Payment") will be extended to July 1, 2021. In the event the Company satisfies the Initial Exchange Condition (as defined below) and provided that the Company reports net revenue of at least $142.5 million for the year ended December 31, 2020 and complies with the global excess liquidity requirement (the "Maturity Extension Conditions"), the maturity date shall be extended from April 2, 2023 to December 22, 2023 and the second amortization date shall be extended from April 2, 2022 to April 2, 2023. Further, the Fourth Facility Agreement provides that the interest payment date due April 1, 2020 will be payable in paid-in-kind interest by increasing the principal amount of the loans by an amount equal to the interest that has accrued.

The Fourth Facility Amendment provided for the exchange of the existing notes representing the First Out Waterfall Notes for amended notes (the "Amended First Out Waterfall Notes"). The Amended First Out Waterfall Notes reduced the Fixed Conversion Price under the existing notes from the Fixed Conversion Price to $2.00 (the "New Fixed Conversion Price"); provided that if the Initial Exchange Condition (as defined below) is not met by June 11, 2020, then such price shall revert to the Fixed Conversion Price. The Amended First Out Waterfall Notes provide that the Company may require Deerfield to convert up to $40.0 million of principal amount (the "Forced Conversion Cap") provided that the arithmetic average of the volume weighted average price of the Company's common stock on each of the fifteen (15) consecutive trading days ending on the conversion date (the "Forced Conversion 15 Day VWAP"), and the closing price on the conversion date, is greater than 200% of the New Fixed Conversion Price into shares of the Company's newly created Series DF-1 Preferred Stock, par value $0.001 per share (the "Preferred Stock"), at a price per share equal to the product of (i) the Preferred Exchange Rate (as defined below) and (ii) and 85% of the lesser of the closing price of the common stock on such conversion date (the "Closing Price") and the Forced Conversion 15 Day VWAP, provided that such lesser price is greater than or equal to 170% of the New Fixed Conversion Price and other conditions are met (each such conversion, a "Forced Conversion"). A Forced Conversion may only occur once every 31 calendar days and any individual Forced Conversion may not exceed the lesser of (i) $3.5 million or (ii) the Forced Conversion Cap less any prior Forced Conversions or Discretionary Conversions (as defined below). The Fourth Facility Amendment also removed the Mandatory Conversion Feature.

Deerfield also has the option to convert up to $60.0 million (less any amounts converted pursuant to Forced Conversions) of the Company's outstanding debt (any such conversion, a "Discretionary Conversion") into, at Deerfield's option and subject to the Ownership Cap (as defined below), shares of Common Stock at a rate equal to the greater of the New Fixed Conversion Price and 85% of the 15 Day VWAP, provided that such conversion price is not less than the Floor Price (as defined below) (the "Discretionary Common Conversion Rate") or shares of Preferred Stock at a rate (the "Discretionary Preferred Conversion Rate") equal to the product of (i) the Preferred Exchange Rate (as defined below) multiplied by (ii) the Discretionary Common Conversion Rate.

The Preferred Stock is convertible into common stock at an initial rate of 100 shares of common stock for each share of Preferred Stock, as may be adjusted pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series DF-1 Preferred Stock (the "Certificate of Designation") (the "Preferred Exchange Rate"). Pursuant to the Certificate of Designation, 1,150,000 shares of Preferred Stock have been authorized for issuance and shall be designated from the 5,000,000 shares of preferred stock authorized to be issued under the Amended and Restated Certificate of Incorporation. The Preferred Stock does not possess any voting rights. The Preferred Stock is subject to customary adjustments for stock events. The Preferred Stock provides that in no event may Deerfield convert the Preferred Stock into shares of common stock if such conversion would result in Deerfield beneficially owning more that 4.985% of the Company's outstanding common stock (the "Ownership Cap"). Upon voluntary or involuntary liquidation, holders are entitled to receive the Liquidation Amount ($0.001 per share) plus dividends declared but unpaid, and thereafter participate with the common stock on an as converted basis. There are no deemed liquidation provisions contemplated by the Certificate of Designation. The Amended First Out Waterfall Notes also revises Deerfield's existing right to convert a portion of the outstanding principal amount of the first-out waterfall loan into a maximum of 1,430,001 shares of the Company's common stock at the current conversion price to Deerfield may, at its option, convert into 1,430,001 shares of common stock at the Discretionary Common Conversion Rate, or the equivalent number of shares of Preferred Stock at the Discretionary Preferred Conversion Rate.

The Fourth Facility Amendment provides that, in the event that on or prior to the ninetieth (90th) day following the receipt of regulatory approval to sell Alto in the United States, but in any event no later than June 30, 2020, net sales of Alto shall be in excess of $1.0 million (the "Initial Exchange Condition"), Deerfield will exchange 8.333% of the principal amount of the First Out Waterfall Notes, including any such principal that has resulted from payment-in-kind ("PIK") interest payments made on or prior to such date, plus any accrued PIK interest thereon through such exchange date into shares of Preferred Stock (the "Initial Exchange") at a rate equal to the Preferred Exchange Rate multiplied by $0.8282 (the "Floor Price"). In addition, upon consummation of the Initial Note Exchange, payment of the remaining portion of the First Amortization Payment will be extended until the Second Amortization Date (as defined in the Facility Agreement) and maturity date in accordance with the Facility Agreement. On March 13, 2020, the Company obtained FDA approval to sell Alto in the United States.

In addition, in the event that the Initial Exchange has occurred and the Company completes the first submission to the FDA of a full PMA application with respect to the Nellix EVAS System on or prior to September 30, 2021, Deerfield will exchange $2.5 million into shares of Preferred Stock (the "Nellix Submission Exchange") at a rate (the "Conditional Exchange Rate") equal to the product of the (i) Preferred Exchange Rate multiplied by (ii) the 85% of the lesser of (x) the Closing Price and (y) the 15 Day VWAP (the "Conditional Price"). In the event that the Initial Exchange and the Nellix Submission Exchange have occurred and the Company receives the PMA from the FDA with respect to the Nellix EVAS System as shall be necessary for the sale of the Nellix EVAS System in the United States on or prior to June 30, 2022 (the "Nellix Approval Exchange Condition"), Deerfield will exchange $7.5 million into shares of Preferred Stock (the "Nellix Approval Exchange") at the Conditional Exchange Rate. In the event that the Initial Exchange, the Nellix Submission Exchange and the Nellix Approval Exchange have occurred and net sales of the Nellix EVAS System are in excess of $10.0 million within nine months of satisfaction of the Nellix Approval Exchange Condition, Deerfield will exchange $10.0 million into shares of Preferred Stock (the "Nellix Sales Exchange", together with the Nellix Submission Exchange and the Nellix Approval Exchange, the "Nellix Exchanges") at the Conditional Exchange Rate. Notwithstanding the above, none of the foregoing exchanges shall take place if the Conditional Price at the time of such exchange is less than the Floor Price.

The Fourth Facility Amendment provides that if, during the period beginning on the first business day following satisfaction of the Initial Exchange Condition and ending on the date that is three months thereafter, the Company completes an equity financing resulting in net proceeds to the Company of at least $5.0 million and subject to certain other conditions set forth in the Fourth Facility Amendment, then Deerfield will exchange $0.50 of principal of First Out Waterfall Notes for each $1 of net proceeds up to an aggregate of $20 million in net proceeds into shares of Preferred Stock at a rate equal to the Preferred Exchange Rate multiplied by the lowest price per share of common stock purchased in such financing, provided that such price per share is not less than the Floor Price. Deerfield would also receive the number of such other securities, if any, issued with each share of common stock sold in such financing for each as-converted share of Common Stock issued to Deerfield.

Further, the Fourth Facility Amendment also provides, upon signing, the Company shall pay a restructuring fee of $2.0 million in cash or a combination of shares of common stock at the Floor Price and shares of Preferred Stock at a rate equal to the product of the Floor Price multiplied by the Preferred Exchange Rate. The Company elected to satisfy the fee by issuing 950,000 shares of common stock and 14,649 shares of Preferred Stock at signing.

The Fourth Facility Amendment provides that, upon the satisfaction of the Initial Exchange Condition, the Company will amend the outstanding 2017 Deerfield Warrants and 2018 Deerfield Warrants to reduce the exercise price of the Warrants to $1.50. All other material terms and conditions of the 2017 Deerfield Warrants and 2018 Deerfield Warrants remain the same.

The Fourth Facility Amendment also provides that, upon completion of the Initial Note Exchange, the remaining interest payments on the First Out Waterfall Notes will be due monthly. For 18 months beginning with the first calendar month following completion of the Initial Note Exchange the Company will, subject to certain conditions precedent, make such interest payments in shares of Preferred Stock at a rate equal to the product of (i) the Preferred Exchange Rate as of the interest payment date multiplied by (ii) ninety percent (90%) of the lesser of (a) the closing price on the date immediately preceding the interest payment date and (b) the 15 Day VWAP immediately preceding the interest payment date (the “18 Months Interest Exchange”).

The Company evaluated the accounting for Fourth Facility Amendment transaction and determined it represented an extinguishment of the previously issued First Out Waterfall Notes under the Second Facility Amendment, primarily due to the addition and significance of the conversion features as described above. During the three months ended March 31, 2020, the Company recorded a loss on debt extinguishment of $3.4 million, which includes the $2.0 million restructuring fee paid in common stock and Preferred Stock and change in fair value of the Deerfield Warrants of $0.5 million, offset by the removal of $1.4 million of derivative liabilities associated with the debt prior to the transaction.

Any outstanding principal under the Deerfield Facility Agreements will accrue interest at a rate equal to 5.00% payable in cash and 4.75% payable in kind. The Deerfield Facility Agreements contain the same operating covenants applicable to First Credit Amendment.

The Company’s obligations under the Deerfield Facility Agreements are secured by a first priority security interest in substantially all of the Company’s assets including intellectual property, with the priority of such security interest being pari passu with the security interest granted to Deerfield pursuant to the Restated Credit Agreement.

During the three months ended March 31, 2020 and March 31, 2019, the Company did not convert any principal amounts.

As of March 31, 2020, the Company had a carrying amount of $135.6 million, inclusive of deferred financing costs of $2.4 million, related to the Term Loan. As of March 31, 2020, annual interest expense on the Term Loan will range from $5.3 million to $34.7 million from the effectiveness of the Fourth Facility Amendment date through maturity.

Upon a change of control of the Company, if the acquirer satisfies certain conditions set forth in the Deerfield Facility Agreements, such acquirer may assume the outstanding principal amount under the Deerfield Facility Agreements without penalty. If such acquirer does not satisfy the conditions set forth in the Deerfield Facility Agreements, Deerfield may, at its option, require the Company to repay the outstanding principal balance under the Facility Agreement plus, depending on the timing of the change of control transaction, the Company may be required to pay a make-whole premium and will be required to pay a change of control fee.

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

At any time on or after April 2, 2021 (the "First Amortization Date"), the Company has the right to prepay any amounts owed under the Deerfield Facility Agreements without premium or penalty, unless such prepayment occurs in connection with a change of control of the Company, in which case the Company must pay Deerfield a change of control fee unless such change of control occurs beyond a certain period after the maturity date. At any time prior to the First Amortization Date, any prepayment made by the Company will be subject to a make-whole premium and, if such prepayment occurs in connection with a change of control of the Company, a change of control fee.

Any amounts drawn under the Deerfield Facility Agreements may become immediately due and payable upon customary events of default, as defined in the Deerfield Facility Agreements, or the consummation of certain change of control transactions, as described above.

Deerfield Warrants

In connection with the execution of the Original Facility Agreement and the Restated Facility Agreement, the Company issued warrants to Deerfield (the "Original 2017 Deerfield Warrants" and the "Original 2018 Deerfield Warrants," respectively). In connection with entry into the Second Facility Amendment, the Company amended the Original 2017 Deerfield Warrants and the Original 2018 Deerfield Warrants in order to reduce the exercise price, which was further reduced by the Fourth Facility Amendment (as amended, the "2017 Deerfield Warrants" and the "2018 Deerfield Warrants"; collectively, the "Deerfield Warrants") as summarized below:

	Number of shares of common stock	Original Exercise Price	Second Amendment Exercise price	Fourth Amendment Exercise Price
2017 Deerfield Warrants	647,001	$ 92.31	$ 6.61	$ 1.50
2018 Deerfield Warrants	875,001	$ 47.11	$ 6.61	$ 1.50

The number of shares of common stock of the Company into which the Deerfield Warrants are exercisable and the exercise price of the Deerfield Warrants will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock of the Company.

The 2017 Deerfield Warrants expire on the 7th anniversary of the Agreement Date. Subject to certain exceptions, the 2017 Deerfield Warrants contain limitations such that the Company may not issue shares of common stock of the Company to Deerfield upon the exercise of the 2017 Deerfield Warrants if such issuance would result in Deerfield beneficially owning in excess of 4.985% of the total number of shares of common stock of the Company then issued and outstanding.

The holders of the 2017 Deerfield Warrants may exercise the 2017 Deerfield Warrants for cash, on a cashless basis or through a reduction of an amount of principal outstanding under the Term Loan. In connection with certain major transactions, the holders may have the option to convert the 2017 Deerfield Warrants, in whole or in part, into the right to receive the transaction consideration payable upon consummation of such major transaction in respect of a number of shares of common stock of the Company equal to the Black-Scholes value of the 2017 Deerfield Warrants, as defined therein, and in the case of other major transactions, the holders may have the right to exercise the 2017 Deerfield Warrants, in whole or in part, for a number of shares of common stock of the Company equal to the Black-Scholes value of the 2017 Deerfield Warrants.

The 2018 Deerfield Warrants expire on the 7th anniversary of the Restated Agreement Date. The holders of the 2018 Deerfield Warrants may exercise the 2018 Deerfield Warrants for cash, on a cashless basis, or by reduction of the principal owed to Deerfield pursuant to the Restated Facility Agreement.

As a result of the amendment to the Deerfield Warrants in connection with entry into the Fourth Facility Amendment, the change in fair value in the Deerfield Warrants was $0.5 million. The foregoing was charged to loss on debt extinguishment

The Fourth Facility Amendment provides that the Company will amend the strike price on the 2017 Warrants and 2018 Warrants. The current strike price on the Deerfield Warrants is $6.61 but will be reduced to $1.50 upon satisfaction of the Initial Note Exchange Condition. Due to the existence of this contingent adjustment provision the Deerfield Warrants are classified as derivative liabilities and are subject to subsequent remeasurement

Derivative Liabilities

In accordance with Accounting Standards Codification ("ASC") 815, "Derivatives and Hedging", and ASC 470, "Debt", the Company assessed whether any provisions within the Fourth Facility Amendment constitute embedded derivatives requiring bifurcation from the host instrument, and assessed the fair values of any such features. The Company determined that the Deerfield Discretionary Conversion, Nellix Exchanges and 18 Months Interest Exchange effectively provided the holders with embedded put option derivatives meeting the definition of an "embedded derivative" pursuant to ASC 815. Consequently, the embedded derivatives were bifurcated and accounted for separately. The Fourth Facility Amendment retained a provision that, upon a change of control of the Company, Deerfield may declare the outstanding principal of the loans to be immediately due and payable in full, together with any accrued and unpaid interest, a "Change of Control" fee, and a specified make-whole amount (prior to the First Amortization Date). This feature remained substantively the same as outlined under the previous Second Facility Amendment. The Company concluded that this provision meets the definition of a derivative and requires bifurcation and separate accounting pursuant to ASC 815.

On February 24, 2020, the Company measured the fair value of the above embedded derivatives at $12.0 million and recorded the amount within accrued expenses and other current liabilities in the Condensed Consolidated Balance Sheet.

For the three months ended March 31, 2020 and 2019, the Company recorded income of $10.2 million and expense of $2.0 million, respectively, as a fair value adjustment of the derivative liabilities. Adjustments to the fair value of the derivative liabilities are recognized within other income (expense), net in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

The value of the above derivative liabilities were estimated using a "with" and "without" approach utilizing observable and unobservable inputs causing this to be a Level 3 measurement. In the "with" scenario, the fair value the Deerfield notes host instrument was estimated, including the cash flows resulting from the bifurcated embedded derivatives. In the "without" scenario the value of the Deerfield notes host instrument absent the embedded derivatives were estimated. The difference between the values estimated in the "with" and "without" scenarios represents the value of the derivative liabilities. In each approach, the Deerfield notes host instrument was valued using a Monte Carlo simulation in a risk-neutral framework, simulating future stock prices using Geometric Brownian Motion. Changes in the value of the derivative liabilities were primarily driven by changes in the Company's stock price, expected volatility, and market yields.

Deerfield Revolver

On the Restated Agreement Date, the Company entered into a Credit Agreement (the "Restated Credit Agreement") with Deerfield ELGX Revolver, LLC ("Deerfield Revolver"), pursuant to which the Company may borrow up to the lesser of $50.0 million or its applicable borrowing base from time to time prior to April 2, 2022 (the "ABL Facility").

On November 18, 2018, the Company and Deerfield amended the Restated Credit Agreement pursuant to that certain First Amendment to Amended and Restated Credit Agreement, dated November 20, 2018 ("First Credit Amendment"), which amendment permitted the Company to incur debt pursuant to the JLL Note, subject to certain conditions.

On March 31, 2019, the Company entered into a Second Amendment to Credit Agreement and First Amendment to Guaranty and Security Agreement (the "Second Credit Amendment" and collectively with the Restated Credit Agreement and First Credit Amendment, the "Deerfield Credit Agreements"). The Second Credit Amendment includes conforming revisions to reflect the changes in the Second Facility Amendment. In addition, the Second Credit Amendment extends the maturity date of the Deerfield Credit Agreements to the earlier of (i) April 2, 2023 or (ii) the date the loans pursuant to the Deerfield Facility Agreements have been repaid in full.

On February 24, 2020, the Company entered into a Fourth Amendment to Credit Agreement (the "Fourth Credit Amendment") with Deerfield Revolver and certain funds managed by Deerfield Management Company, L.P., dated as of August 9, 2018. The Fourth Credit Amendment includes conforming revisions to reflect the changes in the Fourth Facility Amendment. In addition, the Fourth Credit Amendment provides that if the Company satisfies the Maturity Extension Conditions, the credit agreement maturity date will extend to the earlier of (i) December 22, 2023 or (ii) the date the loans pursuant to the Facility Agreement have been repaid in full.

The borrowing base consists of eligible accounts, eligible inventory and eligible equipment. Any outstanding principal under the ABL Facility will accrue interest at a rate equal to the London Interbank Offered Rate ("LIBOR") (with a 1% floor) plus 5.50% payable in cash. The interest rate will accrue on a minimum amount of $9.75 million, whether or not such amount is drawn (which amount in excess of the revolver usage accruing interest will not be subject to the unused line fee). The Company is subject to other fees in addition to interest on the outstanding principal amount under the ABL Facility, including a commitment fee of $0.5 million ($0.2 million payable upon closing, $0.2 million payable on the 1st anniversary of the closing and $0.1 million payable on the 2nd anniversary of the closing), a $1.0 million fee upon the expiration of the ABL Facility, and an early commitment termination or reduction fee of 2.5% in the 1st year, 1.5% in the 2nd year, 0.5% in the 3rd year and 0% thereafter. The Company recorded $0.6 million in deferred financing costs, including the commitment fee, related to the ABL Facility and presented these costs as a deferred asset, to be subsequently amortized as interest expense over the term of the ABL Facility, on the Company's Condensed Consolidated Balance Sheets. In conjunction with entering in the Second Credit Amendment, the Company recorded as additional $0.4 million in deferred financing costs.

The Deerfield Credit Agreements have a $17.5 million minimum global liquidity requirement, net revenue tests, fixed charge coverage, capital expenditure limitations and operating expense tests. No event of default with respect the Company's financial covenants had been declared as of March 31, 2020. The Deerfield Credit Agreements also contain various representations and warranties, events of default, and affirmative and negative covenants, customary for financings of this type, including reporting requirements, requirements that the Company maintain timely reporting with the SEC and restrictions on the ability of the Company and its subsidiaries to incur additional liens on their assets, incur additional indebtedness and acquire and dispose of assets outside the ordinary course of business.

The Company's obligations under the Deerfield Credit Agreements are secured by a first priority security interest in substantially all of the Company's assets including intellectual property, with the priority of such security interest being pari passu with the security interest granted to Deerfield pursuant to the Company's Deerfield Facility Agreements (as described above).

As of March 31, 2020, the Company had 10.5 million outstanding borrowings and 0.7 million in deferred financing costs relating to the ABL Facility. The remaining borrowings available was 4.5 million.

3.25% Convertible Senior Notes due 2020

On November 2, 2015, the Company issued $125.0 million aggregate principal amount of 3.25% Senior Notes in an underwritten public offering. The 3.25% Senior Notes are governed by a base indenture ("Base Indenture"), as amended and supplemented by the second supplemental indenture relating to the 3.25% Senior Notes (the "Second Supplemental Indenture," and together with the Base Indenture, the "3.25% Senior Notes Indenture"), dated as of November 2, 2015, by and between the Company and the Trustee (as defined therein).

The 3.25% Senior Notes accrue interest at a rate of 3.25% per year, payable semi-annually. The 3.25% Senior Notes mature on November 1, 2020, unless earlier purchased, redeemed or converted into shares of common stock in accordance with the terms of the 3.25% Senior Notes Indenture.

On August 9, 2018, the Company entered into the Restated Facility Agreement with Deerfield, pursuant to which Deerfield and the Company canceled and extinguished the $40.5 million principal amount of the 3.25% Senior Notes held by Deerfield in exchange for an additional $40.5 million of indebtedness under the Restated Facility Agreement (as a last-out waterfall tranche under the Restated Facility Agreement).

On March 31, 2019, the Company and two investors holding $73.4 million of the principal amount of the 3.25% Senior Notes entered into an Exchange Agreement (the "2019 Exchange Agreement") providing for the exchange of the holders' 3.25% Senior Notes for new 5.00% Voluntary Convertible Senior Notes due 2024 (the "2019 5.00% Voluntary Notes") and new 5.00% Mandatory Convertible Senior Notes due 2024 (the "5.00% Mandatory Notes", and together with the 2019 5.00% Voluntary Notes, the "2019 5.00% Notes") which was completed on April 3, 2019.

On February 24, 2020, the Company and three investors holding $11.0 million of the principal amount of the Company's 3.25% Senior Notes entered into an Exchange Agreement (the "2020 Exchange Agreement") providing for the exchange of the holders' existing notes for new 5.00% Voluntary Convertible Senior Notes due 2024 (the "2020 5.00% Voluntary Notes").

As of March 31, 2020, the Company had outstanding borrowings of $0.1 million related to the remaining 3.25% Senior Notes. There were no principal payments due during the term.

2020 5.00% Convertible Senior Notes due 2024

On February 24, 2020, the Company and three investors holding approximately $11.0 million of the principal amount of the Company's 3.25% Senior Notes due 2020 (the "Holders") entered into an Exchange Agreement (the "2020 Exchange Agreement") providing for the exchange of the Holders' existing notes (the "Existing Notes") for new 5.00% Voluntary Convertible Senior Notes due 2024 (the "2020 5.00% Voluntary Notes"). Pursuant to the 2020 Exchange Agreement, on February 24, 2020, the exchanging Holders are exchanging all outstanding principal plus accrued and unpaid interest under the Existing Notes into the same amount of principal of 2020 5.00% Voluntary Notes pursuant to the 2020 Exchange Agreement. The 2020 5.00% Voluntary Notes are being issued in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act") by virtue of Section 4(a)(2) of the Securities Act and Rule 506 thereunder.

The 2020 5.00% Voluntary Notes will be governed by an Indenture (the "2020 Indenture"), by and between the Company and Wilmington, as trustee. The 2020 5.00% Voluntary Notes will accrue interest at a rate of 5.00% per year, payable semi-annually in arrears on April 1 and October 1 of each year, commencing April 1, 2020. The 2020 5.00% Voluntary Notes will mature on April 2, 2024, unless earlier purchased, redeemed or converted in accordance with the terms of the 2020 Indenture. The 2020 Indenture governing the 2020 5.00% Voluntary Notes will contain customary terms and covenants and events of default.

The 2020 5.00% Voluntary Notes will be convertible at the option of each Holder into shares of common stock at any time prior to the close of business on the business day immediately preceding January 1, 2024; provided that, except if the Company undergoes a fundamental change (as defined in the 2020 Indenture) and for certain other customary circumstances of conversion, each Holder may not convert more than 30% the initial aggregate principal amount of its outstanding 2020 5.00% Voluntary Notes per calendar quarter (a "2020 Voluntary Conversion"). Beginning January 1, 2024, until the close of business on the business day immediately preceding the maturity date, the 2020 5.00% Voluntary Notes will be convertible at the option of the holder at any time regardless of the conditions described in this paragraph. The initial conversion rate of the 2020 5.00% Voluntary Notes in a 2020 Voluntary Conversion is 0.4445 shares of the Company's common stock per $1.00 principal amount of the 2020 5.00% Voluntary Notes, which is equivalent to an initial conversion price per share equal to $2.25 (the "2020 Conversion Price"). The conversion rate is subject to adjustment upon the occurrence of certain specified events. Except if the Company undergoes a fundamental change (as defined in the 2020 Indenture) and for certain other customary circumstances of conversion, in no event prior to the close of business on the business day immediately preceding January 1, 2024 may the 2020 5.00% Voluntary Notes be converted in a calendar quarter unless the closing sale price of the Company's common stock for at least twenty (20) trading days during the period of thirty (30) consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 110% of the Conversion Price (subject to adjustment upon the occurrence of certain specified events) (the "2020 Voluntary Conversion Threshold").

The 2020 5.00% Voluntary Notes will be secured by the Company's assets pursuant to a Junior Lien Security Agreement by and between the Company and Wilmington, as collateral agent (the "JLSA"). The JLSA grants a second lien on the Company's assets that is second in priority to the security interests granted (i)_to Deerfield, as agent, pursuant to the Amended and Restated Guaranty and Security Agreement, dated August 9, 2018, by and among the Company, its subsidiaries and Deerfield, as agent, as amended to date and (ii) to Deerfield ELGX Revolver, LLC, as agent ("Deerfield ELGX"), pursuant to the Guaranty and Security Agreement, dated as of August 9, 2018, by and among the Company, its subsidiaries and Deerfield ELGX, as agent. as amended to date. In connection with the issuance of the 2020 5.00% Voluntary Notes, the parties entered into Subordination and Intercreditor Agreement, dated as of February 24, 2020, by and among the Company, Deerfield, Deerfield ELGX and Wilmington, as collateral agent (the "Subordination Agreement"). The Subordination Agreement contains customary provisions associated with the subordination of the security interest of the 2020 5.00% Voluntary Notes.

The 2020 Indenture will provide that in no event may a Holder convert into shares of common stock if such conversion would result in the Holder beneficially owning more that 9.5% of the Company's outstanding common stock.

The Company evaluated the accounting for the 2020 Exchange Agreement transaction and determined it represented an extinguishment of the previously issued 3.25% Senior Notes, primarily due to the addition and significance of the conversion features as described above. During the three months ended March 31, 2020, the Company recorded a gain on debt extinguishment of $2.7 million relating to the exchange of debt instruments.

Upon issuance, the Company was not required to separate the conversion options from the 2020 5.00% Voluntary Notes under ASC 815, "Derivatives and Hedging". However, because the Company has the ability to settle the 2020 5.00% Voluntary Notes in cash, common stock or a combination of cash and common stock, the Company applied the cash conversion guidance contained in ASC 470-20, "Debt With Conversion and other Options", and accounted for the 2020 5.00% Voluntary Notes by allocating the issuance proceeds between the liability-classified debt component and a separate equity component attributable to the conversion options. The equity component is classified in stockholders' equity and the resulting discount on the liability component is accreted such that interest expense equals the Company's borrowing rate for nonconvertible loan products of similar duration. The separation was performed by first determining the fair value of a similar debt that does not have an associated equity component. That amount was then deducted from the initial proceeds of the 2020 5.00% Voluntary Notes as a whole to arrive at a residual amount, which was allocated to the conversion feature that is classified as equity. The initial fair value of the indebtedness was $8 million resulting in a $3.6 million allocation to the embedded conversion option. The embedded conversion option was recorded in stockholders' equity and as a debt discount, to be subsequently accreted to interest expense over the term of the 2020 5.00% Voluntary Notes. Debt issuance costs totaled $120 thousand and were allocated between the liability and the equity components in proportion to the allocation of proceeds and accounted for as debt issuance costs and equity issuance costs, respectively. As a result, $66 thousand attributable to the indebtedness was recorded as deferred financing costs, to be subsequently amortized as interest expense over the term of the 2020 5.00% Voluntary Notes, and $53 thousand attributable to the equity component was recorded as a reduction to additional paid-in-capital in stockholders' equity. During the three months ended March 31, 2020, there was no conversion to common stock.

As of March 31, 2020, the Company had outstanding borrowings of 4.5 million, and deferred financing costs of $0.1 million, related to the 2020 5.00% Voluntary Notes. There were no principal payments due during the term. Annual interest expense on these 2020 5.00% Voluntary Notes will range from $0.9 million to $2.9 million through maturity.

2019 5.00% Convertible Senior Notes due 2024

On April 3, 2019, the Company completed the transactions contemplated by the 2019 Exchange Agreement, issuing $25.0 million of principal amount of the 5.00% Mandatory Notes and $42.0 million of principal amount of the 2019 5.00% Voluntary Notes to the holders. The exchanging holders received $900 principal amount of 2019 5.00% Notes for every $1000 principal amount of 3.25% Senior Notes plus accrued interest.

The 2019 5.00% Voluntary Notes and 5.00% Mandatory Notes are governed by separate Indentures (respectively, the "2019 5.00% Voluntary Notes Indenture" and "5.00% Mandatory Notes Indenture", and collectively, the "2019 Indentures"), each dated April 3, 2019, by and between the Company and Wilmington Trust, National Association, as trustee. The 2019 5.00% Notes will accrue interest at a rate of 5.00% per year, payable semi-annually in arrears on April 1 and October 1 of each year, commencing October 1, 2019. Such interest amount shall be paid, at the Company's option, either in cash or, if certain terms are met in accordance with the 2019 Indentures, shares of common stock or paid in kind. The 2019 5.00% Notes mature on April 3, 2024, unless earlier purchased, redeemed or converted in accordance with the terms of the Indentures. The 2019 Indentures governing the 5.00% Notes contain customary terms and covenants and events of default.

The 2019 5.00% Voluntary Notes are convertible at the option of each holder into shares of common stock at any time on or after July 1, 2020, but prior to the close of business on the business day immediately preceding January 1, 2024, provided that, except if the Company undergoes a fundamental change (as defined in the 2019 5.00% Voluntary Notes Indenture) and for certain other customary circumstances of conversion, each holder may not convert more than 30% the initial aggregate principal amount of his or her outstanding 2019 5.00% Voluntary Notes per calendar quarter (a "2019 Voluntary Conversion"). Thereafter, until the close of business on the business day immediately preceding the maturity date, the 2019 5.00% Voluntary Notes will be convertible at the option of the holder at any time regardless of the conditions described in this paragraph. The initial conversion rate of the 2019 5.00% Voluntary Notes in a 2019 Voluntary Conversion is 0.12103 shares of the Company's common stock per $1.00 principal amount of the 5.00% Notes, which is equivalent to an initial conversion price per share equal to $8.2624 (the "2019 Conversion Price"). The conversion rate is subject to adjustment upon the occurrence of certain specified events. Except if the Company undergoes a fundamental change (as defined in the 2019 5.00% Voluntary Notes Indenture) and for certain other customary circumstances of conversion, in no event prior to the close of business on the business day immediately preceding January 1, 2024 may the 2019 5.00% Voluntary Notes be converted in a calendar quarter unless the closing sale price of the Company's common stock for at least twenty (20) trading days during the period of thirty (30) consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 7.271 (subject to adjustment upon the occurrence of certain specified events) (the "2019 Voluntary Conversion Threshold").

The 5.00% Mandatory Notes provide for the mandatory conversion (a "5.00% Mandatory Conversion") of $1,666,666 of the aggregate principal amount each calendar month for fifteen (15) consecutive months beginning on the calendar month beginning with April 3, 2019, if and only if at the end of the prior calendar month the trailing average VWAP of the last five (5) trading days of the prior calendar month is greater than $6.61. In the event of a 5.00% Mandatory Conversion, $1,666,666 of the 5.00% Mandatory Notes would mandatorily convert at a conversion rate of 0.15129 shares of the Company's common stock per $1.00 principal amount of the 5.00% Notes, which is equivalent to a price per share equal to $6.61. The 5.00% Mandatory Notes will be convertible at the option of each holder into shares of common stock at the 5.00% Voluntary Conversion Price at any time prior to the close of business on the business day immediately preceding January 1, 2024, provided that, except if the Company undergoes a fundamental change (as defined in the 5.00% Mandatory Notes Indenture) and for certain other customary circumstances of conversion, each holder may not convert more than 30% of the initial aggregate principal amount of his or her outstanding New Mandatory Note per calendar quarter, and provided further, that (i) voluntary conversions may be effected only if the 5.00% Voluntary Conversion Threshold has been achieved and (ii) a voluntary conversion may not take place in the same calendar quarter as a 5.00% Mandatory Conversion. Thereafter, until the close of business on the business day immediately preceding the maturity date, the 5.00% Mandatory Notes will be convertible at the option of the holder at any time regardless of the conditions described in this paragraph.

The Indentures provide that in no event may a holder convert, whether in a 2019 Voluntarily Conversion or a 5.00% Mandatory Conversion or otherwise, into shares of common stock if such conversion would result in the holder beneficially owning more that 9.5% of the Company's outstanding common stock.

Upon issuance, the Company was not required to separate the conversion options from the 5.00% Notes under ASC 815, "Derivatives and Hedging". However, because the Company has the ability to settle the 5.00% Notes in cash, common stock or a combination of cash and common stock, the Company applied the cash conversion guidance contained in ASC 470-20, "Debt With Conversion and other Options", and accounted for the 5.00% Notes by allocating the issuance proceeds between the liability-classified debt component and a separate equity component attributable to the conversion options. The equity component is classified in stockholders' equity and the resulting discount on the liability component is accreted such that interest expense equals the Company's borrowing rate for nonconvertible loan products of similar duration. The separation was performed by first determining the fair value of a similar debt that does not have an associated equity component. That amount was then deducted from the initial proceeds of the 5.00% Notes as a whole to arrive at a residual amount, which was allocated to the conversion feature that is classified as equity. The initial fair value of the indebtedness was $67.2 million resulting in a $41.2 million allocation to the embedded conversion option. The embedded conversion option was recorded in stockholders' equity and as a debt discount, to be subsequently accreted to interest expense over the term of the 5.00% Notes. Debt issuance costs totaled $1.2 million and were allocated between the liability and the equity components in proportion to the allocation of proceeds and accounted for as debt issuance costs and equity issuance costs, respectively. As a result, $0.5 million attributable to the indebtedness was recorded as deferred financing costs, to be subsequently amortized as interest expense over the term of the 5.00% Notes, and $0.7 million attributable to the equity component was recorded as a reduction to additional paid-in-capital in stockholders' equity. During the three months ended March 31, 2020, there was no conversion to common stock.

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

As of March 31, 2020, the Company had a carrying amount of $27.6 million, inclusive of deferred financing costs of $0.4 million, related to the 5.00% Notes. Annual interest expense on these 5.0% Notes will range from $4.4 million to $14.7 million through maturity.

Japan Lifeline Co., Ltd. Subordinated Promissory Note

On November 20, 2018, the Company issued the JLL Note to JLL, the Company's Japanese distributor, pursuant to which the Company converted a $4.3 million refund payable to a note payable. The amount owing under the JLL Note accrues interest at a rate of 2.5% per annum and, subject to the terms of the subordination agreement among the Company, JLL and certain Deerfield entities entered into on November 20, 2018, would become due and payable on the earlier of: (i) December 31, 2023; or (ii) the date the JLL Note is declared due and payable by JLL upon the occurrence of certain events of default.

Principal Maturities of Long-term Debt

The aggregate principal maturities of long-term debt as of March 31, 2020 are as follows:

	Term loan facility	Convertible notes	Other debt	Total
Year ending December 31,				
2020	$ —	$ 150	$ —	$ 150
2021	21,099	—	—	21,099
2022	74,398	—	—	74,398
2023	74,398	—	4,281	78,679
2024	—	73,126	—	73,126
	$ 169,895	$ 73,276	$ 4,281	$ 247,452

Due to the substantial doubt about the Company's ability to continue operating as a going concern, the Company is in default under the Facility Agreement and Credit Agreement with its lender, Deerfield. We have entered into forbearance agreements with Deerfield which provide that Deerfield will not exercise its default rights under the Facility Agreements until June 15, 2020 or earlier upon certain conditions. If Deerfield were to exercise its default rights, such default would result in a cross default under the Company's 5.00% Notes and 2020 5.00% Voluntary Notes. If Deerfield were to exercise its default rights, other lenders may then declare a default and the Company may be unable to repay the amounts owed without raising additional capital. If the Company is unable to repay the amounts owed, it may be forced to declare bankruptcy. Therefore, the entire amount of borrowings of $135.6 million from Deerfield and the $32.1 million 5% Notes and 2020 5.00% Voluntary Notes as at March 31, 2020 has been classified as current in these financial statements. Further, the Company would be required to pay exit fees totaling $11.1 million under the Facility Agreement and the remaining $0.1 million commitment fee under the Credit Agreement. Deerfield has not declared a default.

7. Revenue Disaggregation

The Company disaggregated revenue in accordance with the new revenue standard to depict how the nature, amount, timing, and uncertainty of revenue and cash flows are affected by economic factors. These economic factors are primarily attributable to different geographic regions and the timing of transfer of control of products to customers. Accordingly, sales in which control of the product has passed to the customer at the time of procedure or implant into a patient or at the time of shipment have been bifurcated as "Implant-based" and "Shipment-based" revenue, respectively. The tables below includes a reconciliation of disaggregated revenue with the Company's reportable segment:

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

	Three Months Ended March 31,					
	2020			2019		
	Implant-based	Shipment-based	Total	Implant-based	Shipment-based	Total
United States	$ 18,324	$ 305	$ 18,629	$ 22,463	$ 323	$ 22,786
International	$ 2,992	$ 6,889	$ 9,881	$ 3,807	$ 9,013	$ 12,820
Total Revenue	$ 21,316	$ 7,194	$ 28,510	$ 26,270	$ 9,336	$ 35,606

8. Commitments and Contingencies

(a) Leases

The Company determines whether an arrangement is a lease at inception. The Company leases facilities located in Irvine, California and Santa Rosa, California and an office located in ‘s-Hertogenbosch, the Netherlands. These facility lease agreements require the Company to pay variable operating costs, including property taxes, insurance and maintenance based on costs incurred or actual usage. The Company’s facility leases do not contain any residual value guarantees. In addition, the Company has certain equipment and automobiles under long-term agreements that were not material for the three months ended March 31, 2020.

All facility leases are accounted for as operating leases. A right-of-use asset, representing the underlying asset during the lease term, and a lease liability, representing the payment obligation arising from the lease, are recognized on the balance sheet at lease commencement based on the present value of the payment obligation. For operating leases, expense is recognized on a straight-line basis over the lease term. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet.

The Company primarily uses its incremental borrowing rate in determining the present value of lease payments as the Company's facility leases generally do not provide an implicit rate.

The Company’s facility leases have remaining lease terms ranging from less than 3 years to 9 years, some of which include options to extend the lease term for up to five years.

For the three months ended March 31, 2020, components of facility lease costs consist of $0.8 million in operating lease expense and $0.2 million in variable lease costs.

Maturities of facility lease liabilities by fiscal year for our operating leases are as follows as of March 31, 2020:

Remainder of 2020	$ 2,708
2021	3,751
2022	3,860
2023	2,949
2024	2,848
2025	2,905
2026 and thereafter	9,433
Total lease payments	$ 28,454
Less: Imputed Interest	(15,145)
Present value of operating lease liabilities	$ 13,309

As of March 31, 2020, the current portion of the Company’s operating lease liabilities was $1.9 million and is classified within accrued expenses and other current liabilities in the Company’s Consolidated Balance Sheets.

As of March 31, 2020, the weighted-average remaining lease term was 7.6 years and weighted-average discount rate was 22.1%.

(b) Employment Agreements and Retention Plan

The Company has employment agreements with certain of its executive officers under which payment and benefits would become payable in the event of termination by the Company for any reason other than cause, death or disability or termination by the employee for good reason (collectively, an "Involuntary Termination") prior to, upon or following a change in control of the Company. The severance payment will generally be in a range of 6 to 18 months of the employee's then current salary for an Involuntary Termination prior to a change in control of the Company, and will generally be in a range of 18 to 24 months of the employee's then current salary for an Involuntary Termination upon or following a change in control of the Company.

(c) Legal Matters

The Company is from time to time involved in various claims and legal proceedings of a nature it believes is normal and incidental to a medical device business. These matters may include product liability, intellectual property, employment, and other general claims. Such cases and claims may raise complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. The Company accrues for contingent liabilities when it is probable that a liability has been incurred and the amount can be reasonably estimated. The accruals are adjusted periodically as assessments change or as additional information becomes available.

Stockholder Securities Litigation

On January 3, 2017 and January 9, 2017, two stockholders purporting to represent a class of persons who purchased the Company's securities between August 2, 2016 and November 16, 2016, filed lawsuits against the Company and certain of its officers in the United States District Court for the Central District of California (the "District Court"). The lawsuits allege that the Company made materially false and misleading statements and failed to disclose material adverse facts about its business, operational and financial performance, in violation of federal securities laws, relating to United States Food and Drug Administration (the "FDA") pre-market approval for the Company's Nellix EVAS System. On May 26, 2017, the plaintiffs filed an amended complaint extending the class period to include persons who purchased the Company's securities between May 5, 2016 and May 18, 2017 and adding certain factual assertions and allegations regarding the Nellix EVAS System. The plaintiffs sought unspecified monetary damages on behalf of the alleged class, interest, and attorney's fees and costs of litigation. The first lawsuit, Nguyen v. Endologix, Inc. et al., Case No. 2:17-cv-0017 AB (PLAx) (C.D. Cal.) ("Nguyen"), was consolidated with the second lawsuit, Ahmed v. Endologix, Inc. et al, Case No. 8:17-cv-00061 AB (PLAx) (C.D. Cal.), and lead Nguyen plaintiff filed a consolidated First Amended Complaint. On December 5, 2017, the District Court granted Endologix's motion to dismiss lead plaintiff's First Amended Complaint, with leave to amend. On January 9, 2018, lead plaintiff filed a Second Amended Complaint and on March 12, 2018, the Company filed its Motion to Dismiss lead plaintiff's Second Amended Complaint with prejudice. On September 6, 2018, the District Court dismissed the Second Amended Complaint with prejudice and, on October 5, 2018, lead plaintiff filed a notice of appeal, and on March 15, 2019, lead plaintiff filed its opening brief with the appellate court. In April 2019, the Company filed its response brief to plaintiff's appeal. The Appellate Court's hearing on the appeal occurred in February 2020, and the Company expects the Appellate Court's decision to be rendered later in 2020. The Company believes these lawsuits are without merit and continues to defend itself vigorously.

Stockholder Derivative Litigation

As of June 11, 2017, four stockholders have filed derivative lawsuits seeking unspecified monetary damages on behalf of Endologix, the nominal plaintiff, based on allegations substantially similar to those alleged by lead plaintiff in Nguyen. Those actions consist of: Sindlinger v. McDermott et al., Case No. BC662280 (Los Angeles Superior Court); Abraham v. McDermott et al., Case No. 30-2018-00968971-CU-BT-CSC (Orange County Superior Court); and Green v. McDermott et al., Case No. 8:17-cv-01155-AB (PLAx), which has been consolidated with Cocco v. McDermott et al., Case No. 8:17-cv-01183-AB (PLAx) (C.D. Cal.). The Company believes these lawsuits are without merit and continues to defend itself vigorously.

(e) Concentrations of Risk and Major Customer

For the three months ended March 31, 2020 and 2019, there was one customer that represented 10% or more of consolidated revenue. As of March 31, 2020 and December 31, 2019, there was one customer that represented 10% or more of consolidated accounts receivable.

9. Contingently Issuable Common Stock

On October 27, 2010, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Nepal Acquisition Corporation, a wholly-owned subsidiary of the Company, Nellix, Inc. ("Nellix"), certain of Nellix's stockholders named therein and Essex Woodlands Health Ventures, Inc., as representative of the former Nellix stockholders. On December 10, 2010 (the "Nellix Closing Date"), the Company completed its acquisition of Nellix. The purchase price consisted of shares of the Company's common stock issuable as of the Nellix Closing Date. Additional payments, solely in the form of shares of the Company's common stock will be made upon the achievement of a revenue milestone and a regulatory approval milestone (collectively, the "Nellix Milestones"). Under the Merger Agreement, the ultimate value of the contingently issuable common stock would be determined on the date that each Nellix Milestone is achieved. The number of issuable shares would be established using an applicable per share price, which is subject to a ceiling and/or floor, resulting at the closing of the merger in a potential maximum of approximately 1,020,000 shares issuable upon the achievement of the Nellix Milestones. As of the Closing Date, the fair value of the contingently issuable common stock was estimated to be $28.2 million.

The Merger Agreement provides that, in addition to the shares of common stock of the Company issued to the former Nellix stockholders at the Nellix Closing Date, if the Company receives approval from the FDA to sell one of Nellix's products in the United States (the "PMA Milestone"), the Company will issue additional shares of its common stock to the former stockholders of Nellix. The dollar value of the shares of the Company's common stock to be issued upon achievement of the PMA Milestone will be equal to $15.0 million (less the dollar value of certain cash payments and other deductions). The price per share of the shares of the Company's common stock to be issued upon achievement of the PMA Milestone is subject to a stock price floor of $45.00 per share but not subject to a stock price ceiling.

The value of the contingently issuable common stock is derived using a discounted income approach model, with a range of probabilities and assumptions related to the timing and likelihood of achievement of the PMA Milestone (which include Level 3 inputs and the Company's stock price (Level 1 input) as of the balance sheet date). These varying probabilities and assumptions and changes in the Company's stock price have required fair value adjustments of the contingently issuable common stock in periods subsequent to the Nellix Closing Date.

The fair value of the contingently issuable common stock will continue to be evaluated on a quarterly basis until milestone achievement occurs, or until the expiration of the "Earn-Out Period," as defined within the Merger Agreement. Adjustments to the fair value of the contingently issuable common stock are recognized within other income (expense), net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. See the "Fair Value Measurements" section of Note 3 for further details. As of March 31, 2020, the fair value of the contingently issuable common stock was presented in non-current liabilities.

At March 31, 2020 the Company's stock price closed at $0.69 per share. Thus, had the PMA Milestone been achieved on March 31, 2020 the contingently issuable common stock would have comprised approximately 333,149 shares (based on the 30-day average closing stock price ending 5 days prior to the announcement, subjected to the stock price floor of $45.00 per share), representing a value of $0.2 million.

10. Income Taxes

The Company applied an estimated annual effective tax rate ("ETR") approach for calculating a tax provision for interim periods. The Company recorded a provision for income taxes of $28 thousand and provision for income taxes of $39 thousand for the three months ended March 31, 2020 and 2019, respectively. The Company's ETR was (0.14)% and (0.2)% for the three months ended March 31, 2020, and 2019, respectively. The Company's ETR for the three months ended March 31, 2020 differs from the U.S. federal statutory tax rate of 21% primarily as a result of nondeductible expenses (including the Nellix contingently issuable common stock), state income taxes, foreign income taxes, and the impact of a full valuation allowance on its deferred tax assets.

The Company has evaluated the available evidence supporting the realization of its deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that the domestic and foreign deferred tax assets will not be realized. Due to such uncertainties surrounding the realization of the domestic and foreign deferred tax assets, the Company maintained a valuation allowance against a substantial portion of its deferred tax assets as of March 31, 2020. If and when the Company determines that it will be able to realize some portion or all of its deferred tax assets, an adjustment to its valuation allowance on its deferred tax assets would have the effect of increasing net income in the period(s) such determination is made.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. ASU 2019-12 simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation, the methodology for calculating incomes taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 is effective in 2021 and interim periods within that year, and permits for early adoption. The Company elected to early adopt ASU 2019-12, effective for the quarter ended March 31, 2020, on a prospective approach. Therefore, the Company is no longer applying the exception to the intraperiod tax allocation rules which used to apply when the Company had pre-tax book losses in continuing operations and gains in other components of income.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act also contained modifications on the limitation of business interest for tax years beginning in 2019 and 2020. The modifications to Section 163(j) increase the allowable business interest deduction from 30% of adjusted taxable income to 50% of adjusted taxable income. The Company is currently evaluating the impact of the CARES Act, but at present does not expect that the provisions of the CARES Act would result in a material impact on the financial statement.

11. Restructuring Charges

In the three months ended March 31, 2020 and 2019, the Company recorded $0.0 million and $0.4 million, respectively, in restructuring costs within operating expenses related to focused reductions of its workforce. The Company began substantially formulating plans around this workforce reduction during the first quarter of 2016 in conjunction with its merger of TriVascular Technologies, Inc. The targeted reductions and other restructuring activities were initiated to provide efficiencies and re-align resources as well as to allow for continued investment in strategic areas and drive growth.

In September 2019, the Company continued its restructuring activities including: restructuring certain aspects of its business and operations to re-prioritize its sales and marketing efforts; rationalizing its international presence and related expenses; streamlining its workforce and taking other measures to increase efficiencies; decreasing its cash consumption and decreasing its cost to serve; and refocusing its business on strong execution of its core strategies. The Company determined to streamline and restructure certain of its operations and implement certain management changes. These plans have resulted in significant changes in the composition of the senior management team.

As of March 31, 2020, the Company estimated that it will incur a total of $16.7 million in restructuring charges upon the completion of the plan, of which $16.7 million has already been incurred since the first quarter of 2016.

(all tabular amounts presented in thousands, except share, per share and per unit data, and number of years)

The recognition of restructuring charges requires that the Company make certain judgments and estimates regarding the nature, timing and amount of costs associated with the planned reductions of workforce. At the end of each reporting period, the Company will evaluate the remaining accrued balance to ensure that no excess accruals are retained and the utilization of the provisions are for their intended purpose in accordance with developed plans. The following table reflects the movement of activity of the restructuring reserve for the three months ended March 31, 2020:

	One-time termination benefits
Accrual balance as of December 31, 2019	$ 90
Utilization	(10)
Accrual balance as of March 31, 2020	$ 80

The accrual balance as of March 31, 2020 is classified within accrued expenses and other current liabilities on the Company's Condensed Consolidated Balance Sheet.

12. Subsequent Events

PPP Loan

On May 5, 2020, the Company entered into a promissory note (the "Promissory Note") with Bank of America, N.A., dated May 1, 2020, that provides for a loan in the amount of $9.8 million (the "PPP Loan") pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). The PPP Loan matures on May 5, 2022 and bears interest at a rate of 1.0% per annum. Monthly amortized principal and interest payments are deferred for six months after the date of disbursement. The Promissory Note contains events of default and other provisions customary for a loan of this type. The Paycheck Protection Program provides that the use of PPP Loan amount shall be limited to certain qualifying expenses. All or a portion of the PPP Loan may be forgiven upon application by the Company beginning 60 days, but not later than 120 days, after loan approval and upon documentation of expenditures in accordance with certain specified requirements. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight week period beginning on the date of loan approval. Not more than 25% of the forgiven amount may be for non-payroll costs. The amount of the PPP Loan eligible to be forgiven will be reduced if the Company's full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. The Company will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above. The Company intends to apply for forgiveness of a portion of the loan in accordance with the terms of the CARES Act to the extent applicable.

Additionally, on May 5, 2020, the Company entered into the Amendment to Facility Agreements, dated as of May 4, 2020, among the Company, the guarantors party thereto, the lenders party thereto, Deerfield ELGX Revolver, LLC and Deerfield Private Design Fund I.V., L.P. (the "Amendment"). The Amendment amends the Credit Agreement, dated August 9, 2018, by and among the Company, certain of its subsidiaries, the lenders party thereto and Deerfield ELGX Revolver, LLC and amends the Term Loan Facility Agreement, dated as of August 9, 2018, among the Company, certain of its subsidiaries, the lenders party thereto and Deerfield Private Design Fund I.V., L.P., as amended from time to time, to permit the company to incur indebtedness in the form of the PPP Loan.

Deerfield Forbearance Agreements

On May 26, 2020, we entered into forbearance agreements with Deerfield which provide that Deerfield will not exercise its default rights under the Facility Agreements until June 15, 2020 or earlier upon certain conditions. If the event that we are unable to reach an agreement with Deerfield prior to expiration of the forbearance, or if we are unable to extend the forbearance, Deerfield may exercise its default rights under the Facility Agreements. As of March 31, 2020, we had approximately $180.4 million outstanding under the Deerfield Agreements. Additionally, we would be required to pay exits fees totaling $11.1 million under the Facility Agreement and the remaining $0.1 million commitment fee under the Credit Agreement. If Deerfield were to exercise its default rights, such default would result in a cross default under our 5.00% Notes and our 5.00% Voluntary Notes. As of March 31, 2020, we had $62.0 million outstanding under our 5.00% Notes and $11.1 million outstanding under our 5.00% Voluntary Notes.

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

Special Note Regarding Forward-Looking Statements

In addition to historical information, 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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward looking statements are intended to qualify for the safe harbor established by the Private Securities Litigation Reform Act of 1995. You can identify forward-looking statements by the use of forward-looking terminology such as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should" or "will" or the negative of these terms or other comparable terminology, or by discussions of strategies, opportunities, plans or intentions. In addition, any statements that refer to projections of our future financial performance, trends in our businesses, or other characterizations of future events or circumstances are forward-looking statements. We have based these forward-looking statements largely on our current expectations based on information currently available to us and projections about future events and trends affecting the financial condition of our business. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These 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. Actual results could differ materially from those projected in forward-looking statements as a result of the following factors, among others:

- continued market acceptance, use and endorsement of our products;
- quality control problems with our products;
- consolidation in the health care industry;
- the success of our clinical trials relating to products under development;
- our ability to grow and maintain strong relationships with certain key physicians;
- continued growth in the number of patients qualifying for treatment of abdominal aortic aneurysms ("AAA") through our products;
- our ability to effectively compete with the products offered by our competitors;
- the level and availability of third party payor reimbursement for our products;
- our ability to effectively develop new or complementary products and technologies;
- our ability to manufacture our endovascular systems to meet demand;
- our ability to grow product revenues;
- changes to our international operations including currency exchange rate fluctuations;
- our ability to effectively manage our business and keep pace with our anticipated growth;
- our ability to develop and retain a direct sales force in the United States and select European countries;
- the nature of and any changes to domestic and foreign legislative, regulatory and other legal requirements that apply to us, our products, our suppliers and our competitors;
- the timing of and our ability to obtain and maintain any required regulatory clearances and approvals;
- our ability to protect our intellectual property rights and proprietary technologies;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- product liability claims;
- pending and future litigation;
- reputational damage to our products caused by the use, misuse or off-label use of our products or government or voluntary recalls of our products;
- our utilization of single source suppliers for specialized components of our product lines;
- our ability to attract, retain, and motivate qualified personnel;
- our ability to make future acquisitions and successfully integrate any such future-acquired businesses;
- our ability to maintain adequate liquidity to fund our operational needs and research and developments expenses;
- our ability to identify and manage risks; and
- general macroeconomic and world-wide business conditions.

Our actual results, performance or achievements may differ materially from any future results, performance or achievements expressed or implied from such forward-looking statements. Important factors that could cause our actual results, performance or achievements to differ materially from our expectations are disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission ("SEC") on March 11, 2020, and in this Quarterly Report on Form 10-Q for the fiscal period ended March 31, 2020, including but not limited to those factors discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors," "Consolidated Financial Statements" and "Notes to Consolidated Financial Statements." All subsequent written and oral forward-looking statements attributable to us or by persons acting on our behalf are expressly qualified in their entirety by these cautionary statements.

Our forward-looking statements speak only as of the date each such statement is made. We expressly disclaim any intention or obligation to update or revise any financial projections or any forward-looking statements after the date hereof to conform such statements to actual results or to changes in our opinions or expectations, except as required by applicable law or the rules and regulations of the SEC and The NASDAQ Stock Market, LLC.

Overview

Our Business

We develop, manufacture, market and sell innovative medical devices for the treatment of aortic disorders. Our products are intended for the minimally invasive endovascular treatment of AAA. Our AAA products are built on one of two platforms:

- Traditional minimally-invasive endovascular aneurysm repair ("EVAR"); or
- Endovascular aneurysm sealing ("EVAS"), our innovative solution for sealing the aneurysm sac while maintaining blood flow.

Our current EVAR products include the AFX® Endovascular AAA System ("AFX System"), the VELA® Proximal Endograft ("VELA"), and the Ovation® Abdominal Stent Graft System ("Ovation System"). Our current EVAS product is the Nellix® Endovascular Aneurysm Sealing System ("Nellix EVAS System"). We sell our products through a direct sales force in the United States and internationally through a combination of direct sales and a network of third party distributors and agents.

See Item 1 of the Annual Report, entitled "Business," for a discussion of:

- Market Overview and Opportunity
- Our Products
- Product Developments and Clinical Trials
- Manufacturing and Supply
- Marketing and Sales
- Competition

When used in this Quarterly Report on Form 10-Q, "we," "our," "us" or "Endologix," refer to Endologix, Inc. and our consolidated subsidiaries, unless otherwise expressly stated or the context otherwise requires. Endologix®, AFX®, Duraply®, VELA®, IntuiTrak®, ActiveSeal®, Nellix®, Ovation®, Ovation Prime®, Ovation Alto®, and CustomSeal® are registered trademarks of Endologix, Inc. or its subsidiaries.

The Nellix® EndoVascular Aneurysm Sealing System has a CE Mark and is an investigational device in the United States. The Ovation Alto® System has obtained FDA approval in the United States and is presently an investigational device in the EU.

Impact of COVID-19 Pandemic

During the first quarter of 2020, we were subject to challenging social and economic conditions created as a result of the novel strain of coronavirus, SARS-CoV-2 ("COVID-19"). The resulting impact of the COVID-19 outbreak created various financial impacts to our operations as a result of taking necessary precautions for essential personnel to operate safely both in person as well as remotely. Cost incurred include items like incremental payroll costs, consulting support, IT infrastructure and facilities related costs.

The extent of the impact of the COVID-19 outbreak on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on our customers and our sales cycles, employee or industry events, and effect on our vendors, all of which are uncertain and cannot be predicted. To date, we have experienced a number of deferred or cancelled procedures as a result of the strain put on the healthcare system. There can be no assurances these procedures will be rescheduled when healthcare systems normalize. We may experience constrained supply or curtailed customer demand that could materially adversely impact our business, results of operations and overall financial performance in future periods. Specifically, we may experience impact from changes in how we and companies worldwide conduct business due to the COVID-19 pandemic, including but not limited to restrictions on travel and in-person meetings, production delays, closures of manufacturing facilities, warehouses and logistics supply and distribution chains and staffing shortages, decreases or delays in customer demand and spending, difficulties or changes to our sales process and customer support. As of the filing date of this Form 10-Q, the extent to which COVID-19 may impact our financial condition or results of operations or guidance is uncertain. The effect of the COVID-19 pandemic will not be fully reflected in our results of operations and overall financial performance until future periods. See Risk Factors for further discussion of the possible impact of the COVID-19 pandemic on our business.

Highlights of Our Product Development Initiatives, Clinical Trials and Regulatory Approvals

Overview

Our focus is to continually develop innovative and cost-effective medical devices for the treatment of aortic disorders. We believe that our ability to develop new technologies is key to our future growth and success. Historically, we have focused on developing our EVAR and EVAS products to treat infrarenal AAA, including initial development of products to treat complex AAA anatomies. However, we expect to devote more resources in the future to developing, enhancing and obtaining expanded indications for our current EVAR and EVAS products and to develop new product indications to treat more complex anatomies. We have the following trials in process to build independent and collective clinical and economic evidence of clinical safety and effectiveness:

Nellix EVAS System

Our Nellix EVAS System is designed to seal the aneurysm and provide blood flow to the legs through two blood flow lumens. The Nellix EVAS System consists: of (i) bilateral covered stents with endobags; (ii) a biocompatible polymer injected into the endobags to seal the aneurysm; and (iii) a delivery system and associated accessories. The Nellix EVAS System is intended to seal the entire aneurysm sac effectively excluding the aneurysm and reducing the likelihood of future aneurysm rupture. We have the following trials in process to build independent and collective clinical and economic evidence of clinical safety and effectiveness:

- *EVAS FORWARD Investigational Device Exemption ("IDE").* We conducted this pivotal clinical trial to evaluate the safety and effectiveness of the Nellix EVAS System. This study is a prospective single arm registry which enrolled 179 patients at 29 centers in the United States and Europe. In November 2014, we completed enrollment in the study, and we submitted the one year results to the United States Food and Drug Administration ("FDA") in March 2016. In May 2016, we announced the results of the one-year clinical data from the EVAS FORWARD IDE study that demonstrate that the Nellix EVAS System met the study primary endpoints for major adverse events at 30 days (safety) and treatment success at one year (effectiveness). Two-year imaging revealed a signal of migration, leading to a field safety notification issued in October 2016 and a dedicated root cause analysis, resulting in refinements to the IFU. Following the implementation of the refined IFU, the Nellix EVAS system is applicable to treat an estimated 40% of AAA patients with a traditional aneurysm.

Subsequently, the two-year results from the trial were published in the Journal of Vascular Surgery in March 2018. This data was previously announced in June 2017 at the Society of Vascular Surgery Vascular Annual Meeting ("VAM"). Key highlights from the Nellix United States IDE trial two-year clinical data are included below:

- Freedom from all endoleaks (95.1%), rupture (99.4%) and all-cause mortality (93.8%) among all patients.
- Highest freedom of type II endoleaks, ever reported at two years (96.6%) among all patients.
- When applying the refined IFUs for Nellix, patients at the two-year follow up demonstrated 95.9% freedom from Type IA endoleak, migration >10mm, and sac growth.

- *EVAS2 IDE.* In May 2017, we announced the decision to seek FDA approval of the Nellix EVAS System by conducting a confirmatory clinical study with the refined IFU and the Company's next generation Nellix device design, the "Nellix 3.5 EVAS System." The Nellix 3.5 EVAS System incorporates design improvements to enhance ease of use and offers physicians more sizes to treat more patients with AAA. In October 2017, we announced our receipt of IDE approval from the FDA to commence a confirmatory clinical study to evaluate the safety and effectiveness of the Nellix 3.5 EVAS System for the endovascular treatment of infrarenal AAA. EVAS2 will prospectively evaluate the refined IFU and the Nellix 3.5 EVAS System. The study is approved to enroll up to 105 primary patients, with one-year follow-up data required for the pre-market approval ("PMA") application. We commenced EVAS2 patient enrollment in March 2018 and completed enrollment in May 2020.

- *EVAS FORWARD Global Registry*. This registry is designed to provide real world clinical results to demonstrate the effectiveness and applicability of the Nellix EVAS System. The first phase of the registry included 300 patients enrolled in up to 30 international centers. The first patient in the registry was treated in October 2013, and in September 2014, we announced completion of patient enrollment in the EVAS FORWARD Global Registry. In November 2016, we announced positive two-year results on 300 patients from the EVAS FORWARD Global Registry at the Annual Symposium on Vascular and Endovascular Issues (the "VEITH Symposium"). The following outcomes were presented at the VEITH Symposium:

  - 37% of patients having complex anatomies;
  - 98.1% freedom from any persistent endoleaks at latest follow-up;
  - No secondary interventions for Type II endoleaks;
  - 97.4% freedom from aneurysm-related mortality; and
  - 98.5% freedom from cardiovascular mortality.

In 2017, we commenced the EVAS FORWARD Global Registry 2, a post market evaluation of the Nellix 3.5 EVAS System.

- *ASCEND Registry.* In April 2016, we announced the first data presentation with one-year outcomes from the ASCEND Registry, a physician-initiated registry of the Nellix EVAS System used with aortic branch stent grafts for the treatment of patients with complex AAAs. The results of the study were formally published in the peer-reviewed Journal of Endovascular Therapy in December 2017.

In September 2017, we announced CE Mark approval for the Nellix EVAS System with the refined IFU. The Nellix EVAS System is being studied in the United States under an IDE. Following a thorough review of supporting clinical data, our Notified Body, together with an independent clinical reviewer, determined that the Nellix EVAS System, with the refined IFU, met the applicable safety and clinical performance requirements.

In April 2018, we announced the results of a study, which was presented by Marc Schermerhorn, M.D., Chief of Vascular Surgery at Beth Israel Deaconess Medical Center, at the Late-Breaking Aortic Trials Session during the Charing Cross 40th International Symposium. The results of the study were also formally published in the Annals of Vascular Surgery in October 2019. This retrospective, propensity-weighted study compared long-term survival for the Nellix EVAS System with traditional EVAR. The study reported significantly higher three-year survival for EVAS patients as compared to EVAR patients. Those patients with larger aneurysms (greater than 5.5 cm in diameter) treated with EVAS had half the mortality at three years as compared to those treated with traditional EVAR systems. The retrospective study included 333 EVAS patients from the original Nellix United States IDE Trial and 15,431 patients from the Society for Vascular Surgery Vascular Quality Initiative, all of whom were treated between 2014 and 2016. The patients were propensity weighted for AAA size, patient demographics, and cardiovascular risk factors. The primary outcome was overall survival, with a secondary analysis of overall survival stratified by aneurysm size.

In January 2019, we announced that in order to ensure optimal outcomes for patients, the Nellix EVAS System will, for the foreseeable future, only be available for use at approved centers outside of the United States in a clinical investigation setting with pre-screened patients that adhere to the current anatomical indications for use. All cases will be pre-screened by a physician panel to ensure adherence to protocol and use in accordance with current product indications. Compassionate use requests will be reviewed in accordance with the process established by us and associated national competent authorities. The existing inventory has been voluntarily recalled.

In January 2019, we announced that the CE Mark for the Nellix EVAS System had been suspended by our Notified Body following a voluntary recall and field safety notification issued by us on January 4, 2019. Suspension of the CE Mark means that we may not affix the CE Mark and sell the Nellix EVAS System in the European Union ("EU") during the term of the suspension.

In June 2019, we announced that the CE Mark for the Nellix EVAS System had been reinstated by GMED, the EU Notified Body for the Nellix EVAS System. The reinstatement followed an assessment of clinical evidence.

In August 2019, we announced that we have received IDE approval from the FDA to commence a new pivotal study to evaluate the safety and effectiveness of the Nellix Chimney EndoVascular Aneurysm Sealing System ("ChEVAS") for the endovascular treatment of complex AAA. The ChEVAS system is an endovascular AAA therapy designed to combine the Nellix 3.5 endograft with parallel visceral stents to enable treatment of patients with juxta-renal, para-renal, and suprarenal AAA. The application of EVAS for patients with complex aneurysms is expected to offer innovative new technology to a group of patients that are underserved by the current standard of care.

AFX System and VELA

The AFX System, which is comprised of AFX and AFX2 (discussed in further detail below), consists of: (i) a cobalt chromium alloy stent covered by expanded polytetrafluoroethylene (commonly referred to as ePTFE) graft material; and (ii) accompanying delivery systems. Once fixed in its proper position on the abdominal aortic bifurcation, the AFX System provides a conduit for blood flow, thereby relieving pressure within the weakened or "aneurysmal" section of the vessel wall, which greatly reduces the potential for the AAA to rupture. In February 2014, we launched a new proximal extension in the United States, VELA, designed to be used in conjunction with our AFX bifurcated device. VELA features a circumferential graft line marker and controlled delivery system that enable predictable deployment and final positional adjustments. We began a commercial introduction of VELA in Europe in January 2015.

In September 2014, we announced a new clinical study called Looking at EVAR Outcomes by Primary Analysis of Randomized Data ("LEOPARD"). This study was designed to compare outcomes of the AFX System versus other commercially available EVAR devices. We designed the LEOPARD study to randomize and enroll at least 400 patients at up to 80 leading centers throughout the United States and commenced enrollment in the first quarter of 2015. The centers were a mix of our current and new customers, with each investigator selecting one competitive device to randomize against the AFX System. The LEOPARD study is being led by an independent steering committee of leading physicians who are responsible for presenting the results over the 5-year follow-up period.

Positive results from LEOPARD were presented at the VEITH Symposium in November 2019. Based on those who completed follow-up, the one-year freedom from Aneurysm Related Complications ("ARC") shows that overall the AFX System has a comparable performance to other devices. Analysis of individual clinical outcomes suggests that different EVAR approaches may have advantages in different patient populations. The AFX System remains the only device that preserves the patient's aortic bifurcation.

In December 2015, we announced that the AFX System for the treatment of AAA received Shonin approval from the Japanese Ministry of Health, Labor and Welfare ("MHLW").

In February 2016, we announced the completion of the first United States commercial implant of AFX2, which reduces procedure steps for the delivery and deployment of the bifurcated endograft. AFX2 also facilitates peripheral EVAR, ("PEVAR"), by providing the lowest profile contralateral access through a 7F introducer. These improvements bring together our ActiveSeal® technology, DuraPly® PTFE graft material and VELA, into an integrated new EVAR system.

In December 2016, we received notice from our Notified Body that the CE Mark for AFX and AFX2 would be suspended due to reports of Type III endoleaks with AFX with Strata graft material ("AFX Strata"), a prior generation of the AFX device. For our current generation of AFX products, we had implemented device and graft material improvements and updated IFUs resulting in a substantial reduction in reported Type III endoleaks. We provided documentation of the foregoing reduction in Type III endoleaks to our Notified Body. In January 2017, we received notice from our Notified Body that the CE Mark for AFX and AFX2 had been reinstated, effective immediately.

Additionally, in December 2016, we placed a temporary hold on shipments of AFX and AFX2 to complete an investigation of quality concerns with some sizes of these devices. Subsequently, we removed the temporary hold and resumed shipments of all sizes of AFX and the smaller diameter sizes of AFX2 and initiated a voluntary recall: of (i) the small remaining quantity of original AFX Strata; and (ii) the larger diameter sizes of AFX2. In January 2017, we removed the temporary hold and resumed shipments of the remaining larger diameter sizes of AFX2.

In July 2018, we sent a voluntary safety notice ("Safety Notice") to healthcare professional ("HCP") users of the AFX System to provide updated information on comparative AFX Type III endoleak rates, patient-tailored surveillance recommendations, and recommendations for intervening through an AFX device or re-intervening on an AFX device. No product was removed from the field as part of that safety update action.

In October 2018, the FDA classified the July 2018 Safety Notice as a Class I recall. The FDA defines a Class I recall as including a firm's correction of a marketed product in circumstances where there is a reasonable probability that use of or exposure to the device would cause serious adverse health consequences or death.

The clinical conditions resulting in this Class I recall classification (Type III endoleaks) are principally related to AFX with Strata material. The AFX with Strata material was replaced by AFX incorporating the DuraPly material in both AFX and AFX2 devices. Strata was last manufactured in 2014, last sold in 2016, and removed from global inventories in the first half of 2017. There is no AFX with Strata product remaining in any commercial market.

No product return is required under this recall, and no further action by HCPs were required in addition to the Safety Notice. The guidance provided in the July 2018 Safety Notice remains current.

On October 8, 2019, our AFX2 product received a 3-year shelf-life approval from the FDA. On October 28, 2019, the FDA issued a safety update pertaining to our AFX system, in which the FDA referenced data from an integrated healthcare system (Rothenberg et. al.), published in a conference abstract and presented at American College of Surgeons Clinical Congress 2019 on October 28, 2019. The FDA interpreted such data as suggesting that there "may be a higher than expected risk of Type III endoleaks occurring with the use of AFX with Duraply and AFX2 endovascular grafts." Both we and the FDA noted meaningful limitations in the referenced data, including with respect to our currently commercially available AFX2 system. We are assessing the referenced data and comparing them to our own multiple data sets, including data from the LEOPARD trial (the only randomized controlled trial of EVAR providing the highest level evidence on AFX Duraply and AFX2 systems), real-world data from a vascular registry, our benchmarked complaint data, and meta-analyses of current literature. The FDA safety update does not constitute a recall or correction to the AFX System, including the AFX2 system.

Ovation System

The Ovation System consists of: (i) a radiopaque nitinol suprarenal stent with integral anchors; (ii) a low-permeability polytetrafluoroethylene ("PTFE"), aortic body graft that contains a network of inflatable rings filled with a liquid polymer that solidifies during the deployment procedure; (iii) nitinol iliac limb stents encapsulated with PTFE; and (iv) accompanying ultra-low profile delivery systems, auto injector and fill polymer kit. The Ovation System creates a custom seal that conforms to anatomical irregularities and has a ultra-low profile delivery system allowing for percutaneous access.

In May 2011, we initiated a 3-year European Post-Market Registry to enroll 500 patients across 30 European centers. Enrollment ended in December 2013. In January 2017, we announced positive 3-year results from the Ovation EU Post-Market Registry. The data was presented at the 2017 Leipzig Interventional Course ("LINC") meeting and showed that the Ovation System has the broadest range of patient applicability on IFU of all commercially available infrarenal endovascular AAA devices. The resulting outcomes included:

- 99% freedom from aneurysm-related mortality;
- 99% freedom from migration, rupture, and conversion;
- 97% freedom from Type I/III endoleak; and
- Excellent freedom from secondary intervention for occlusion (97%), Type I endoleak (97%) and Type II endoleak (95%).

In October 2014, we initiated the LIFE Study to illustrate the potential advantages of a "Fast Track" protocol including PEVAR, no general anesthesia, no time in ICU and a one-night stay in the hospital with the Ovation System. In May 2016, we announced the completion of enrollment of 250 patients at 34 sites participating in the LIFE Study. In February 2018, the results of the one-month clinical data from the LIFE Study were published in the Journal of Endovascular Therapy. These results demonstrate that the Ovation System met the study primary endpoint for major adverse events at 30 days. The following are highlights of the publication, with outcomes covering one-month follow-up:

- Low major adverse event rate of 0.4%;
- No ruptures, conversion, or secondary interventions;
- No type III endoleaks and low Type I endoleaks (0.4%);
- Fast-Track completed in 216 patients (87%), with positive results compared to non-Fast-Track patients;
- Procedure time of 84 minutes vs. 110 minutes;
- General anesthesia use 0% vs. 18%;
- ICU stay 0% vs. 32%; and
- Mean hospital stay 1.2 days vs. 1.9 days.

In August 2015, we enrolled the first subject in the LUCY Study, a multi-center post-market registry designed to explore the clinical benefits associated with EVAR using the Ovation System in female patients with AAA, as compared to males. This was the first prospective study evaluating EVAR in females, a population that has historically been underrepresented in EVAR clinical trials. We announced completion of enrollment of 225 patients in the LUCY Study in February 2017. The 30-day LUCY data showed that, in women, the ultra-low profile (14F) Ovation System device resulted in:

- At least 28% greater EVAR eligibility for women with AAA;
- 1.3% major adverse events;
- No deaths;
- No proximal endoleaks;
- No limb occlusion;
- Low readmission rate of 3.9%; and
- 100% procedural success.

In June 2018 at the VAM, the 1-year results of the LUCY Study were announced in the late-breaking clinical trial session. Despite having more complex anatomies at the time of the index procedure women continue to demonstrate similar outcomes to men through one year. The 1-year outcomes of freedom from conversion, rupture, AAA-related mortality and device-related reintervention were similar between the two arms.

In February 2015, the FDA approved the next generation Ovation iX Iliac Stent Graft for the Ovation System, and in July 2015, the FDA approved the Ovation iX Abdominal Stent Graft System. In September 2015, the first patients were treated with the Ovation iX Abdominal Stent Graft System in Europe, and in August 2015, we initiated the launch of the Ovation iX System in the United States.

In November 2016, we announced at the VEITH Symposium that the 5-year results from the Ovation Global Pivotal Trial were positive and showed the following outcomes:

- Broad patient applicability, with 40% of the patients treated outside the labeled indications of other EVAR devices;
- Stable aortic neck diameters with an average expansion of 0.1mm, compared to 5.3mm as reported with other EVAR devices;
- 96.6% freedom from secondary interventions related to type I endoleak; and
- No migration or conversions.

In August 2016, we announced that the first two patients had been treated with Ovation Alto, which is the newest device in the Ovation System platform of abdominal stent graft systems. Ovation Alto is an investigational device, currently not approved in any market. It expands EVAR to include the treatment of patients with complex AAAs, specifically patients with very short or otherwise complex aortic neck anatomy. This is achieved by the conformable O-rings with CustomSeal® polymer that have been repositioned near the top of the endograft, providing seal just below the renal arteries. In November 2016, we received IDE approval from the FDA to conduct a clinical study with Ovation Alto in the United States.

In March 2017, we announced the enrollment of the first patients in the Expanding Patient Applicability with Polymer Sealing Ovation Alto Stent Graft (“ELEVATE”) IDE clinical study, our pivotal clinical trial to evaluate the safety and effectiveness of Ovation Alto for the repair of infrarenal AAAs. The ELEVATE IDE clinical trial is approved to enroll 75 patients at up to 16 centers in the United States. In February 2018, we announced the final patient enrollment in the ELEVATE IDE clinical study.

In September 2019 and December 2019, the Effectiveness of Custom Seal with Ovation: Review of Evidence (“ENCORE,”) reports regarding the study of polymer endovascular aneurysm repair (“Polymer EVAR”) using Ovation System were published in the Journal of Vascular Surgery. ENCORE is a pooled retrospective analysis of the 5 prospective clinical trials and registries and encompasses 1,296 patients, nearly 160 centers and over 200 investigators in the United States, Europe and Latin America. The studies within ENCORE had predefined follow-up periods ranging from 1 month to up to 5 years, and across the studies the median follow up was greater than 2 years. At 5 years, the ENCORE analysis included the following results for the Ovation System based on the available data:

- 99% freedom from AAA-related mortality;
- 99% freedom from conversion;
- 99% freedom from rupture;
- 98% freedom from reintervention for Type Ia endoleak; and
- 93% freedom from all device-related reintervention.

In February 2019, we announced that the Ovation System for the treatment of AAA received Shonin approval from the MHLW.

In March 2020, we announced FDA approval for our Alto Abdominal Stent Graft System. Approval was based on our regulatory submission that includes the ELEVATE IDE clinical study. Pursuant to the terms of approval, the first 100 patients after commercial launch will be included in a post approval imaging study to determine consistency in device selection between Endologix’s internal imaging services and those of the implanting physicians.

Characteristics of Our Revenue and Expenses

Revenue

Revenue is derived from sales of our EVAR and EVAS products (including extensions and accessories) to hospitals upon completion of each AAA repair procedure, or from sales to distributors upon title transfer (which is typically at shipment), provided our other revenue recognition criteria have been met. Our global revenue does not reflect a significant degree of seasonality. However, for our implant-based revenue, the number of medical procedures incorporating our products is generally lower during summer months. We believe that this trend may be due to the summer holiday season in Europe and the United States.

Cost of Goods Sold

Cost of goods sold primarily consists of compensation (including stock-based compensation) and benefits of production personnel and production support personnel. Cost of goods sold also includes depreciation expense for production equipment, amortization of developed technology, production materials and supplies expense, allocated facilities-related expenses, and certain direct costs such as shipping.

Research and Development

Research and development primarily consist of compensation (including stock-based compensation) and benefits for research and development personnel, materials and supplies, research and development consultants, outsourced and licensed research and development costs, and allocated facilities-related costs. Our research and development activities primarily relate to the development and testing of new devices and methods to treat aortic disorders.

Clinical and Regulatory

Clinical and regulatory expenses primarily consist of compensation (including stock-based compensation) and benefits for clinical and regulatory personnel, regulatory and clinical payments related to studies, regulatory costs related to registration and approval activities, and allocated facilities-related costs. Our clinical and regulatory activities primarily relate to obtaining regulatory approval for the commercialization of our devices.

Marketing and Sales

Marketing and sales expenses primarily consist of compensation (including stock-based compensation) and benefits for our sales force, clinical specialists, internal sales support functions and marketing personnel. It also includes costs attributable to marketing our products to our customers and prospective customers.

General and Administrative

General and administrative expenses primarily consist of compensation (including stock-based compensation) and benefits for personnel that support our general operations such as information technology, executive management, financial accounting, and human resources. General and administrative expenses also include bad debt expense, patent and legal fees, financial audit fees, insurance, recruiting fees, other professional services and allocated facilities-related expenses.

Results of Operations

In December 2019, a novel strain of coronavirus, which causes COVID-19, was identified. Due to the rapid and global spread of the virus, on March 11, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. To slow the proliferation of COVID-19, governments have implemented extraordinary measures, which include the mandatory closure of businesses, restrictions on travel and gatherings, and quarantine and physical distancing requirements. In addition, in March 2020, the U.S. Surgeon General and the American College of Surgeons issued guidance advising that elective surgical procedures be curtailed or deferred and hospitals in the U.S. and globally have, to varying degrees, suspended elective surgeries. While certain abdominal aortic aneurysm procedures treating larger-diameter or ruptured aneurysms are deemed essential and certain surgeries, like in cases of trauma, cannot be delayed, we are seeing a significant reduction in procedural volumes as hospital systems and/or patients elect to defer abdominal aortic aneurysm procedures with smaller-diameter, less-severe aneurysms. As a result of these measures, we have experienced substantial reductions in procedural volumes and anticipate this trend will continue during the pandemic. In addition, restrictions on the ability to travel as well as the temporary closures of our facilities and the facilities of our suppliers has adversely affected our business. Further, due to the travel restrictions and physical distancing requirements, the Company has been limited in its ability to train and educate surgeons on the Company’s surgical techniques and products, which may impact its ability to scale demand once healthcare services return to normal. These restrictions have also impacted the Company’s manufacturing capabilities and distribution and warehousing operations as it reduces capacity and implements policies to prioritize the health and safety of employees and contractors.

Although the cumulative impact of these disruptions has had a significant impact on our business, as of the date of this filing, due to uncertainties regarding the duration and scope of the current COVID-19 pandemic, the Company cannot predict the specific extent to which the COVID 19 pandemic will have on its business and financial results.

Operations Overview - Three Months Ended March 31, 2020 versus 2019

The following table presents our results of continuing operations and the related percentage of the period's revenue (in thousands, except percentages):

	Three Months Ended March 31,			
	2020		2019	
Revenue	$ 28,510	100.0 %	$ 35,606	100.0 %
Cost of goods sold	13,378	46.9 %	12,407	34.8 %
Gross profit	15,132	53.1 %	23,199	65.2 %
Operating expenses:				
Research and development	3,536	12.4 %	4,787	13.4 %
Clinical and regulatory affairs	3,165	11.1 %	3,785	10.6 %
Marketing and sales	14,496	50.8 %	16,786	47.1 %
General and administrative	10,119	35.5 %	9,416	26.4 %
Restructuring costs	—	— %	419	1.2 %
Total operating expenses	31,316	109.8 %	35,193	98.8 %
Loss from operations	(16,184)	(56.8)%	(11,994)	(33.7)%
Total other expense, net	(1,904)	(6.7)%	(9,995)	(28.1)%
Net loss before income taxes	(18,088)	(63.4)%	(21,989)	(61.8)%
Income tax expense	(28)	(0.1)%	(39)	(0.1)%
Net loss	$ (18,116)	(63.5)%	$ (22,028)	(61.9)%

Comparison of the Three Months Ended March 31, 2020 versus 2019 `

Revenue

	Three Months Ended March 31,			
	2020	2019	Variance	Percent Change
	(in thousands)			
Revenue	$ 28,510	$ 35,606	$ (7,096)	(19.9)%

United States Sales. Net sales totaled $18.6 million in the three months ended March 31, 2020, a 18.4% decrease from 22.8 million in net sales in the three months ended March 31, 2019, largely driven by the impact case deferrals related to the COVID-19 pandemic.

International Sales. Net sales of products in our international regions totaled $9.9 million in the three months ended March 31, 2020, a 22.7% decrease from $12.8 million in net sales of products in our international regions in the three months ended March 31, 2019. The decrease was primarily driven by product sunsets in Latin America, exit of South Korea and the impact of COVID-19 pandemic.

Cost of Goods Sold, Gross Profit, and Gross Margin

	Three Months Ended March 31,			
	2020	2019	Variance	Percent Change
	(in thousands)			
Cost of goods sold	$ 13,378	$ 12,407	$ 971	7.8 %
Gross profit	15,132	23,199	(8,067)	(34.8)%
Gross margin percentage (gross profit as a percent of revenue)	53.1%	65.2%		

Gross margin percentage for the three months ended March 31, 2020 decreased to 53.1% from 65.2% for the three months ended March 31, 2019. The decrease in gross profit margin was primarily attributable to unfavorable geographic mix and lower volumes in the three months ended March 31, 2020 compared to prior year period.

Operating Expenses

	Three Months Ended March 31,			
	2020	2019	Variance	Percent Change
	(in thousands)			
Research and development	$ 3,536	$ 4,787	$ (1,251)	(26.1)%
Clinical and regulatory affairs	3,165	3,785	(620)	(16.4)%
Marketing and sales	14,496	16,786	(2,290)	(13.6)%
General and administrative	10,119	9,416	703	7.5 %
Restructuring costs	—	419	(419)	(100.0)%

Research and Development. The $1.3 million decrease in research and development expenses for the three months ended March 31, 2020, as compared to the prior year period, was attributable to timing of project spending and prudent expense management.

Clinical and Regulatory Affairs. The $0.6 million decrease in clinical and regulatory affairs expenses for the three months ended March 31, 2020, as compared to the prior year period, was attributable to expense timing and prudent expense management.

Marketing and Sales. The $2.3 million decrease in marketing and sales expenses for the three months ended March 31, 2020, as compared to the prior year period, was attributable to lower sales volume, lower headcount and prudent expense management.

General and Administrative. The $0.7 million increase in general and administrative expenses for the three months ended March 31, 2020, as compared to the prior year period was primarily attributable to higher legal and finance costs associated with debt restructuring.

Restructuring costs. The $0.4 million decrease in restructuring costs for the three months ended March 31, 2020, as compared to the prior year period was attributable to one-time restructuring activities in 2019.

Other Expense, Net

	Three Months Ended March 31,			
	2020	2019	Variance	Percent Change
	(in thousands)			
Other expense, net	$ (1,904)	$ (9,995)	$ 8,091	(81.0)%

Other expense, net of $1.9 million for the three months ended March 31, 2020 consists primarily of interest expense of $10.5 million, foreign currency translation loss of $1.1 million and loss on debt extinguishment of $0.7 million, which was partially offset by income from changes in fair value of derivative liabilities of $10.2 million and fair value of contingent consideration related to the Nellix acquisition of $0.3 million. Other expense. net of $10.0 million for the three months ended March 31, 2019 consists primarily of interest expense of $8.5 million and expense from changes in fair value of derivative liabilities of $2.0 million, which was partially offset by the fair value of contingent consideration related to the Nellix acquisition of $0.2 million.

Income Tax Expense

	Three Months Ended March 31,			
	2020	2019	Variance	Percent Change
	(in thousands)			
Income tax expense	$ (28)	$ (39)	$ 11	<100%

Our income tax expense was $28 thousand and our effective tax rate was (0.14)% for the three months ended March 31, 2020 due to our tax positions in various jurisdictions. During the three months ended March 31, 2020 and 2019, we had operating legal entities in the U.S., Canada, Italy, New Zealand, Poland, Singapore and the Netherlands (including registered sales branches in certain countries in Europe).

Liquidity and Capital Resources

The chart provided below summarizes selected liquidity data and metrics as of March 31, 2020, December 31, 2019 and March 31, 2019:

	March 31, 2020	December 31, 2019	March 31, 2019
	(in thousands, except financial metrics data)		
Cash, cash equivalents and restricted cash	$ 42,235	$ 42,760	$ 10,896
Accounts receivable, net	$ 18,951	$ 22,392	$ 25,991
Total current assets	$ 88,518	$ 93,703	$ 69,961
Total current liabilities	$ 229,157	$ 55,793	$ 44,153
Working capital surplus	$ (140,639)	$ 37,910	$ 25,808
Current ratio	0.4	1.7	1.6
Days sales outstanding (“DSO”)	60	58	65
Inventory turnover	2.1	1.8	1.7

Operating Activities

In the three months ended March 31, 2020, cash used in operating activities was $9.3 million. This was primarily the result of a net loss of $18.1 million, non-cash operating expenses of $2.0 million, and changes in operating assets and liabilities of $6.7 million. In the three months ended March 31, 2019, our operating activities used $13.7 million in cash. This was primarily the result of a net loss of $22.0 million, non-cash operating expenses of $10.9 million, and changes in operating assets and liabilities of $2.6 million.

During the three months ended March 31, 2020 and 2019, our cash collections from customers totaled $31.7 million and $30.6 million, respectively, representing 111.2% and 86.0% of reported revenue for the same periods.

Investing Activities

Cash used in investing activities was $0.1 million for the three months ended March 31, 2020 and March 31, 2019. This consisted of $0.1 million used for machinery and equipment purchases.

Financing Activities

Cash provided by financing activities was $9.1 million for the three months ended March 31, 2020, as compared to cash provided by financing activities of $0.0 million in the prior year period. For the three months ended March 31, 2020, cash provided by financing activities consisted of proceeds from our revolving line of credit of $10.5 million, which was offset by $1.4 million used in deferred financing costs.

Credit Arrangements

See Note 6 of the Notes to the Condensed Consolidated Financial Statements for a discussion of our credit arrangements.

Future Capital Requirements

We believe that the future growth of our business will depend upon our ability to successfully develop new technologies for the treatment of aortic disorders and successfully bring these technologies to market. We expect to incur significant expenditures in completing product development and clinical trials for our products.

The timing and amount of our future capital requirements will depend on many factors, including:

- the need for working capital to support our sales growth;
- the need for additional capital to fund future development programs;
- the need for additional capital to fund strategic acquisitions;
- our requirements for additional facility space or manufacturing capacity;
- our requirements for additional information technology infrastructure and systems; and
- adverse outcomes from potential litigation and the cost to defend such litigation.

We have limited capital resources and expect to incur further losses for the foreseeable future. The Company’s recurring operating losses, net operating cash flow deficits, and an accumulated deficit, raise substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of the accompanying consolidated financial statements. We presently have several operating subsidiaries outside of the United States. As of March 31, 2020, these subsidiaries held an aggregate of $4.5 million in foreign bank accounts to fund their local operations. These balances related to undistributed earnings, are deemed by management to be permanently reinvested in the corresponding countries in which our subsidiaries operate. Management has no present or planned intention to repatriate foreign earnings into the United States and may have to repatriate any foreign earnings to meet those needs, we would then need to accrue, and ultimately pay, incremental income tax expenses on such “deemed dividend,” unless we then have sufficient net operating losses to offset this potential tax liability.

We will require additional capital to sustain our operations and make the investments we need to execute upon our business plan. If we are unable to generate sufficient revenue from our existing business plan, we will need to obtain additional equity or debt financing. Further, the COVID-19 outbreak has negatively impacted the global economy and financial markets which could interfere with our ability to access financing. If we attempt to obtain additional debt or equity financing, we cannot assume that such financing will be available on favorable terms, if at all. Further, it may cause substantial dilution (in the case of an equity financing), or may contain burdensome restrictions on the operation of our business (in the case of debt financing). Lastly, if we are not able to obtain required financing, we may need to curtail our operations and/or our planned product development.

Contractual Obligations

Contractual obligation payments by year with initial terms in excess of 1 year were as follows as of March 31, 2020 (in thousands):

		Payments due by period						
	Total	Remainder of 2020	2021	2022	2023	2024	2025	Thereafter
Debt obligations	$ 272,889	$ 250	$ 22,951	$ 83,591	$ 92,970	$ 73,127	$ —	$ —
Interest on debt obligations	39,089	8,532	12,645	10,052	6,003	1,857	—	—
Operating lease obligations	29,080	2,888	3,939	3,992	3,015	2,908	2,905	9,433
Purchase commitments	1,087	$ 249	$ 838	—	—	—	—	—
Total	$ 342,145	$ 11,919	$ 40,373	$ 97,635	$ 101,988	$ 77,892	$ 2,905	$ 9,433

Debt obligations includes interest payable in kind on our term loan facility and a $11.1 million exit fee under our credit facility agreement with affiliates of Deerfield Management Company, L.P. (collectively, “Deerfield”). Interest on debt obligations includes interest on the 5% convertible notes, which shall be paid, at the Company's option, either in cash or, if certain terms are met in accordance with the 5% convertible notes indentures, shares of common stock or paid in kind. See Note 6 of the Notes to the Condensed Consolidated Financial Statements for a discussion of long-term debt obligations and Note 8(a) of the Notes to the Condensed Consolidated Financial Statements for a discussion of operating lease obligations.

Due to the substantial doubt about the Company’s ability to continue operating as a going concern, the Company is in default under the Facility Agreement and Credit Agreement with its lender, Deerfield. We have entered into forbearance agreements with Deerfield which provide that Deerfield will not exercise its default rights under the Facility Agreements until June 15, 2020 or earlier upon certain conditions. If Deerfield were to exercise its default rights, such default would result in a cross default under the Company’s 5.00% Notes and 2020 5.00% Voluntary Notes. If Deerfield were to exercise its default rights, other lenders may then declare a default and the Company may be unable to repay the amounts owed without raising additional capital. If the Company is unable to repay the amounts owed, it may be forced to declare bankruptcy. Therefore, the entire amount of borrowings of $135.6 million from Deerfield and the $32.1 million 5% Notes and 2020 5.00% Voluntary Notes as at March 31, 2020 has been classified as current in these financial statements. Further, the Company would be required to pay exit fees totaling $11.1 million under the Facility Agreement and the remaining $0.1 million commitment fee under the Credit Agreement. Deerfield has not declared a default.

Off-Balance Sheet Arrangements

Other than the purchase commitments described above, we do not have any off-balance sheet arrangements as of March 31, 2020.

Critical Accounting Policies and Estimates

We have prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States (“GAAP”). The preparation of the financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the periods presented. Management evaluates its estimates on an ongoing basis, including those related to: (i) the collectibility of customer accounts; (ii) whether the cost of inventories can be recovered; (iii) the value of goodwill and intangible assets; (iv) the realization of tax assets and estimates of tax liabilities; (v) the likelihood of payment and the value of contingent liabilities; and (vi) the potential outcome of litigation. Such estimates are based on management’s judgment which takes into account historical experience and various assumptions. Nonetheless, actual results may differ from management’s estimates.

See Part II, Item 7 of the Annual Report for a discussion of our critical accounting policies and estimates. There have been no other material changes in our critical accounting policies and estimates from those disclosed in the Annual Report.

The price of our common stock has declined significantly and may continue to fluctuate in future periods. Fluctuations in our stock price may negatively affect the liquidity of our common stock, which could further adversely impact our stock price. If the recent negative volatility of our market capitalization is sustained, we may perform impairment tests more frequently and it is possible that our goodwill could become impaired, which could result in a material charge and adversely affect our results of operations. To date, we have not recorded any impairment charges.

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. The new guidance modifies the disclosure requirements on fair value measurements. The Company adopted this standard on January 1, 2020, and adoption of this standard did not have a material impact on the Company's consolidated financial statement presentation or results.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC are not expected to have a material effect on our consolidated financial statements.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We do not believe that we currently have material exposure to interest rate or foreign currency transaction risks.

Interest rate risk. We are exposed to market risk for changes in interest rates applicable to our credit facility agreement with Deerfield. Any outstanding principal under the credit facility will accrue interest at a rate equal to the London Interbank Offered Rate (with a 1% floor) plus 5.50%, payable in cash. The interest rate will accrue on a minimum amount of $9.75 million, whether or not such amount is drawn. As of March 31, 2020, we had $10.5 million outstanding under our credit facility.

The remainder of our debt, which is comprised of a term loan facility, convertible senior notes and other note payable, bear fixed interest, and therefore, would not be subject to interest rate risk. For a complete summary of our debt, see Note 6 of the Notes to the Condensed Consolidated Financial Statements.

Foreign currency transaction risk. While a majority of our business is denominated in the United States dollar, a portion of our revenue and expenses are denominated in foreign currencies. Fluctuations in the rate of exchange between the United States dollar and the Euro or the British Pound Sterling may affect our results of operations and the period-to-period comparisons of our operating results. Foreign currency transaction gains and losses are caused by transactions denominated in a currency other than our or our respective subsidiaries' functional currency and must be remeasured at each balance sheet date or upon settlement. Realized and unrealized foreign exchange gains and losses resulted in approximately $1.1 million of gains during the three months ended March 31, 2020, primarily related to intercompany payables and receivables associated with our European operations. We expect to continue to limit our exposure through future settlements.

Item 4. CONTROLS AND PROCEDURES.

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures, as of the end of the period covered by this Quarterly Report on Form 10-Q, were effective to ensure 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 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. LEGAL PROCEEDINGS

Refer to Note 8(c) of the Notes to the Condensed Consolidated Financial Statements for a discussion of our legal proceedings.

We are from time to time involved in various other legal proceedings, most of which are routine litigation in the normal course of our business. We believe that the resolution of the legal proceedings in which we are involved will not have a material adverse effect on our financial position or results of operations.

Item 1A. RISK FACTORS

Before deciding to invest in our company, or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and other reports we have filed with the SEC. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, may also affect our business operations. If any of these risks are realized, our business, financial condition, or results of operations could be seriously harmed and, in that event, the market price for our common stock could decline and you may lose all or part of your investment.

These risk factors should be considered in connection with evaluating the forward-looking statements contained in the Quarterly Report on Form 10-Q. These factors could cause actual results and conditions to differ materially from those projected in our forward-looking statements.

Risks Related to Our Business

We have limited capital resources and will likely need additional funding before we are able to achieve profitability. If we are unable to raise additional capital on attractive terms, or at all, we may be unable to sustain our operations.

We have limited capital resources and expect to incur further losses for the foreseeable future. In particular our revenues have significantly declined as a result of the COVID-19 pandemic. A significant percentage of our products are utilized in elective surgeries or procedures, which may be deferred or avoided altogether due to COVID-19 outbreak, materially impacting our financial results. The COVID-19 outbreak has materially impacted our operations and financial results and continues to be fluid and uncertain, making it difficult to forecast the final impact it could have on our future operations or financial results.

As of March 31, 2020, we had approximately $42 million of cash, cash equivalents and investments available-for-sale. The Company's recurring operating losses, net operating cash flow deficits, and an accumulated deficit, raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the accompanying consolidated financial statements. As a result of this determination, we are in default under the Facility Agreement and the Credit Agreement and Deerfield may exercise its default rights. As of March 31, 2020, we had approximately $180.4 million outstanding under the Deerfield Agreements. Additionally, we would be required to pay exits fees totaling $11.1 million under the Facility Agreement and the remaining $0.1 million commitment fee under the Credit Agreement. We have entered into forbearance agreements with Deerfield which provide that Deerfield will not exercise its default rights under the Facility Agreements until June 15, 2020 or earlier upon certain conditions. If Deerfield were to exercise its default rights, such default would result in a cross default under our 5.00% Notes and our 5.00% Voluntary Notes. As of March 31, 2020, we had $62.0 million outstanding under our 5.00% Notes and $11.1 million outstanding under our 5.00% Voluntary Notes. If Deerfield were to exercise its default rights, other lenders may then declare a default and we may be unable to repay the amounts owed without raising additional capital. If we are unable to repay the amounts owed, we may be forced to declare bankruptcy.

The consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has not made any adjustments to the accompanying consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

All of our revenue is generated from a limited number of products, and any decline in the sales of these products, including as a result of negative perceptions regarding our financial stability, or any material departure in expected revenues from our products as against forecasts, will negatively impact our business.

We have focused heavily on the development and commercialization of a limited number of products for the treatment of AAA. If we are unable to continue to achieve and maintain market acceptance of these products and do not achieve sustained positive cash flow from operations, we will be constrained in our ability to fund development and commercialization of improvements and other product lines. Recently, the COVID-19 pandemic has materially harmed our sales as non-essential procedures have been deferred or canceled. There can be no assurance that these procedures will be rescheduled once the healthcare system normalizes.

In addition, if we are unable to market our products as a result of a manufacturing or quality problem or failure to maintain regulatory approvals, we would lose our only source of revenue and our business would be negatively affected. For example, in collaboration with certain EU regulatory authorities and GMED, the EU Notified Body for our Nellix EVAS System, we decided in early 2019 that, until determined otherwise, the Nellix EVAS System will only be available in the EU at approved centers in a clinical investigation setting with all cases pre-screened by a physician panel to ensure adherence to protocol and use in accordance with current product indications.

We may not succeed in commercializing our products for several reasons, including:

- physicians and hospitals may continue relying on (or revert back to) open surgical repair, or use the other approved EVAR devices available for patients;
- our direct sales force may not be large enough, or effective enough in its efforts, to train and educate physicians and hospitals about the benefits of our products so as to drive adoption and continued use of our products;
- coverage and reimbursement for our products may not be sufficient for customers to choose our devices when in need of an EVAR device;
- challenges in the manufacturing, validation and testing of our products may require us to take actions that delay or otherwise hinder new product introductions or that impact currently available products;
- new technologies, or improved products by competitors, may limit or reduce adoption and use of our products;
- clinical results associated with our products may not be deemed sufficient by us or applicable regulatory authorities to support the approval or commercial use of such products, or may not be sufficiently robust to drive widespread adoption or use;
- adverse regulatory or other governmental statements, findings or reports regarding our products, specifically, our EVAR or EVAS technology and products, may adversely affect the regulatory status and market for our products generally; and

- negative publicity about, or actual or perceived problems with our products or with EVAR or EVAS devices and technologies generally, could discourage physician and hospital adoption or use of our products.

If we are unable to educate physicians and hospitals about the advantages of our products, do not achieve significantly greater market acceptance of our products, do not obtain or maintain required regulatory approvals for our products, are subjected to adverse regulatory actions, do not regain momentum in our sales activities, or fail to significantly grow our market share, we will not be able to grow our revenue and our business and financial condition will be adversely affected.

Furthermore, sales of our products may be adversely impacted by negative perceptions regarding our financial stability relative to that of our competitors and our ability to sustain our business operations on a long-term basis. We have determined that there is substantial doubt regarding our ability to continue as a going concern which has resulted in a default under the Facility Agreements. We have entered into forbearance agreements with Deerfield which provide that Deerfield will not exercise its default rights under the Facility Agreements until June 15, 2020 or earlier upon certain conditions. There can be no assurance that we will be able reach an agreement with Deerfield prior to expiration of the forbearance, or that we will be able to extend the forbearance. If we are unable to reach an agreement with Deerfield or extend the forbearance prior to its expiration, Deerfield may exercise its default rights under the Facility Agreements. We will need to raise substantial additional capital in the near future. If we are unable to access substantial additional capital or further restructure our indebtedness in the near future as needed and in a timely manner and upon terms reasonably favorable to us, our financial stability and prospects may be adversely impacted. Further, our technical, human and other resources and capabilities, as well as our revenues and market share, are considerably smaller than those of our principal competitors. Negative perceptions of our overall financial stability, and resources and market share limitations, may cause our customers, suppliers and strategic partners, as well as independent distributors and third party payors, to question our ability to continue to sell our products, provide customer service, support our commercial organization and fulfill our strategic objectives. These concerns may arise from a number of factors, including our recent and projected financial results, our recent and projected cash positions, recent changes in and volatility of our stock price, perceptions about the dilutive impact of our financing and restructuring transactions, our current level of indebtedness and debt service costs, the competitive environment in our industry, and uncertainties regarding the regulatory environment for our products. Any such concerns, whether actual or perceived, could cause customers to delay the purchase of our products or purchase our competitors' products.

If our essential employees who are unable to telework become ill or otherwise incapacitated, our operations may be adversely impacted.

As a medical device manufacturer, we fall within a "critical essential infrastructure" sector, specifically the "Healthcare/Public Health" sector, and we are considered exempt under various stay at home/shelter in place orders, including the California Executive Order N-33-20 ("Stay at Home Order") dated March 19, 2020. Accordingly, our employees in California and other locations may continue to work because of the importance of our operations to the health and well-being of citizens in the states in which we operate. Consistent with these Stay at Home Orders, we have implemented telework policies wherever possible for appropriate categories of "nonessential" employees. "Essential" employees that are unable to telework continue to work at our facilities, and we have implemented appropriate safety measures, including social distancing, face covering, temperature checking and increased sanitation standards. We are following guidance from the Center for Disease Control and the Occupational Safety and Health Administration regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees, and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among its workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and wellbeing of our "essential" employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that they may otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

If we fail to develop and retain our direct sales force, our business could suffer.

We have a direct sales force in the United States and in certain European countries. As we seek to increase our commercialization efforts with respect to existing products, and expand our commercialization efforts for new products, we will need to retain and develop our direct sales personnel to build upon their experience with our products and their relationships with customers. There is significant competition for sales personnel with experience in medical device sales, and the departure of high-performing sales personnel, or of leadership personnel within our sales organization, can lead to a significant loss of revenue, which could cause us to achieve revenue below our projections. If we are unable to attract, motivate and develop qualified sales personnel and thereby maintain and expand our commercial organization, we may not be able to maintain or increase our revenue in line with our forecasts or those of market participants. Further, we have experienced attrition within our sales organization in recent years, including with respect to key leadership positions, and if we are unable to retain and motivate the high-performing members of our sales force, we may suffer a loss of revenues that may not be recoverable in the near-term or at all. Also, if our sales personnel are not sufficiently trained or qualified to successfully market and sell our products, our sales results and financial condition will be adversely affected.

We are in a highly competitive market segment, which is subject to rapid technological change. If our competitors are better able to develop and market products that are safer, more effective, less costly, easier to use, or otherwise more attractive than the products that we may develop, our business will be adversely impacted.

Our industry is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products for use in the treatment of AAA. We face competition from both established and development stage companies. Many of the companies developing or marketing competing products enjoy several advantages over us, including:

- greater financial and human resources for product development, sales and marketing and patent litigation;
- greater name recognition;
- long established relationships with physicians, customers, and third party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives;
- more established sales and marketing programs, and distribution networks;
- greater experience in conducting research and development, manufacturing, clinical trials, preparing regulatory submissions, and obtaining regulatory clearance or approval for products and marketing approved products; and
- greater buying power and influence with suppliers.

Our competitors may develop and patent processes or products earlier than us, obtain regulatory clearance or approvals for competing products more rapidly than us, and develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition in recruiting and retaining qualified scientific, sales, and management personnel, establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies and technology licenses complementary to our products or advantageous to our business. If our competitors are more successful than us in these matters, our business may be harmed.

If third party payors do not provide reimbursement for the use of our products, our revenue may be negatively impacted.

Our success in marketing our products depends in large part on whether domestic and international government health administrative authorities, private health insurers and other organizations will reimburse customers for the cost of our products. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. In the United States, the healthcare industry is increasingly focused on cost containment as government and private health insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with third-party payors. If sufficient reimbursement is not available for our current or future products, in either the United States or internationally, the demand for our products may be adversely affected or we may decide to cease commercial activities in any such region.

We are currently engaging in certain operational restructuring efforts which we may be unsuccessful in executing and, even if successful, may lead to undesirable outcomes.

We are currently restructuring certain aspects of our business and operations to reprioritize our sales and marketing efforts, rationalize our international presence and related expenses, streamline our workforce and take other measures to increase efficiencies, facilitate access to capital to fund operations as needed, decrease our cash consumption and decrease our cost to serve, while refocusing our business on strong execution of our core strategies. These restructuring plans reflect assumptions and analyses based on our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we consider appropriate under the circumstances. Whether our restructuring efforts will prove successful depends on a number of factors, including, but not limited to: (i) our ability to access the capital markets, when needed, on terms acceptable to us or at all, and to maintain adequate liquidity to satisfy our debt covenants and to allow us to execute our business plans, (ii) our ability to service or refinance our existing indebtedness and pay off such indebtedness as it comes due, (iii) our ability to maintain suppliers', hospitals', medical facilities' and practitioners' confidence in our products, (iv) our ability to obtain regulatory approvals for our new products and product iterations and to maintain our material product approvals, (v) our ability to efficiently reduce our operational expenditures, while retaining key employees and programs, and (vi) the overall success of our business. In addition, as long as these cost restructuring efforts continue, and for a substantial time afterwards, our employees may face considerable distraction and uncertainty and we may experience increased levels of employee attrition. The implementation of these restructuring efforts has occupied a substantial portion of the time and attention of our management and may continue to impact our business, including revenue.

Our success depends on the growth in the number of AAA patients treated with endovascular devices and the general support for EVAR and EVAS technologies in the medical community.

We estimate that over 200,000 people a year are diagnosed with AAA in the United States, and that in 2019 approximately 74,000 people underwent aneurysm repair, either via EVAR or open surgical repair. Our growth will depend upon an increasing percentage of patients with AAA being diagnosed, and an increasing percentage of those diagnosed receiving EVAR, as opposed to undergoing open surgical repair. Initiatives to increase screening for AAA include the Screening Abdominal Aortic Aneurysms Very Efficiently Act ("SAAAVE"), which was signed into law on February 8, 2006 in the United States. SAAAVE provides for one-time AAA screenings for men who have smoked at some time in their lives, and men or women who have a family history of the disease. Beginning January 1, 2007, screening has also been provided as part of the "Welcome to Medicare" physical. Such general screening programs may never gain wide acceptance. The failure to diagnose more patients with AAA could negatively impact our revenue growth.

Furthermore, certain recent industry guidance in the EU has questioned the safety and effectiveness of EVAR and EVAS. In May 2018, the United Kingdom's National Institute for Health and Care Excellence ("NICE") issued draft guidance on AAA diagnosis and management that, among other things, states that patients should not be offered EVAR if open surgical repair is suitable. In November 2018, the European Society for Vascular Surgery (the "ESVS") presented its updated guidelines on the treatment of AAA which included a strong negative recommendation regarding the use of EVAS in clinical practice outside of studies approved by research ethics committees and only with informed consent from the patients, until adequately evaluated. In March 2020, NICE finalized its guidance on AAA diagnosis and management which suggests a continued role for EVAR in certain standard as well as complex cases, while still favoring open surgical repair in many settings. These recommendations and guidelines, and other recommendations and guidelines that may be released from time to time, may adversely affect the growth in the number of AAA patients that are treated with endovascular devices, and adversely affect the commercial availability and customer adoption of our EVAR and EVAS products, which in turn could have a material adverse effect on our financial condition.

Our success depends on convincing physicians to use, and continue to use, our products in more endovascular AAA procedures and to assist us in development of new products.

If we are unable to continue to educate physicians on the use of our products to drive use of our products and to use our products in more endovascular AAA procedures, our business could be negatively impacted. Further, we rely on these professionals to provide us with considerable knowledge and experience regarding the research, development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants, inventors, and public speakers. If we are unable to maintain our strong relationships with the professionals who use and support our products and continue to receive their advice and input, many of our products may not be developed and marketed in line with the needs and expectations of such professionals, which could have a material adverse effect on our consolidated earnings, financial condition, and/or cash flows. The COVID-19 pandemic has resulted in our representatives being unable to visit hospitals in order to educate physicians. We do not know how long the current healthcare protocols will remain in place. If our representatives are unable to visit hospitals in order to educate physicians, it may harm our ability to convince physicians to use, and continue to use, our products.

If we or our third party suppliers fail to comply with extensive FDA regulations relating to the manufacturing of our products or any component part, or otherwise encounter manufacturing problems, this could harm our reputation, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and sell our products may be harmed.

Our manufacturing facilities and the manufacturing facilities of any of our third party component manufacturers, critical suppliers or third party sterilization facilities are required to comply with strict quality controls and highly complex and rigorous quality requirements, including the FDA's Quality System Regulation ("QSR") which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of the products we sell. Medical device quality controls are extremely important due to the serious and costly consequences of a product failure. Problems can arise during the process of manufacturing our products and product components for a number of reasons, including equipment malfunction, failure to maintain or follow necessary protocols and procedures, raw material problems or human error.

The FDA and other regulatory authorities, and their respective representatives, may evaluate our compliance with the QSR and similar quality regulations in other jurisdictions outside of the United States, in a variety of ways, including through periodic announced or unannounced inspections, which could disrupt our operations and interrupt our manufacturing. If, in conducting an inspection of our manufacturing facilities or the manufacturing facilities of any of our third party component manufacturers, critical suppliers or third party sterilization facilities, investigators observe conditions or practices that are believed to violate the QSR or other applicable regulations, these investigators may recommend, and the applicable regulatory authorities may take, administrative or enforcement actions, including a corporate warning letter, consent decree, product seizure, injunction and/or civil or criminal prosecution, which could result in total or partial suspension of a facility's production and/or distribution activities, product recalls, fines, civil penalties, suspension or termination of regulatory authorities' review of product applications, heightened product liability exposure, and adverse publicity. Thus, an adverse inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse inspections could also delay or lead to revocation of FDA or other regulatory approval of our products and could have an adverse effect on our production, sales and profitability.

We and any of our third party suppliers may also encounter other problems during manufacturing including failure to maintain or follow specific protocols and procedures, equipment malfunction, component or raw materials shortages and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our products also subjects us to risks that could harm our business, including problems relating to the sterilization of our products, errors in manufacturing processes and defects in components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacture of the product or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products and could, therefore, have a material adverse effect on our business, financial condition and results of operations.

Our international operations involve operating risks, which could adversely impact our net sales, results of operations and financial condition.

Sales of our products outside of the United States represented approximately 34% of our revenue in 2019. In select countries in Europe, Asia Pacific, Latin America and other targeted international geographies, we market and sell our products through a network of third party distributors and agents. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive United States and foreign governmental trade, import and export, and custom regulations and laws.

Pursuant to the SEC rules regarding disclosure of the use of certain minerals in our products, known as "conflict minerals," which are mined from the Democratic Republic of the Congo and adjoining countries, we are required to disclose the procedures we employ to determine the sourcing of such minerals, and metals produced from those minerals. Our adherence to these rules could adversely affect the sourcing, supply and pricing of materials used in our products, which could increase our expenses In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs associated with possible changes to products, processes, or sources of supply as a consequence of such verification activities. Although we intend to disclose that we utilized certain of the four conflict minerals in our products in our conflict minerals report for the 2019 calendar year, we have been unable in all instances to determine that our sources of these minerals have been certified as "conflict free." We may continue to face difficulties in gathering this information in the future.

Compliance with these regulations is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the United States Foreign Corrupt Practices Act, UK Bribery Act 2010, import/export regulations and requirements such as those imposed by the U.S. Department of Treasury's Office of Foreign Assets Control and U.S. Department of Commerce's Bureau of Industry and Security, and anti-boycott laws and similar laws in foreign jurisdictions. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities, including as the result of the loss of one or more of our product registrations in these foreign jurisdictions. We may determine not to renew one or more of our product registrations in foreign jurisdictions at this time given the meaningful costs of renewing such registrations, including opportunity costs of allocating necessary resources to these renewals, when measured against the potential market opportunities. We and our distributors are required to expend considerable resources to comply with the laws of foreign jurisdictions in which our products are sold. These legal, regulatory and other requirements, individually and in the aggregate, may impact our decisions regarding where to obtain or maintain our product registrations, and the determination not to obtain or maintain a product registration in a certain country or territory may have a negative impact on our relationship with our distributors.

A significant portion of our sales outside of the United States are denominated in local currencies and not in United States dollars. Measured in local currency, a substantial portion of our international sales was generated in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of our international sales varies with currency exchange rate fluctuations. Decreases in the value of the United States dollar relative to the Euro or the British Pound Sterling, as well as other currencies, have the effect of increasing our reported revenue even when the volume of international sales has remained constant. Increases in the value of the United States dollar relative to the Euro or the British Pound Sterling, as well as other currencies, have the opposite effect and, if significant, could have a material adverse effect on our reported revenue and results of operations.

Public health threats such as COVID-19 could have a material adverse effect on our operations, the operations of our business partners, and the global economy as a whole.

Public health threats and other highly communicable diseases, outbreaks of which have already occurred in various parts of the world, could adversely impact our operations, as well as the operations of our customers, suppliers, distributors and other business partners. For example, the outbreak in December 2019 of a novel coronavirus (COVID-19) has resulted in decreased economic activity in China, as well as a number of other countries, and the scope of the outbreak and its impacts is continuing to expand. We anticipate that our business activities will be adversely affected by the COVID-19 outbreak, but it is not currently possible to understand the full extent of the direct and indirect impacts on our business, the business of our partners, or the global economy as a whole.

The COVID-19 outbreak, or other similar outbreaks or epidemics, may have an adverse effect on the overall productivity of our workforce, and we may be required to take extraordinary measures to ensure the safety of our employees and those of our business partners. These measures could require that our employees refrain from traveling to their normal workplace for extended periods of time, which in turn could result in a decrease in our commercial activities, or result in higher costs or other inefficiencies. In addition, our employees may be required to take time off for extended periods of time due to illness or as a result of government-imposed changes to daily routines, including school closures. These impacts could result in delays in or the suspension of our manufacturing operations, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions. In particular, if we were required to suspend our manufacturing operations, we may encounter severe product shortages, which would adversely affect our results of operations and harm our reputation. We are also dependent upon our suppliers for many of our product components, and the outbreak could have a material adverse impact on the operations of one or more of our suppliers, which could prevent them from timely delivering products to us. Further, our business would be harmed if our customers seek to limit or prevent access by our sales and clinical support teams (or the sales and clinical support teams of our distribution partners) to their operating rooms, or to their facilities generally, which we have already experienced in certain locations. Finally, the outbreak has resulted in restrictions on domestic and international travel, which could have a negative impact on our customer engagement efforts, including through the cancellation or postponement of Company-sponsored educational events, as well as third-party conferences, trade shows and similar events.

We expect any further spread of the COVID-19 outbreak, or even the threat or perception that this could occur, could have a material adverse effect on our business, operations and financial results.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions.

The risks associated with international operations include the following:

- major public health issues such as the outbreak of a pandemic or epidemic (such as Sudden Acute Respiratory Syndrome, Avian Influenza, H7N9 virus, the Ebola virus, or COVID-19), which could cause disruptions to our commercial operations or supply chain, or the commercial operations and supply chain of our customers, manufacturers, partners and other third-party collaborators;
- difficulties in enforcing or defending intellectual property rights;
- pricing pressure that may require us to curtail or terminate operations in certain jurisdictions;
- a shortage of high-quality sales people and distributors;
- changes in third party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;
- rulings, findings, reports, recommendations or guidance from governmental or industry entities that are adverse to our products or to EVAR/EVAS products and technologies generally;
- the imposition of additional United States and foreign governmental controls or regulations;
- political, economic and social instability;
- disruptions caused by regional natural disasters, such as hurricanes, landslides, floods, earthquakes or other similar events,
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables in certain jurisdictions;
- the imposition of costly and lengthy new export licensing requirements or other trade restrictions;
- the imposition of United States or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity.

If we experience any of these risks, it could have a material adverse impact on our financial condition and results of operations.

We depend on our officers and other skilled personnel to operate our business effectively. If we are not able to retain our current employees or recruit additional qualified personnel, our business will suffer and our future revenue and profitability will be impaired.

We are highly dependent on the skills and experience of our executive officers and key employees. In most cases, our officers and key employees may terminate their employment and work elsewhere without notice and without cause or good reason. Due to the specialized knowledge of each of our officers with respect to our products and operations, and the limited pool of people with relevant experience in the medical device field, the loss of service of one or more of these individuals could significantly affect our ability to operate and manage our business. The announcement of the loss of one or more of our key personnel could negatively affect our stock price. In particular, we believe that the skills and experience of Mr. Onopchenko, our Chief Executive Officer, are important to our success. The loss of Mr. Onopchenko's services could significantly affect our ability to operate and manage our business and could negatively affect our stock price.

Under Mr. Onopchenko's leadership, we streamlined and restructured certain of our operations and implemented certain management changes. These plans resulted in significant changes in the composition of the senior management team. The loss of these members of senior management, and any future attrition resulting from or arising during planned restructuring efforts (whether such attrition is expected or unexpected), could significantly impact our ability to operate and manage our business and could negatively impact our financial results. We anticipate that we may further augment our leadership team as we deem necessary or advisable. There is no assurance that our executive team will be successful in implementing our restructuring efforts and executing our long-term strategies, or will remain with us over the longer-term.

We also depend on our scientific and technical personnel for successful product development and innovation, which are critical to the success of our business. In addition, to succeed in the implementation of our business strategy, our management team must rapidly execute our sales strategy, obtain anticipated FDA clearances and approvals, achieve market acceptance of our products and further develop products, while addressing our strategic objectives through the implementation and enhancement of effective planning, manufacturing and operating processes. We have experienced a significant level of employee attrition in recent years, including within our sales organization. In addition, we compete for personnel against companies with more expansive product offerings and greater technical and financial resources. Successfully managing our business will require us to attract and retain talented and experienced management, sales, and technical personnel, but there is no guaranty that we will be able to hire or retain such personnel.

If we are unable to provide meaningful equity incentives to our key employees, it could adversely affect our ability to retain these key employees, which in turn could affect our ability to implement our business strategies.

We are highly dependent upon the members of our management team, as well as high-performing sales representatives and other key employees. Many of these individuals have been employed by us for many years, have played integral roles in the growth of our business, and will continue to provide value to us. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. At this time, the vast majority of our outstanding equity awards, which are generally issued in the form of stock options, are significantly out-of-the-money, are unlikely to be exercised in the future absent material increases in our stock price, and as a result, provide little value to employees holding such awards. Further, for certain reasons, including the material decrease in the trading price of our common stock over the past couple of years, we have experienced significant shortages in the total number of shares of our common stock available for issuance under our Amended and Restated 2015 Stock Incentive Plan, as amended (the "2015 Plan"). We have been required to ask our stockholders to approve significant increases in the number of shares reserved for issuance under the 2015 Plan, but we do not believe that these increases will be sufficient to address the Company's future equity compensation objectives. If our stockholders do not approve any future proposal by us to increase the share reserve under the 2015 Plan (or any successor or similar plan) as we deem necessary, we may be materially limited in our ability to offer equity incentives to our existing employees, which could meaningfully affect our ability to retain our key employees and to execute on our business strategies. Even if we do issue significant additional equity incentives, whether or not these incentives are subject to certain conditions precedent including the availability of sufficient shares for issuance under our 2015 Plan (or any successor or similar plan), there can be no assurance that we will be able to attract and retain key executive talent. A loss of any of our key personnel may have a material adverse effect on our ability to execute our business strategy.

The actions and omissions of our third party distributors may subject us to revenue, compliance and other risk.

We depend in part on medical device distributors and strategic relationships for the marketing and sale of our products outside of the United States and outside of certain countries in Europe. We depend on these distributors' efforts to market our products effectively and in accordance with all applicable laws, rules and regulations, yet we are unable to control their efforts completely. For instance, if our distributors fail to provide us or applicable governmental authorities with timely quality, regulatory or other required notifications, including with respect to adverse events or other matters potentially affecting patient safety, then we could incur risk, including the risk of non-compliance with applicable FDA regulations or the regulations of the foreign jurisdiction(s) in which the distributors sell our products, and our business could suffer. In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products, including marketing and promotion of our products in accordance with applicable laws and regulations. If our distributors fail to effectively market and sell our products, or to do so in full compliance with applicable laws, our operating results and business may suffer.

If clinical trials of our current or future products do not produce the results necessary to support regulatory clearance or approval in the United States or elsewhere, we will be unable to commercialize these products.

We are currently conducting clinical trials. We will likely need to conduct additional clinical trials in the future to support new product approvals, for approval for new indications for the use of our products, or to support the use of existing products. Clinical testing is expensive, and typically takes many years, and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously-approved protocol, or place a clinical study on hold;
- patients do not enroll in, do not enroll at the rate we expect, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the rate we expect;

- patients experience serious or unexpected adverse side effects for a variety of reasons that may or may not be related to our products, such as the advanced stage of co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold or terminated;
- sites participating in an ongoing clinical study may withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or are inconsistent with the investigator agreement, clinical study protocol, good clinical practices, and other FDA and Institutional Review Board requirements;
- failure to complete data collection analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy of our products;
- the study design is inadequate to demonstrate safety and efficacy of our products; or
- the results of the study do not meet the study endpoints.

Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing in addition to those we have planned. For example, in 2017, the FDA required us to initiate a confirmatory trial, called EVAS2, of our Nellix EVAS System because it deemed the results of our EVAS1 trial insufficient to support regulatory clearance. Our failure to adequately demonstrate the efficacy and safety of any of our devices would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that device or indication for use.

We depend on a significant number of third party suppliers, including single sourced suppliers that supply numerous components for our product lines, and any disruption in the supply of such materials could impair our ability to manufacture our products or meet customer demand for our products in a timely and cost effective manner.

We currently rely, and expect to continue to rely, on third party suppliers to supply components of our current products and our potential future products. Our reliance on these third party suppliers, many of which are single source suppliers, exposes our operations to disruptions in supply, including disruptions caused by:

- failure of our suppliers to comply with regulatory or quality requirements, or to comply with our specifications;
- failure of our suppliers to timely notify us of changes to the components they supply;
- contractual or other disputes with any such supplier, including with respect to compliance with product supply and/or payment terms;
- change of ownership of a supplier through acquisition or sale of a business
- any strike or work stoppage;
- disruptions in shipping;
- manufacturing limitations or other restrictions on availability or use of raw materials or components necessary for the development, testing, manufacture or sale of our products;
- a natural disaster or extraordinary event caused by fire, flood, earthquakes, environmental accidents or health epidemics; or
- a supply shortage experienced by a single source supplier.

For our business strategy to be successful, our suppliers must be able to provide us with components in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed-upon specifications, at acceptable costs and on a timely basis.

We do not have long-term supply agreements with many of our suppliers and, in many cases, we make our purchases on a purchase order basis. As a result, our ability to purchase adequate quantities of our components or products may be limited. Additionally, our suppliers may encounter problems that limit their abilities to manufacture components or products for us, including financial difficulties, change in ownership or damage to their manufacturing equipment or facilities. If we fail to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer. Furthermore, negative perceptions among our suppliers regarding our overall financial stability, and our ability to sustain our business operations on a long-term basis, may cause one or more of our suppliers to limit, suspend or terminate their relationships with us, or to claim that our financial condition causes them to demand different payment or supply terms. To the extent that we seek financial concessions from our suppliers, including with respect to payment or supply terms, these suppliers may decline to grant such concessions and may further respond by limiting or terminating their sales of product components to us.

Dependence on a significant number of sole suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Moreover, in some cases, we do not have long-standing relationships with our suppliers and the limited size of our order quantities for certain components may not be sufficient to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us. We have in the past been, and we may in the future be, required to make significant “last time” purchases of component inventory that is being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires would limit our ability to meet, or possibly prevent us from meeting, our sales commitments, which could harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to meet our own quality requirements, the FDA or other regulatory agencies, and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional regulatory approvals. Any disruption of this nature, or any increased expenses associated with any such disruption, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and have a material adverse impact on our operating results.

If we are unable to protect our intellectual property, our business may be negatively affected.

Our success depends significantly on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions, to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our pending United States and foreign patent applications may not issue as patents or may not issue in a form that will be advantageous to us. Any patents we have obtained, or will obtain, may be challenged by re-examination, inter partes review, opposition or other administrative proceeding, or in litigation. Such challenges could result in a determination that the patent is invalid. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. To the extent our intellectual property protection is inadequate, or is found to be invalid, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors’ products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all. In addition, changes in United States patent laws could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders.

We also own trade secrets and confidential information that we try to protect by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants and other parties. However, such agreements may not be honored or, if breached, we may not have sufficient remedies to protect our confidential information. Further, our competitors may independently learn our trade secrets or develop similar or superior technologies. To the extent that our employees, consultants or others apply technological information to our projects that they develop independently or others develop, disputes may arise regarding the ownership of proprietary rights to such information, and such disputes may not be resolved in our favor. If we are unable to protect our intellectual property adequately, our business and commercial prospects will likely suffer.

The medical device industry is subject to extensive patent litigation, and if our products or processes infringe upon the intellectual property of third parties, or if we are involved in a claim that our products or processes infringe upon the intellectual property of third parties, the sale of our products may be challenged and we may have to defend costly and time-consuming legal proceedings.

Like other medical device companies, we receive notices of alleged patent infringement from third parties in the ordinary course of our business. We are required to assess each of these claims and then determine appropriate disposition of each claim, which can take significant time, effort and financial resources. We are currently in the process of addressing a small number of these types of matters.

We may need to engage in expensive and prolonged litigation to assert or defend any of our intellectual property rights or to determine the scope and validity of rights claimed by other parties. With no certainty as to the outcome, litigation could be too expensive for us to pursue. Our failure to pursue or prevail in such litigation could result in the loss of our rights, which could substantially hurt our business.

If we elect to settle an infringement claim, any such settlement could be on unfavorable financial or other terms that could affect our revenue, gross margins and other financial results.

Our failure to assert our intellectual property rights, or the potential for intellectual property litigation, could force us to do one or more of the following:

- stop selling, making, or using products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, licensing, or using products, which license may not be available on reasonable terms, or at all;
- redesign our products, processes or services; or
- subject us to significant liabilities to third parties.

If any of the foregoing occurs, we may be unable to manufacture and sell our products and may suffer severe financial harm. Whether or not an intellectual property claim is valid, the cost of responding to it, in terms of legal fees and expenses and the diversion of management resources, could harm our business.

We may face product liability claims that could result in costly litigation and significant liabilities.

The manufacture, marketing and sale of our commercial products, and the clinical testing of our products under development, may expose us to significant risk of product liability claims. Historically, we have had a small number of product liability claims relating to our products, none of which either individually, or in the aggregate, resulted in a material negative impact on our business. As the result of recent field Safety Notices and related regulatory communications involving our AFX and Ovation systems, as well as commercial withdrawal of our Nellix EVAS System and related regulatory communications, we may see an increase in product liability activity. For instance, we have experienced a recent increase in lawsuits regarding the Company’s legacy AFX with Strata product. These and any additional product liability claims may have, individually or in the aggregate, a negative impact on our business if they are not resolved on terms favorable to the Company. Such claims could divert our management from pursuing our business strategy and may be costly to defend. Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- injury to our relationships with our customers;
- significant litigation and other costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;

- loss of revenue; and
- the inability to commercialize new products or maintain existing product approvals.

Although we have, and intend to maintain, product liability insurance, the coverage limits of our insurance policies may not be adequate to protect us from liabilities that we may incur, and one or more claims brought against us for uninsured liabilities or in excess of our insurance coverage may have a material adverse effect on our business and results of operations. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our reputation and financial condition, strain our management and other resources and adversely affect or eliminate the prospects for commercialization or sales of a product which is the subject of such claim. Further, if one or more product liability lawsuits regarding our products survive our efforts to dismiss such lawsuits on federal pre-emption grounds (that is, that state tort claims are pre-empted by federal law regarding the PMA process), then we could face increased risk and expenses from existing lawsuits and from other potential lawsuits that may then be filed. In addition, a recall of our products, whether or not as a result of a product liability claim, could result in decreased demand for our products, injury to our reputation, significant litigation and other costs, substantial monetary awards to or costly settlements with patients, loss of revenue and our inability to commercialize new products or product candidates.

We are currently involved in litigation, and may face future claims, that could adversely affect our business and financial condition, divert management's attention from our business, and subject us to significant liabilities.

On January 3, 2017 and January 9, 2017, two stockholders purporting to represent a class of persons who purchased our securities between August 2, 2016 and November 16, 2016, filed lawsuits against us and certain of our officers in the United States District Court for the Central District of California (the "District Court"). The lawsuits allege that we made materially false and misleading statements and failed to disclose material adverse facts about our business, operational and financial performance, in violation of federal securities laws, relating to FDA PMA for our Nellix EVAS System. On May 26, 2017, the plaintiffs filed an amended complaint extending the class period to include persons who purchased our securities between May 5, 2016 and May 18, 2017 and adding certain factual assertions and allegations regarding the Nellix EVAS System. The plaintiffs sought unspecified monetary damages on behalf of the alleged class, interest, and attorney's fees and costs of litigation. The first lawsuit, Nguyen v. Endologix, Inc. et al., Case No. 2:17-cv-0017 AB (PLAx) (C.D. Cal.) ("Nguyen"), was consolidated with the second lawsuit, Ahmed v. Endologix, Inc. et al, Case No. 8:17-cv-00061 AB (PLAx) (C.D. Cal.), and lead Nguyen plaintiff filed a consolidated First Amended Complaint. On December 5, 2017, the District Court granted our motion to dismiss lead plaintiff's First Amended Complaint, with leave to amend. On January 9, 2018, lead plaintiff filed a Second Amended Complaint, and on March 12, 2018, we filed our Motion to Dismiss this Second Amended Complaint with prejudice. On September 6, 2018, the District Court dismissed the Second Amended Complaint with prejudice. On October 5, 2018, lead plaintiff filed a notice of appeal, and on March 15, 2019, lead plaintiff filed its opening brief with the appellate court. In April 2019, we filed our response brief to plaintiff's appeal. The Appellate Court's hearing on the appeal occurred in February 2020, and the Company expects the Appellate Court's decision to be rendered later in 2020. The Company believes these lawsuits are without merit and continues to defend itself vigorously.

As of June 11, 2017, four stockholders have filed derivative lawsuits seeking unspecified monetary damages on behalf of Endologix, the nominal plaintiff, based on allegations substantially similar to those alleged by lead plaintiff in Nguyen. Those actions consist of: Sindlinger v. McDermott et al., Case No. BC662280 (Los Angeles Superior Court); Abraham v. McDermott et al., Case No. 30-2018-00968971-CU-BT-CSC (Orange County Superior Court); and Green v. McDermott et al., Case No. 8:17-cv-01155-AB (PLAx), which has been consolidated with Cocco v. McDermott et al., Case No. 8:17-cv-01183-AB (PLAx) (C.D. Cal.).

Although we believe that these lawsuits are without merit and intend to defend ourselves vigorously, we are not able to predict the ultimate outcome of these lawsuits. It is possible that they could cause us to incur substantial costs and that they could be resolved adversely to us, result in substantial damages, result in or be connected to additional claims, and divert management's attention and resources, any of which could harm our business. While we maintain director and officer liability insurance, the amount of insurance coverage may not be sufficient to cover these claims and other claims to which we may become subject, and the continued availability of this insurance cannot be assured. Protracted litigation, including any adverse outcomes, may have an adverse impact on our business, results of operations or financial condition and could subject us to adverse publicity and require us to incur significant legal fees.

If our facilities or systems are damaged or destroyed, we may experience delays that could negatively impact our revenue or have other adverse effects.

Our facilities and systems may be affected by natural or man-made disasters. We currently conduct our manufacturing, development and management activities in Santa Rosa, California and Irvine, California, near known earthquake fault zones and seasonal wildfire activity. Our finished goods inventory is split between our Santa Rosa and Irvine locations, our distribution center in Tilburg, the Netherlands, and other forward stocking locations. We have taken precautions to safeguard our facilities and systems, including insurance, health and safety protocols, and off-site storage of computer data. However, our facilities and systems may be vulnerable to earthquakes, fire, storm, power loss, telecommunications failures, physical and software break-ins, software viruses and similar events which could cause substantial delays in our operations, damage or destroy our equipment or inventory, and cause us to incur additional expenses. In addition, the insurance coverage we maintain may not be adequate to cover our losses in any particular case and may not continue to be available to us on acceptable terms, or at all.

Any failure to maintain the security of our information technology systems, or the loss, theft, misuse, or unauthorized disclosure of confidential or sensitive information, could interrupt our business processes or systems, damage our relationships with customers, suppliers or employees, and expose us to litigation or regulatory proceedings, any of which could materially adversely affect our business, financial condition or results of operations.

We rely on information technology systems to store, process and transmit a significant amount of confidential or sensitive information, including the personal information of our employees and other individuals, information relating to our customers and suppliers, and information regarding our products and product development efforts, as well as our proprietary business, financial, operational and strategic data. We also rely on our information technology and global communication systems to manage and support a variety of critical business processes and activities, including manufacturing, supply chain, distribution, sales, billing and customer service.

The protection of our confidential or sensitive information, as well as information relating to our employees and other individuals, customers and suppliers, is vitally important to us as the loss, theft, misuse or unauthorized disclosure of such information could lead to significant reputational or competitive harm, cause our suppliers to reconsider their relationships with us, result in litigation, expose us to regulatory proceedings, and subject us to significant liabilities, fines and penalties. For example, we could be subject to regulatory or other actions pursuant to domestic and international privacy laws, including newer regulations such as the CCPA, which took effect on January 1, 2020, Action on the Protection of Personal Information in Japan and the GDPR in the EU. As a result, we believe our future success and growth depends, in part, on the ability of our business processes and systems to prevent the theft, loss or misuse of this confidential or sensitive information, and to respond quickly and effectively if security incidents do occur.

As with many businesses, we are subject to numerous data privacy and security risks, which may prevent us from maintaining the privacy of confidential or sensitive information, result in the interruption of our business processes and activities, and require us to expend significant resources attempting to protect such information and respond to incidents, any of which could materially adversely affect our business, financial condition or results of operations. As has been well documented in the media, the frequency of cyber-attacks, data incidents, computer viruses and similar incidents has increased in recent years, while the complexity and sophistication of these types of attacks and incidents have also increased. We have experienced and are continually at risk of being subject to these types of incidents.

Although we take the security of our information technology systems seriously, there can be no assurance that the security measures we implement will effectively prevent unauthorized persons from obtaining unauthorized access to our systems and information. Despite the implementation of reasonable security measures by us and our third party providers, our systems, sites, and information may be susceptible to cyber-attacks, data incidents, computer viruses or similar incidents. Therefore, despite our significant efforts, we may be unable to anticipate these incidents or implement adequate preventive measures in response. In addition, our information technology systems may be subject to damage, disruptions or shutdowns due to power outages, failures during the process of upgrading or replacing software, hardware failures, telecommunication failures, user errors or catastrophic events, any of which could have a material adverse impact on our business, financial condition or results of operations.

While we maintain insurance coverage that may, subject to policy terms and conditions, cover certain aspects of the losses associated with cyber-attacks, data incidents, computer viruses and similar incidents, such insurance coverage may be insufficient to cover all losses and would not remedy any damage to our reputation. In addition, we may face difficulties in recovering any losses from our insurance provider, and any losses we recover may be lower than we expect.

We may never realize the expected benefits of our business combination transactions.

In addition to developing new products and growing our business internally, we have sought to grow through combinations with complementary businesses. Examples include our merger with TriVascular in 2016 and our merger with Nellix in 2010. Such business combination transactions involve risks, including the risk that we may fail to realize some or all of the anticipated benefits of the transaction. For example, the success of our business combination transactions largely depends on our ability to achieve anticipated regulatory approvals and growth opportunities for existing products and potential new products. Our ability to realize these benefits, and the timing of this realization, depend upon a number of factors and future events, many of which we cannot control. With respect to the acquired products and technologies, these factors and events include, without limitation, the results of clinical trials, the receipt and maintenance of applicable regulatory approvals, obtaining and maintaining intellectual property rights and further developing an effective sales and marketing organization in global markets. Although we carefully plan our business combination transactions, we may be unable to realize the expected benefits of such transactions.

We are subject to credit risk from our accounts receivable related to our product sales, which include sales within countries that are currently experiencing economic turmoil.

The majority of our accounts receivable arise from product sales in the United States. However, we also have significant receivable balances from customers within the EU, Japan, Brazil and Singapore. Our accounts receivable in the United States are primarily due from public and private hospitals. Our accounts receivable outside of the United States are primarily due from public and private hospitals and independent distributors. Our historical write-offs of accounts receivable have not been significant.

We monitor the financial performance and credit worthiness of our customers so that we can properly assess and respond to changes in their credit profile. Our independent distributors and sub-dealers operate in certain countries where economic conditions continue to present challenges to their businesses and, thus, could place the amounts that they owe to us at risk. These distributors are owed amounts from public hospitals that are funded by their governments. Adverse financial conditions in these countries may continue, negatively affecting the length of time that it will take us to collect associated accounts receivable or impact the likelihood of ultimate collection.

Consolidation in the healthcare industry could have an adverse effect on our revenue and results of operations.

The healthcare industry has been consolidating, and organizations such as group purchasing organizations, independent delivery networks, and large single accounts continue to consolidate purchasing decisions for many of our healthcare provider customers. As a result, transactions with customers are larger, more complex, and tend to involve more long-term contracts. The purchasing power of these larger customers has increased, and may continue to increase, causing downward pressure on product pricing. If we are not one of the providers selected by one of these organizations, we may be precluded from making sales to its members or participants. Even if we are one of the selected providers, we may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, we may be required to commit to pricing that has a material adverse effect on our revenue and profit margins, business, financial condition and results of operations. We expect that market demand, governmental regulation, third party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances, which may exert further downward pressure on the prices of our products and could adversely impact our business, financial condition and results of operations.

Risks Related to Our Financial Condition

We have a history of operating losses and may be required to obtain additional funds to pursue our business strategy.

We have a history of operating losses and will need to seek additional capital in the future. Due to substantial doubt about our ability to continue as a going concern for one year from the issuance of the accompanying consolidated financial statements, we will need to obtain additional financing to pursue our business strategy, to discharge existing indebtedness as it comes due, to respond to new competitive pressures or to act on opportunities to acquire or invest in complementary businesses, products or technologies. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- the results of our commercialization efforts for our existing and future products;
- the revenue generated by sales of our existing and future products;
- the need for additional capital to fund existing and future development programs;
- the need to adapt to changing technologies and technical requirements, and the costs related thereto;

- the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property;
- the costs of defending or responding to any litigation or investigations initiated by third parties, including intellectual property and securities litigation;
- the establishment of high-volume manufacturing and increased sales and marketing capabilities; and
- whether we are successful if we enter into collaborative relationships with other parties.

In addition, we are required to make periodic interest payments to the holders of our senior convertible notes and our senior secured lender under our term loan, and to make periodic amortization payments of principal. Further, under our term loan, we are required to pay certain termination and related fees upon termination of such loan. We may also be required to purchase our senior convertible notes from the holders thereof upon the occurrence of a fundamental change involving our company, or to refinance our senior convertible notes prior to their maturity dates. To finance the foregoing, we may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, or at all.

The sale of additional equity or convertible debt securities, or the conversion of a portion of our outstanding indebtedness into common stock as provided in our agreements with our convertible note holders and with our senior secured lenders, could result in additional dilution to our stockholders. If we borrow additional funds or issue debt securities, these securities could have rights superior to holders of our common stock and could contain covenants that will restrict our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates, or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, and the growth of our business will be harmed.

Changes in the credit environment and covenant restrictions under our financing arrangements may adversely affect our business and financial condition.

Future volatility in the global financial markets could increase borrowing costs or affect our ability to access the capital markets. Further, our ability to enter into or maintain existing financing arrangements on acceptable terms, including our amended and restated facility agreement and credit agreement ("Amended Credit Agreement"), each dated August 9, 2018, with affiliates of Deerfield Management Company, L.P. (collectively, "Deerfield"), (each as amended to date, collectively the "Deerfield Agreements"), in respect of our $160.5 million term loan facility and $50.0 million revolving loan facility, respectively, could be adversely affected if there is a material decline in the demand for our products or the prices that we can command for our products, our customers become insolvent or decide to reduce or discontinue their purchase of our products, we encounter significant regulatory, quality, manufacturing or compliance issues, or any other material adverse event occurs that impacts our business. The Deerfield Agreements contain a number of restrictive and negative covenants, including, but not limited to, the absence of a going concern, the incurrence additional indebtedness, maintenance of our listing on Nasdaq, compliance with certain financial covenants, and numerous others. Any deterioration in our revenue, key financial ratios, or non-compliance with certain financial, reporting, regulatory, operational or other covenants or terms in existing or future loan or credit agreements, including the Deerfield Agreements, may result in an event of default under such agreements, which also could adversely affect our business and financial condition. As a result of our determination that there is substantial doubt regarding our ability to continue as a going concern, we are in a default under the Deerfield Agreements. We have entered into forbearance agreements with Deerfield which provide that Deerfield will not exercise its default rights under the Facility Agreements until June 15, 2020 or earlier upon certain conditions. There can be no assurance that we will be able reach an agreement with Deerfield prior to expiration of the forbearance, or that we will be able to extend the forbearance. If we are unable to reach an agreement with Deerfield or extend the forbearance prior to its expiration, Deerfield may exercise its default rights under the Facility Agreements.

The occurrence of an event of default under our Deerfield Agreements and the exercise by Deerfield of its default rights could result in an increase to the applicable interest rate, an acceleration of all obligations, an inability to access the revolving loan facility under the Amended Credit Agreement, a requirement to repay all obligations in full and a right by Deerfield to exercise all remedies available to them. If we are unable to pay those amounts, Deerfield could proceed against the collateral granted to it pursuant to the Deerfield Agreements and we may in turn lose access to any sources of borrowing availability we may have. Any declaration of an event of default by Deerfield could also trigger an event of default under our outstanding convertible senior notes requiring the repayment of principal and interest outstanding under such notes. Further, if we are unable to repay our indebtedness and Deerfield institutes foreclosure proceedings against our assets, we could be forced into bankruptcy or liquidation and equity holders may lose the entire value of their investment. In any such bankruptcy or liquidation scenario, the value that we receive for our assets could be significantly lower than the values reflected in our financial statements.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to make scheduled payments of the principal of, to pay interest on, to pay any cash due upon amortization of or to refinance our indebtedness, including the senior convertible notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time.

In April 2019, we consummated a restructuring of our indebtedness. Pursuant to an exchange agreement with two existing investors, we exchanged (the "2019 Exchange") approximately $73.4 million of the $84.5 million principal amount of our outstanding 3.25% Convertible Senior Notes due 2020 (the "2.35% Notes") for $25.0 million of principal amount of new 5.00% Mandatory Convertible Senior Notes due 2024 (the "5.00% Mandatory Notes") and approximately $42.0 million of principal amount of the 5.00% Voluntary Convertible Senior Notes due 2024 (the "5.00% Voluntary Notes", and together with the 5.00% Mandatory Notes, the "5.00% Notes"). The 5.00% Notes are convertible into common stock of the Company, on either a mandatory or voluntary basis, subject to satisfaction of certain conditions precedent (including satisfaction of certain stock price thresholds and compliance with aggregate ownership limitations). Simultaneously with the consummation of the Exchange, the Deerfield Agreements were amended to provide for, among other things, (i) the reduction of our global excess liquidity covenant from $22.5 million to $17.5 million and the reduction of the minimum net revenue financial covenants; and (ii) reduction of our first term loan repayment amount to Deerfield, due April 2021, from $40 million to $20 million (and accompanying $10 million increase in each of our respective term loan repayments to Deerfield due in April 2022 and April 2023). The Company does not anticipate that the large majority of the mandatory and voluntary conversions of the 5.00% Notes into shares of our common stock will occur; thus we may be required to pay these debt obligations in cash as they become due, unless we can refinance or exchange such notes on terms acceptable to the holders thereof.

In February 2020, pursuant to an exchange agreement with three existing investors, we exchanged (the "2020 Exchange") approximately $11.0 million of the remaining $11.1 million principal amount of our 3.25% Notes plus accrued and unpaid interest for $11.1 million of principal amount of new 5.00% Voluntary Convertible Senior Notes due 2024 (the "5.00% Voluntary Notes"). The 5.00% Voluntary Notes are convertible into common stock of the Company, on a voluntary basis, subject to satisfaction of certain conditions precedent (including satisfaction of certain stock price thresholds and compliance with aggregate ownership limitations).

Further, approximately $0.2 million of the 3.25% Convertible Senior Notes remain outstanding after the 2019 Exchange and 2020 Exchange and will be subject to repayment upon maturity in November 2020 unless earlier exchanged or refinanced. We may not have sufficient cash to satisfy our repayment obligations as they become due, which could result in a default on our debt obligations.

Concurrently with the 2020 Exchange, we further amended the Deerfield Agreements in order to, among other things, extend the first amortization payment date from April 2021 to July 2021 and to establish a series of milestone events, the achievement of which would require Deerfield to convert up to approximately $70.7 million into shares of our Series DF-1 Preferred Stock, subject to satisfaction of certain other conditions precedent (including satisfaction of certain stock price thresholds). In total, more than $100 million of the aggregate $160.5 million outstanding principal amount (in addition to the preexisting right of Deerfield to obtain up to 1.43 million shares of common stock upon the conversion of a portion of the outstanding indebtedness under the term loan) is potentially convertible into shares of our common stock or Series DF-1 Preferred Stock. In addition, in the event we achieve net sales of our Alto product of at least $1.0 million by June 30, 2020 and provided that we report net revenue of at least $142.5 million for the year ended December 31, 2020 and complies with the global excess liquidity requirement, the maturity date shall be extended from April 2, 2023 to December 22, 2023 and the second amortization date shall be extended from April 2, 2022 to April 2, 2023. Further, the amendment provides that the interest payment date due April 1, 2020 will be payable in paid-in-kind interest by increasing the principal amount of the loans by an amount equal to the interest that has accrued. If we are unable to achieve the milestones, we will be unable to convert the outstanding debt into equity and will instead be required to continue to service the debt and, eventually, repay the debt which will put additional pressure on our financial situation. There can be no assurances that we will be able to continue to service our debt or, if required, repay our debt when due and payable.

We have limited resources to invest in research and development and to grow our business and may need to raise additional funds in the future for these activities.

We believe that our growth will depend, in significant part, on our ability to develop new technologies for the treatment of AAA and technology complementary to our current products. Our existing resources may not allow us to conduct all of the research and development activities that we believe would be beneficial for our future growth. As a result, we may need to seek funds in the future to finance these activities. If we are unable to raise funds on favorable terms, or at all, we may not be able to increase our research and development activities and the growth of our business may be negatively impacted.

The expense and potential unavailability of insurance coverage for our company may have an adverse effect on our financial position and results of operations.

While we currently have insurance for our business, property, directors and officers, and product liability, such insurance coverage is increasingly costly and the scope of coverage is narrower, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to cover the amounts outside of or in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant costs associated with loss or damage that could have an adverse effect on our financial position and results of operations. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all. We do not have the financial resources to self-insure, and it is unlikely that we will have these financial resources in the foreseeable future. Our product liability insurance covers our products and business operations, but we may need to increase and expand this coverage commensurate with our expanding business.

Risks Related to Regulation of Our Industry

Healthcare policy changes, including recent federal legislation to reform the United States healthcare system, may have a material adverse effect on us.

In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators and third party payors to control these costs and, more generally, to reform the United States healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. Moreover, as discussed below, recent federal legislation would impose significant new taxes on medical device makers such as us. The adoption of some or all of these proposals, including the recent federal legislation, could have a material adverse effect on our financial position and results of operations.

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the “PPACA”). The total cost imposed on the medical device industry by the PPACA may be up to approximately $20 billion over ten years. Elements of the PPACA include comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions, which may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products or product enhancements that will be accepted by the market in a timely manner.

It is important to our business that we continue to build a more extensive product offering for treatment of AAA. Our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products, or these products may not be accepted by physicians or the payors who financially support many of the procedures performed with our products. Recent industry guidance from NICE and the ESVS raises concerns regarding the regulatory and commercial prospects for EVAR and EVAS products in Europe. In the United States, the FDA’s requirement that we complete the EVAS2 confirmatory trial has delayed the commercial introduction of the Nellix EVAS System in the United States. Further, recent public communications from FDA regarding our AFX endografts have suggested that there may be higher than expected risk of Type III endoleaks occurring with our AFX with Duraply and AFX2 endografts. Any public FDA communications and any similar communications from other relevant regulatory authorities that call into question the safety and efficacy profiles of our products could materially and adversely affect our business. In the future we may face additional, similar regulatory constraints.

In addition to conforming with an evolving regulatory landscape, the success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- properly identify and anticipate physicians' and patients' needs;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from pre-clinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- be fully FDA-compliant with marketing of new devices or modified products;
- provide adequate training to potential users of our products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective and regulatory-compliant, dedicated marketing and distribution network.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, our results of operations will suffer.

Our business is subject to extensive governmental regulation that makes it expensive and time consuming for us to introduce new or improved products.

Our products must comply with complex regulatory requirements imposed by the FDA and corresponding state agencies in the United States and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency review processes, and other costly and time-consuming procedures. It often takes a number of years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we face include:

- FDA Regulations (Title 21 CFR);
- EU CE Mark requirements, including the new Medical Device Regulations and MEDDEV 2.7.1 Rev.4, which implement stricter requirements for clinical data to support new product approvals;
- Other international regulatory approval requirements;
- Medical Device Single Audit Program ("MDSAP");
- Medical Device Quality Management System Requirements (21 CFR 820, ISO 13485:2003, EN ISO 13485:2012, ISO 13485:2016, and other similar international regulations);
- Occupational Safety and Health Administration requirements; and
- CDHS requirements.

Government regulation may impede our ability to conduct continuing clinical trials and to manufacture our existing and future products. Government regulation also could delay our marketing of new products for a considerable period of time and impose costly procedures on our activities. The FDA and other regulatory agencies may not approve any of our future products on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals could negatively impact our marketing of any proposed products and reduce our product revenue.

Our products remain subject to strict regulatory controls on manufacturing, marketing and use. We have in the past been required to modify or recall our products after release, either voluntarily or in response to regulatory action or unanticipated difficulties encountered in general use, and we may be required to do so again in the future. Any such action could have a material effect on the reputation of our products and on our business and financial position.

Further, regulations may change, and any additional regulation could limit, delay or restrict our ability to market our products, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development programs and harm our business in unforeseen ways. For example, in the EU, the new MDR was finalized in 2017 and will become effective in May 2020. MDR 2017 will change several aspects of the existing regulatory framework, such as clinical data requirements, and introduce new ones, such as Unique Device Identification. We, and the notified bodies who will oversee compliance with MDR 2017, face uncertainties as MDR 2017 is rolled out and enforced, which, in addition to the increased costs of compliance, creates risks in several areas including the CE marking process and data transparency. If and as regulations are changed or new regulations are added, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

The potential off-label promotion and subsequent off-label use of our products may harm our reputation in the marketplace and result in government investigations and/or penalties.

The products we market have been cleared or approved by the FDA and international regulatory authorities for specific indications for use, including in specific AAA anatomies. Physicians have the discretion, however, to use our products outside of those cleared/approved indications for use, a practice known as "off-label" use. Off-label use of our and our competitors' products by physicians is common in the AAA field. We receive substantial revenue from the sale of our products for use by physicians in cases outside of the cleared/approved indications for use. Though physicians in most countries, including the United States, have the discretion to engage in off-label use of our products, FDA laws and regulations prohibit us from promoting our products for an unapproved use.

Our internal policies and procedures are designed to achieve compliance with these and other applicable requirements, but FDA or other regulatory authorities could determine that our sales, marketing and educational activities, when evaluated in connection with the use of our products in off-label procedures, have constituted or may constitute the unlawful promotion of our products for unapproved use. We specifically have a compliance mechanism in place to investigate and address instances of noncompliance with company policies and procedures, with confirmed violations resulting in disciplinary action up to and including termination. If we are deemed by the FDA or other regulatory bodies to have engaged in the promotion of our products for off-label use, we could be subject to prohibitions on the sale or marketing of our products in the United States or other jurisdictions, face significant fines and penalties, and be required to enter into onerous corporate integrity agreements, consent decrees or similar court or agency-imposed agreements. The imposition of any such fines, penalties or sanctions could affect our reputation and position within the industry and could materially and adversely affect our business, financial condition and results of operations. Additionally, the use of our products for indications other than those cleared/approved by the FDA or international regulatory authorities may result in suboptimal outcomes that could harm our reputation in the marketplace among physicians and patients and lead to product liability claims.

Physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability and similar claims. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance.

Our products may be subject from time to time to product recalls or voluntary market withdrawals that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found or suspected. A government-mandated recall or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. We have engaged in product recalls from time to time, including a voluntary Class II recall of our AFX products with Strata graft material and certain larger sizes of our AFX2 product in late 2016 and early 2017, which recall (i) resulted in expenditure of resources and diversion of management time and attention and (ii) was negatively received in the marketplace. In addition, in October 2018, FDA classified a July 2018 Safety Notice that we issued to users of the AFX Endovascular AAA System as a Class I recall. We may elect to engage, or be required by FDA to engage, in additional recalls or other corrective or safety actions in the future. Any future recalls, which include corrections as well as removals, of any of our products would divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation with customers, and reduce our ability to achieve expected revenue.

We are required to comply with MDR requirements and must report certain malfunctions, deaths, and serious injuries associated with our products to regulatory agencies, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA MDR regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the European Economic Area are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the regulatory agency ("Competent Authority"), in whose jurisdiction the incident occurred. Material noncompliance with these reporting requirements may subject us to adverse regulatory action, including but not limited to receipt of a Warning Letter from FDA and enforcement action by the relevant Competent Authority.

Malfunction of our products could result in future voluntary corrective actions, including recalls, corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We are subject to federal, state and foreign healthcare fraud and abuse, transparency and other laws and regulations governing financial dealings with customers, physicians and payors, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.

Our operations may be directly or indirectly affected by various broad federal, state or foreign healthcare fraud and abuse laws. The federal Anti-Kickback Statute prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce the referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. We are also subject to the federal Health Insurance Portability and Accountability Act ("HIPAA"), which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and federal "sunshine" laws that require transparency regarding financial arrangements with healthcare providers, such as the reporting and disclosure requirements imposed by PPACA regarding any "transfer of value" made or distributed to prescribers and other healthcare providers.

In addition, the federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

Many states have also adopted laws similar to each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third party payor, including commercial insurers as well as laws that restrict our marketing activities with physicians, and require us to report consulting and other payments to physicians. Some states mandate implementation of commercial compliance programs to ensure compliance with these laws. We also are subject to foreign fraud and abuse laws, which vary by country. For instance, in the EU, legislation on inducements offered to physicians and other healthcare workers or hospitals differ from country to country. Breach of the laws relating to such inducements may expose us to the imposition of criminal sanctions.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent healthcare reform legislation has strengthened these laws. Further, there may be additional federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud abuse laws and/or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We may be subject to privacy and security laws and regulations that protect personal health information and other types of personal information, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.

The HIPAA statute, and its implementing regulations, safeguard the privacy and security of individually-identifiable health information. Certain of our operations may be subject to these requirements. Penalties for noncompliance with these rules include both criminal and civil penalties. In addition, the Health Information Technology for Economic and Clinical Health Act ("HITECH Act") expanded federal health information privacy and security protections. Among other things, HITECH makes certain of HIPAA's privacy and security standards directly applicable to "business associates," such as independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also set forth new notification requirements for health data security breaches, increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many states have adopted data privacy and protection legislation offering similar or expanded protections to consumers and imposing security, reporting and notification requirements which are in some instances more stringent than those imposed by HIPAA or HITECH. In California, the CCPA, which took effect on January 1, 2020, imposes new requirements regarding the collection, use and sharing of the personal information of California residents and therefore may place similar ongoing compliance obligations on us. The CCPA permits California's Attorney General to file a civil enforcement action and seek monetary penalties for violations of the CCPA. It also grants to California residents the right to sue for breaches of certain types of personal information, and courts may award statutory damages up to $750 per consumer per incident, or actual damages, whichever is greater. California's Attorney General has proposed draft regulations for implementing the CCPA but regulations have not yet been adopted. The CCPA and its implementing regulations may change periodically, which could have an effect on our business operations if compliance becomes substantially costlier than under current requirements.

The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the GDPR which introduces strict requirements for processing personal data. The GDPR has imposed additional compliance obligations on us, including by mandating additional documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to €20 million or up to 4% of the annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, it has and will continue to require significant effort and expense to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR may change periodically or may be modified by EU national law and could have an effect on our business operations if compliance becomes substantially costlier than under current requirements.

Risks Related to Our Common Stock

We have certain contractual obligations pursuant to which we may be obligated to issue a significant number of additional shares of our common stock, which would result in a substantial amount of dilution to our existing stockholders.

Pursuant to the debt restructuring transactions we consummated in April 2019 and February 2020:

- Up to the entire $25 million of 5.00% Mandatory Notes and $42.02 million of 5.00% Voluntary Notes are potentially convertible into our common stock upon satisfaction of certain conditions, including commencement of the applicable conversion period, achievement of minimum stock price thresholds, and compliance with ownership "blockers" (which are maximum ownership amounts that certain investors can hold at any one time expressed as a percentage of the Company's total outstanding shares of common stock).
- Up to the entire $11.1 million 5.00% Voluntary Notes are potentially convertible into our common stock upon satisfaction of certain conditions, including commencement of the applicable conversion period, achievement of minimum stock price thresholds, and compliance with ownership "blockers" (which are maximum ownership amounts that certain investors can hold at any one time expressed as a percentage of the Company's total outstanding shares of common stock).
- Approximately $100.7 million of the $160.0 million of indebtedness to Deerfield under the Deerfield Agreements are potentially convertible into shares of the Company's common stock or Series DF-1 Preferred Stock (which is convertible into shares of common stock at any time, subject to ownership blockers), either at Deerfield's election, or on a mandatory basis (subject to satisfaction of certain conditions precedent and compliance with ownership blockers).

As the "mandatory" and "voluntary" conversion events referenced above are subject to a number of conditions precedent, the actual dilution that could occur as a result of the remainder of these conversion features, though potentially material, is not susceptible of determination at this time.

In addition, under the terms of our Deerfield Agreements, we have issued warrants to Deerfield to purchase up to an aggregate total of 1,522,002 shares of our common stock. In addition, Deerfield has the right to convert a portion of the indebtedness outstanding under the Deerfield Agreements into a maximum of approximately 1.43 million shares of our common stock.

In addition, under the terms of our merger agreement with Nellix, we agreed to issue additional shares of our common stock to the former stockholders of Nellix as contingent consideration upon our satisfaction of certain milestones related to the Nellix EVAS System, or upon a change of control of our company. In the event the remaining regulatory-based milestone is achieved, we may be obligated to issue up to approximately 330,000 additional shares of our common stock.

These potential issuances of additional shares of our common stock or securities convertible into or exercisable for our common stock, would result in the immediate dilution of the ownership interests of holders of our common stock on the dates of such issuances.

The price of our common stock has declined significantly and may continue to fluctuate in future periods.

The trading price of our common stock has declined significantly in the past 24 months. We believe our stock price has been, and will continue to be, subject to wide fluctuations in response to a variety of factors, including the following:

- actual or anticipated fluctuations in our financial and operating results from period to period;
- our actual or perceived need for additional capital to fund our operations and future debt repayment obligations, and perceptions about the potential dilutive impact of common stock issued pursuant to conversion of portions of our senior convertible notes and Deerfield term loan, and future financing or restructuring transactions;
- regulatory approval of our products or the products of our competitors, the loss of regulatory approvals or clearances, or the failure to obtain regulatory approvals or clearances in a timely manner or at all;
- perceptions regarding the intentions of Deerfield with respect to the exercise of its warrants;
- perceptions regarding our ability to comply with our financial covenants under the Deerfield Agreements;
- perceptions about our financial stability generally, and relative to our competitors, including our ability to sustain our business operations, execute on our strategic plans and achieve profitability;
- market acceptance of our products;
- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- announcements of significant contracts, acquisitions or divestitures by us or our competitors;
- product recalls involving our products or the products of our competitors;

- perceptions regarding the effectiveness of our product quality systems;
- speculative trading practices of market participants;
- issuance of securities analysts' reports or recommendations;
- the failure of our operating results to meet expectations of securities analysts and investors, or to be consistent with our financial guidance;
- threatened or actual litigation, government investigations or enforcement actions;
- changes in healthcare laws or policies in the United States or other countries in which we conduct business; and
- general political or economic conditions and other factors unrelated to our operating performance.

These and other factors might cause the market price of our common stock to fluctuate substantially and to decline even further. Fluctuations in our stock price may negatively affect the liquidity of our common stock, which could further adversely impact our stock price. If the recent negative volatility of our market capitalization is sustained, we may perform impairment tests more frequently and it is possible that our goodwill could become impaired, which could result in a material charge and adversely affect our results of operations.

In recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. These changes may occur without regard to the financial condition or operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce the market price of our common stock.

Trading in our stock over the past 24 months has been limited, which may increase the volatility of the trading price of our stock.

The average daily trading volume in our common stock for the twenty-four months ended March 31, 2020 was approximately 193,000 shares. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices. Moreover, the market price for shares of our common stock may be more volatile because of the relatively low volume of trading in our common stock. When trading volume is low, significant price movement can be caused by the trading of a relatively small number of shares. Volatility in our common stock may result in further downward pressure on the market price of our common stock. If the recent negative volatility of our market capitalization is sustained, we may perform impairment tests more frequently and it is possible that our goodwill could become impaired, which could result in a material charge and adversely affect our results of operations.

Our operating results may fluctuate significantly from quarter to quarter.

There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter, especially around the time of anticipated new product launches or regulatory approvals by us or our competitors. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

- our ability to increase sales from our current products, and to commercialize and sell our future products;
- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- the number and mix of our products sold in each quarter;
- changes in our pricing policies or in the pricing policies of our competitors or suppliers;
- changes in third party payors' reimbursement policies;
- our ability to maintain and motivate our sales force;
- our ability to manufacture products that meet quality and regulatory requirements;
- results of clinical research and trials on our existing and future products;
- the timing and expense associated with obtaining regulatory approval of our products;
- product recalls involving our products or the products of our competitors;
- the timing of revenue and expense recognition associated with our product sales pursuant to applicable accounting standards.

Because of these and possibly other factors, it is possible that in future periods our operating results will not meet investor expectations or those of securities analysts.

In addition, our operating expenses my exceed our projections for various reasons, including unanticipated litigation or regulatory expenses or other costs imposed as a result of third-party actions or omissions. Any such expenses in excess of forecast may exacerbate the quarterly fluctuations in our operating results. If our quarterly or annual operating results fall below the expectation of securities analysts or other market participants, or below the results expressed or implied by our financial guidance, the price of our common stock could decline substantially. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially, and these price fluctuations could result in further pressure on our stock price. We believe quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Any unanticipated change in revenue or other operating results is likely to cause our stock price to fluctuate since such changes reflect new information available to investors and analysts. New information may cause investors and analysts to revalue our business, which could cause a decline in the trading price of our stock.

We may not achieve the projections set forth in our financial guidance, or certain other anticipated goals and objectives that we announce publicly from time to time, which could have a material adverse effect on our business and cause the market price of our shares to decline.

We typically provide financial guidance based on management's then current expectations, which is subject to the risks and uncertainties inherent in all financial forecasting. The failure to achieve our financial guidance, or the projections of securities analysts or other market participants, could have a material adverse effect on our results of operations, and disappoint analysts and investors, which could cause the market price of our common stock to decline.

In addition, we regularly make public announcements relating to our expected achievement of certain goals and objectives regarding our business, such as the timing of commercialization of new products, clinical trials, and regulatory approvals. The actual timing of these events can vary significantly due to a number of factors, including the various risks and uncertainties described in this Annual Report. As a result, we may be unable to achieve our projected goals and objectives in the time periods that we anticipate or at all. The failure to achieve such projected goals and objectives in the time periods that we anticipate could have a material adverse effect on our business, financial condition and results of operations.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could reduce our stock price and prevent our stockholders from replacing or removing our current management.

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;
- provide for the adoption of a staggered board of directors whereby the board is divided into three classes each of which has a different three-year term;
- provide that the number of directors shall be fixed by the board of directors;
- prohibit our stockholders from filling board vacancies;
- prohibit stockholders from calling special stockholder meetings; and
- require advance written notice of stockholder proposals and director nominations.

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our board of directors is authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, and to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our common stock, and the issuance of such shares in the future may reduce the value of our common stock.

We may be at increased risk of securities class action litigation.

In the past, securities class action litigation has been instituted against companies following periods of volatility in the overall market and in the price of a company's securities. We believe this risk may be particularly relevant to us as we have experienced a significant stock price decline in the past 24 months and may experience significant stock price volatility in the future. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business, financial condition and results of operations.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, which could cause investors to lose confidence in our reported financial information and have a negative impact on the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation. In addition, deficiencies in our internal controls could result in enforcement actions by the SEC or other regulatory bodies, which could cause us to incur defense costs and pay penalties or other costs. Furthermore, deficiencies in our internal controls may cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our common stock and do not intend to pay cash dividends for the foreseeable future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. Our revolving credit facility and term loan contain restrictions prohibiting us from paying any cash dividends without the lender's prior approval. Accordingly, investors may have to sell some or all of their shares of our common stock in order to generate cash flow from their investment.

United States federal income tax reform could adversely affect us and our stockholders.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (the "TCJA"), which significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to United States federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. We do not expect tax reform to have a material impact on our projection of minimal cash taxes. Our net deferred tax assets and liabilities were revalued at the newly-enacted U.S. corporate rate, and the impact was recognized in our tax expense, offset by a full valuation allowance, in the year of enactment. We continue to examine the impact that this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecasts of analysts or other market participants, our stock price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline. We believe we are currently at greater risk that analysts may cease coverage of our company due to the recent decline in our stock price and market capitalization.

Item 6. EXHIBIT INDEX

The following exhibits are filed or furnished herewith:

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Filing Date	
10.1	Promissory Note, dated May 1, 2020, from Bank of America, N.A.	8-K	10.1	05/11/20	
10.2	Amendment to Facility Agreements, dated May 4, 2020, by and among the Company, Deerfield ELGX Revolver, LLC and Deerfield Private Design Fund I.V., L.P.	8-K	10.2	05/11/20	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Link Base Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, shall not be deemed “filed” by the registrant for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any of the registrant’s filings under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in any 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.

ENDOLOGIX, INC.

Date: May 27, 2020

/s/ John Onopchenko

Chief Executive Officer
(Principal Executive Officer)

Date: May 27, 2020

/s/ Vaseem Mahboob

Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Chief Executive Officer

I, John Onopchenko, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endologix, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principals;

   c) 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

   d) 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 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: May 27, 2020

By: /s/ John Onopchenko

John Onopchenko

Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer

I, Vaseem Mahboob, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endologix, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principals;

   c) 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

   d) 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 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: May 27, 2020

By: /s/ Vaseem Mahboob

Vaseem Mahboob

Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification of Chief Executive Officer

Pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, John Onopchenko, certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 that:

(1) The Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 780(d)); and

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

Date: May 27, 2020

By: /s/ John Onopchenko

John Onopchenko

Chief Executive Officer

This certification accompanies the Quarterly Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section.

Exhibit 32.2

Certification of Chief Financial Officer

Pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Vaseem Mahboob, certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 that:

(1) The Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 780(d)); and

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

Date: May 27, 2020

By: /s/ Vaseem Mahboob

Vaseem Mahboob

Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Quarterly Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section.