EVANS BANCORP INC
Form 424B5
January 19, 2017
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Filed pursuant to Rule 424(b)(5)
Registration Statement No. 333-210443

PROSPECTUS SUPPLEMENT

To the Prospectus Dated April 22, 2016

400,000 Shares

Common Stock

We are offering 400,000 shares of our common stock, $0.50 par value per share, pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is listed and traded on the NYSE MKT under the symbol EVBN. On January 17, 2017, the last reported price of our common stock on the NYSE MKT was $35.00 per share.

Investing in our common stock involves risks. Please carefully consider the risks discussed in Risk Factors beginning on page S-11 of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement, including the risk factors contained therein, for a discussion of certain factors that you should consider before making your investment decision.

	Per Share	Total
Public offering price	$ 35.00	$ 14,000,000
Underwriting discount	$ 1.925	$ 770,000
Proceeds, before expenses, to Evans Bancorp, Inc.	$ 33.075	$ 13,230,000

The shares of common stock are being offered through the underwriters on a firm commitment basis. We have granted the underwriters a 30-day option to purchase up to 60,000 additional shares of our common stock at the same price and on the same terms.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

These securities are not savings accounts, deposits, or other obligations of a bank or savings association and are not insured by the Federal Deposit Insurance Corporation or any other governmental agency.

The underwriters expect to deliver the common stock in book-entry form only, through the facilities of The Depository Trust Company, against payment on or about January 23, 2017.

Book-Running Manager

SANDLER O NEILL + PARTNERS, L.P.

Co-Manager

HOVDE GROUP, LLC

The date of this prospectus supplement is January 18, 2017.

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Prospectus Supplement

Prospectus

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different or additional information. If anyone provides you with different or additional

information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell our securities in any jurisdiction where the offer or sale is not permitted.

You should assume that the information appearing in this prospectus supplement, the accompanying prospectus and any documents incorporated by reference herein, is accurate as of their respective dates. However, our business, financial condition, liquidity, results of operations, and prospects may have changed since those dates. This prospectus supplement supersedes the accompanying prospectus to the extent it contains information that is different from or in addition to the information in that prospectus.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document consists of two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and certain other matters, and also updates and adds to the information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus, which provides more general information about us, our common stock and other securities that we may offer from time to time, some of which may not apply to this offering. You should read this prospectus supplement and the accompanying prospectus with the additional information described below under the headings Where You Can Find More Information and Incorporation of Certain Documents by Reference. Generally, when we refer to this prospectus we mean this prospectus supplement together with the accompanying prospectus.

If the information set forth in this prospectus supplement differs in any way from the information set forth in the accompanying prospectus, you should rely on the information set forth in this prospectus supplement.

Unless we specifically state otherwise, the information in this prospectus supplement assumes no exercise of the underwriters option to purchase additional shares of our common stock.

We are offering to sell shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any common stock offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

In this prospectus supplement, unless otherwise expressly stated or the context otherwise requires, the terms we, us, the Company, and our refer to Evans Bancorp, Inc. and our subsidiaries on a consolidated basis. References to the Bank refer to Evans Bank, National Association, our wholly-owned subsidiary through which we conduct our banking business, and its subsidiaries.

Currency amounts in this prospectus supplement and the accompanying prospectus are stated in U.S. dollars.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus incorporates important business and financial information about Evans Bancorp from documents filed with the Securities and Exchange Commission (the SEC), with which we file registration statements, periodic reports, proxy statements, and other information. Our SEC filings are available over the Internet, at no cost, from the SEC s website at www.sec.gov and from our website at evansbank.com. You may also read and copy any document we file by visiting the SEC s public reference room in Washington, D.C. The SEC s address in Washington, D.C. is 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. You may also receive copies of documents filed with the SEC, including documents incorporated by reference in this prospectus, at no cost, by addressing your request to:

Corporate Secretary

Evans Bancorp, Inc.

One Grimsby Drive

Hamburg, New York 14075

Except as specifically incorporated by reference in this prospectus supplement, information on the websites listed above is not part of this prospectus supplement. You should rely only on the information contained in, or incorporated by reference into, this document. No one has been authorized to provide you with information that is different from that contained in, or incorporated by reference into, this document. This document is dated January 18, 2017, and you should assume that the information in this document is accurate only as of such date. You should assume that the information incorporated by reference into this document is accurate only as of the date of such incorporated document.

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INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference information into this prospectus supplement. This means that we can disclose important information to you by referring you to another document that we file separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus supplement, except for any information that is superseded by information that is included directly in this document or in a more recent incorporated document.

This prospectus supplement incorporates by reference the documents listed below that we have previously filed with the SEC.

SEC Filings	Period or Filing Date (as applicable)
Quarterly Reports on Form 10-Q	Quarters ended March 31, 2016; June 30, 2016; and September 30, 2016
Annual Report on Form 10-K, as amended by Amendment No. 1 filed on Form 10-K/A	Year ended December 31, 2015
Current Reports on Form 8-K (in each case other than those portions furnished under Item 2.02 or 7.01 of Form 8-K)	May 2, 2016; July 14, 2016 (as amended on August 4, 2016); July 29, 2016; September 22, 2016; and January 17, 2017
The description of our common stock set forth in the registration statement on Form 8-A12B (No. 001-35021) and any amendment or report filed with the SEC for the purpose of updating this description	December 22, 2010

In addition, we also incorporate by reference all future documents that we file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), after the date of our initial registration statement relating to the securities covered by this prospectus until the completion of the distribution of such securities. These documents include periodic reports, such as annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K (other than current reports or portions thereof furnished under Items 2.02 or 7.01 of Form 8-K, unless specifically incorporated herein), as well as proxy statements. The information incorporated by reference contains information about us and our financial condition and is an important part of this prospectus supplement and the accompanying prospectus.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document, including information included or incorporated by reference into this document, may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, (i) the financial condition, results of operations and business of Evans Bancorp; (ii) statements about Evans Bancorp s plans, objectives, expectations and intentions and other statements that are not historical facts; and (iii) other statements identified by words such as expects, anticipates, intends, plans, believes, seeks, estimates, or words of similar meaning. These forward-looking statements are ba current beliefs and expectations of Evans Bancorp s management and are inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond its control. In addition, these forward-looking statements are subject to assumptions with respect to future business strategies and decisions that are subject to change.

The following factors, among others, could cause actual results to differ materially from the anticipated results or other expectations expressed in the forward-looking statements:

- changes in local, regional and international business, economic or political conditions in the regions where we operate or have significant assets;

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changes in trade, monetary and fiscal policies of various governmental bodies and central banks, that could affect the economic environment in which we operate;

changes in laws, regulations, and policies affecting the financial services industry and the application thereof by regulatory bodies;

effective on January 1, 2015 and subject to certain transition periods, changes in minimum capital requirements, adjustments to prompt corrective action thresholds, increased quality of regulatory capital, revised risk-weighting of certain assets, and implementation of a capital conservation buffer, included in the final rule promulgated by the Board of Governors of the Federal Reserve System (the Federal Reserve Board) on July 2, 2013, to implement the so-called Basel III accords;

the interest rate environment may change, causing margins to compress and adversely affecting net interest income;

the risks associated with continued diversification of assets and adverse changes to credit quality;

higher than expected loan losses within one or more segments of our portfolio;

the risks associated with our concentration of commercial real estate loans;

unexpected significant declines in the loan portfolio due to the lack of economic expansion, increased competition, large prepayments or other factors;

declines in the value our investment portfolio, including other-than-temporary impairment charges on our investment securities;

an unexpected decline in real estate values within our market area;

our internal controls and procedures may not be adequate to prevent losses;

cyber attacks, computer viruses or other malware that may breach the security of our websites or other systems to obtain unauthorized access to confidential information, destroy data, disable or degrade service, or sabotage our systems;

increased competition from other financial services companies in our markets; and

the risk that an economic slowdown could adversely affect credit quality and loan originations.

We assume no obligation for updating our forward-looking statements at any time. When considering these forward-looking statements, you should keep in mind these risks and uncertainties, as well as the other cautionary statements made in this prospectus and the prospectus supplement. You should not place undue reliance on any forward-looking statement, which speaks only as of the date made. You should refer to our periodic and current reports filed with the SEC for specific risks that could cause actual results to be significantly different from those expressed or implied by these forward-looking statements. See Where You Can Find More Information above and Risk Factors below.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary is not complete and does not contain all of the information you should consider before investing in the securities offered by this prospectus supplement. You should read this summary together with the entire prospectus supplement, including the section entitled Risk Factors on page S-11, the accompanying prospectus, and the other documents that are incorporated by reference in this prospectus supplement, including our financial statements and the notes to those financial statements, before making an investment decision.

Company Overview

Evans Bancorp, a New York corporation headquartered in Hamburg, New York, was formed in 1988 to become the holding company for Evans Bank. We are registered as a bank holding company with the Board of Governors of the Federal Reserve System under the Bank Holding Company Act of 1956. Our primary business is the operation of Evans Bank, which provides a full range of banking services to consumer and commercial customers throughout Western New York, and Evans National Financial Services, LLC, which owns 100% of the membership interests in The Evans Agency, LLC (TEA), which sells various premium-based insurance policies on a commission basis in the Western New York region. At September 30, 2016, we had total assets of $1.08 billion, net loans of $899.1 million, deposits of $898.0 million and total stockholders equity of $95.2 million. The Company s common stock is traded on the NYSE MKT under the symbol EVBN.

Evans Bank is a nationally chartered bank, established in 1920. The Bank operates 14 full-service banking centers in Erie, Niagara and Chautauqua Counties, New York. The Bank offers deposit products, which include checking and NOW accounts, savings accounts, and certificates of deposit, as its principal source of funding. The Bank s deposits are insured up to the maximum permitted by the Bank Insurance Fund of the Federal Deposit Insurance Corporation (FDIC). The Bank offers a variety of loan products to its customers, including commercial and consumer loans and commercial and residential mortgage loans. The Bank is subject to the supervision, regulation and examination of the Office of the Comptroller of the Currency (the OCC).

TEA is a full service property and casualty insurance agency with offices located throughout Western New York offering personal, commercial and financial services products. For the nine months ended September 30, 2016, TEA had total revenue of $5.2 million. TEA s primary market area is Erie, Chautauqua, Cattaraugus and Niagara counties, New York. Most lines of personal insurance are provided, including automobile, homeowners, boat, recreational vehicle, landlord, and umbrella coverage. Commercial insurance products are also provided, consisting of property, liability, automobile, inland marine, workers compensation, bonds, crop and umbrella insurance. In addition, TEA provides the following financial services products: life and disability insurance, Medicare EE Benefit supplements, long term care, annuities, mutual funds, retirement programs and New York State Disability.

Evans Bancorp s principal executive offices are located at One Grimsby Drive, Hamburg, New York 14075, and its telephone number is (716) 926-2000. Our internet address is evansbank.com. The information contained on our website should not be considered part of this prospectus supplement or the accompanying prospectus, and the reference to our website does not constitute incorporation by reference of the information contained on the website. Additional information about us and our subsidiaries is included in documents incorporated by reference in this prospectus. See Where You Can Find More Information on page S-1 of this prospectus supplement.

Our Strategy and Financial Highlights

Evans Bancorp s strategy is to continue to grow to increase market share and achieve operating scale while improving profitability and returning value to shareholders. Our biggest strength and earnings driver is commercial and small

business lending. We expect to continue to focus on building on this competitive

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advantage by adding personnel in this area. Management plans to look to expand other revenue opportunities in non-interest income in areas such as employee benefits and financial services. Management anticipates continued disruption in the Company s market area in 2017 due to merger activity among competitors, and expects that this will create additional opportunities to increase market share and secure new customer relationships. It is our intention to continue to develop strategies to deepen existing customer relationships with tailored product sets that reward our most loyal customers. We will continue to diversify our sources of revenue and expand non-interest income through insurance and other financial services and products.

Highlights of our strategy include the following:

Expand Asset Base Through Loan Growth We focus on driving profitability through the expansion of our asset base, primarily with organic loan growth and the diversification of our commercial lending capabilities. Because of our focus on customer service, tailored solutions and local credit decisions, we believe that we are positioned to capture customers from larger institutions operating in our primary service area. From December 31, 2011 to September 30, 2016, our total assets increased from $740.9 million to $1.08 billion, an increase of 46.4%, and our net loans and leases increased from $571.9 million to $899.1 million, an increase of 57.2%.

Core Deposit Growth Strong core deposit growth is a key component of our operating strategy. From December 31, 2011 to September 30, 2016, total deposits increased from $616.2 million to $898.0 million, an increase of 45.7%. We focus on high-quality, low-cost deposits to supplement our balance sheet, and on diversifying our deposit portfolio. At September 30, 2016, our core deposits savings and money market accounts, demand accounts and NOW accounts represented 87% of total deposits. Our cost of deposits for the nine months ended September 30, 2016 was 0.59% and our net interest margin was 3.67%.

Risk Management and Asset Quality We diligently monitor and manage the risk of our operations, including the performance of our loan and securities portfolios, loan growth and core deposit growth, and we manage this growth to ensure that we have adequate capital to support our operations. At September 30, 2016, nonperforming loans were $15.3 million, or 1.67% of total loans. Our allowance for loan losses to total loans outstanding was 1.50% at September 30, 2016. In addition, we completed a core system conversion in 2016 to further strengthen internal controls and compliance systems, as well as allow for processing of more complex transactions by our customers. The system conversion is intended to provide additional risk management support as well as more robust information availability to support future growth of the Bank.

Diversify Financial Services and Expand Non-Interest Income In addition to expanding our market area and customer base, we recognize that customers have a wide variety of financial needs that we can position the Company to meet. We believe that increasing the variety of services that we offer will help to increase our customer base and deepen customer relationships within our targeted market areas. Through TEA, we offer personal and commercial lines insurance products and services throughout Western New York. We also believe that the Company will benefit from decreased costs resulting from integrated sales efforts and cross-selling capabilities, increased fee income resulting from the provision of additional services and reduced interest rate risk associated with a diverse revenue mix. Non-interest income represented 25% of

total revenues for the nine months ended September 30, 2016.

Recruit and Retain Superior Talent Our executive management team together has 164 years of experience in the financial services industry, and we carefully screen and select talented candidates for positions at all levels of our organization. We have built a skilled and experienced lending team with a high level of expertise in commercial and small business lending and have a strong team in place to support these diverse lending capabilities. As market disruption continues, we plan to maintain our focus on adding top level talent throughout all aspects of the organization.

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Brand Development We are actively involved in marketing initiatives aimed at increasing brand awareness. We believe that our focus on customer service and developing and maintaining customer experiences and relationships better positions us to attract loan, deposit, insurance and financial services customers in our primary service area from larger national and regional financial institutions. We also believe that disruption in our market place as a result of acquisition activity among competitors provides further opportunity for growth and customer expansion.

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THE OFFERING

Issuer	Evans Bancorp, Inc., a New York corporation.
Common Stock Offered	400,000 shares of common stock, $0.50 par value per share.(1)
Common Stock Outstanding after the Offering	4,700,634 shares of common stock, based on shares outstanding as of January 17, 2017.(2)
Net Proceeds to Us	We estimate that net proceeds from this offering will be approximately $12.9 million (or $14.8 million if the underwriters exercise in full their option to purchase additional shares), after deducting the underwriting discount and estimated offering expenses payable by us.
Use of Proceeds	We intend to use the net proceeds generated by this offering to support our organic growth and for other general corporate purposes, including contributing capital to the Bank. See Use of Proceeds on page S-16 of this prospectus supplement.
Market and Trading Symbol for the Common Stock	Our common stock is listed and traded on the NYSE MKT under the symbol EVBN.
Dividends	We currently pay a semi-annual cash dividend of $0.38 per share. Although we expect to continue paying dividends semi-annually, any future determination to pay dividends on our common stock will be made by our board of directors and will depend upon our results of operations, financial condition, capital requirements, regulatory and contractual restrictions, our business strategy and other factors that our board of directors deems relevant. For additional information, see Market For Common Stock and Our Dividend Policy.
Risk Factors	An investment in our common stock involves risks. You should carefully consider the information contained in, or incorporated by reference into, this prospectus supplement and the accompanying prospectus. In particular, we urge you to consider carefully the factors set forth under Risk Factors beginning on page S-11 of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement before investing in our common stock.

(1) Excludes the underwriters option to purchase up to 60,000 additional shares of our common stock.
(2) Excludes 251,702 shares subject to outstanding compensatory stock options having a weighted average exercise price of $18.66 per share; 147,262 shares reserved for issuance pursuant to our dividend reinvestment and stock purchase plan; and 60,000 shares subject to the underwriters purchase option granted in this offering.

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SUMMARY OF SELECTED FINANCIAL DATA

The following tables set forth consolidated financial data for the Company as of and for each of the five years ended December 31, 2015 (which, other than our financial ratios, has been derived from our audited consolidated financial statements), and as of and for the nine months ended September 30, 2016 and 2015 (unaudited). You should read these tables together with the historical consolidated financial information contained in our consolidated financial statements and related notes, as well as Management s Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2015, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, which have been filed with the SEC and are incorporated herein by reference. Information for the nine months ended September 30, 2016 and 2015 is derived from unaudited interim consolidated financial statements and has been prepared on the same basis as our audited consolidated financial statements and includes, in the opinion of management, all adjustments, consisting of only normal recurring adjustments, necessary to present fairly the data for such period. The results of operations for the nine months ended September 30, 2016 do not necessarily indicate the results which may be expected for any future interim period or for the full year.

	At or For the Nine Months Ended September 30,	
	2016	2015
	(dollars in thousands, except share and per share data) (unaudited)	
Balance Sheet Data		
Assets	$ 1,084,663	$ 920,891
Interest-earning assets	1,013,126	856,013
Investment securities	104,859	106,651
Loans, net	899,140	717,783
Deposits	897,965	782,303
Borrowings	74,136	32,640
Stockholders equity	95,198	89,673
Income Statement Data		
Net interest income	$ 25,845	$ 23,368
Non-interest income	8,609	10,800
Non-interest expense	25,958	24,034
Net income	5,933	6,089
Stock and Related Per Share Data		
Earnings per share basic	$ 1.39	$ 1.44
Earnings per share diluted	1.37	1.41
Cash dividends per share	0.76	0.72
Book value per share	$ 22.20	$ 21.16
Common shares outstanding	4,287,400	4,238,448

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	At or For the Nine Months Ended September 30, 2016	2015
	(dollars in thousands, except share and per share data) (unaudited)	
Performance Ratios		
Return on average assets[1]	0.79%	0.91%
Return on average equity[1]	8.42	9.20
Net interest margin[1][2]	3.67	3.76
Efficiency ratio[3]	74.00	70.34
Dividend payout ratio	54.70	50.00
Capital Ratios		
Tier 1 capital to average assets	9.55%	10.32%
Stockholders equity to total assets	8.78	9.74
Asset Quality Ratios		
Total non-performing assets to total assets	1.41%	0.89%
Total non-performing loans to total loans	1.67	1.12
Net charge-offs to average loans[1]	0.00	0.02
Allowance for loan losses to total loans	1.50	1.84
Other Data		
Number of banking centers	14	13
Full time equivalent employees	260	264

(1) Calculated on an annualized basis.
(2) The net interest margin represents net interest income (fully taxable equivalent) as a percent of average interest-earning assets for the period.
(3) The efficiency ratio represents noninterest expense divided by the sum of net interest income (fully taxable equivalent) and noninterest income.

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	At or For the Year Ended December 31,				
	2015	2014	2013	2012	2011
	(dollars in thousands, except share and per share data)				
Balance Sheet Data					
Assets	$ 939,107	$ 846,809	$ 833,498	$ 809,676	$ 740,902
Interest-earning assets	873,450	785,302	767,629	750,287	682,140
Investment securities	98,758	97,132	102,049	95,807	103,783
Loans, net	761,101	683,131	635,493	573,163	571,910
Deposits	802,982	707,635	706,612	678,992	616,203
Borrowings	32,151	38,808	33,681	42,441	42,340
Stockholders equity	91,256	85,788	80,712	74,828	68,988
Income Statement Data					
Net interest income	$ 31,804	$ 31,099	$ 28,347	$ 27,780	$ 25,988
Non-interest income	13,720	10,273	12,161	12,823	12,432
Non-interest expense	32,698	31,252	29,380	28,792	27,241
Net income	7,843	8,187	7,857	8,132	6,112
Stock and Related Per Share Data					
Earnings per share basic	$ 1.85	$ 1.96	$ 1.88	$ 1.96	$ 1.49
Earnings per share diluted	1.82	1.92	1.85	1.95	1.49
Cash dividends per share	0.72	0.65	0.26	0.68	0.40
Book value per share	21.44	20.41	19.21	17.94	16.72
Common shares outstanding	4,257,179	4,203,684	4,201,362	4,171,473	4,124,892
Performance Ratios					
Return on average assets	0.87%	0.98%	0.96%	1.04%	0.86%
Return on average equity	8.82	9.84	10.06	11.20	9.17
Net interest margin[(1)]	3.80	4.01	3.74	3.84	3.99
Efficiency ratio[(2)]	71.83	70.83	71.98	70.05	69.68
Dividend payout ratio	38.92	33.16	13.83	34.69	26.85
Capital Ratios					
Tier 1 capital to average assets	10.45%	10.84%	10.36%	9.69%	9.71%
Stockholders equity to total assets	9.72	10.13	9.68	9.24	9.31
Asset Quality Ratios					
Total non-performing assets to total assets	1.71%	1.25%	1.65%	1.02%	2.05%
Total non-performing loans to total loans	2.07	1.52	2.12	1.41	2.60
Net charge-offs (recoveries) to average loans	0.12	0.03	(0.04)	0.29	0.26
Allowance for loan losses to total loans	1.66	1.80	1.78	1.67	1.97
Other Data					
Number of banking centers	13	13	13	13	12
Full time equivalent employees	258	251	241	238	242

(1) The net interest margin represents net interest income (fully taxable equivalent) as a percent of average interest-earning assets for the period.
(2) The efficiency ratio represents noninterest expense divided by the sum of net interest income (fully taxable equivalent) and noninterest income.

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RISK FACTORS

An investment in our common stock involves risks. Before making an investment decision, you should carefully read and consider the risk factors described below, which describe the risks related to this offering and ownership of our common stock, as well as the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as may be supplemented by other documents incorporated by reference into this prospectus supplement or the accompanying prospectus. Please refer to Where You Can Find More Information in this prospectus supplement and the accompanying prospectus for discussions of these other filings. Any of these risks, if they occur, could materially adversely affect our business, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect us. In any such case, you could lose all or a portion of your original investment. This prospectus supplement and the accompanying prospectus are qualified in its entirety by those risk factors.

Risks Relating to Our Business

For risks associated with our business and industry, see the section entitled Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2015, which are incorporated in this prospectus supplement by reference, as the same may be updated from time to time prior to the completion of this offering by our future filings under the Exchange Act.

Risks Relating to this Offering and Ownership of Our Common Stock

Historically, the price of our common stock has fluctuated significantly, which may make it difficult for you to resell shares of common stock at prices you find attractive.

Historically, our stock price has fluctuated significantly. For example, for the year ended December 31, 2016, the high sale price per share of our common stock on the NYSE MKT was $37.67 and the low sale price per share was $22.87. On January 17, 2017, the last reported sale price of our common stock on the NYSE MKT was $35.00 per share. We expect that the market price of our common stock will continue to fluctuate and there can be no assurances about the market prices for our common stock, which may make it difficult for you to resell shares of common stock at prices you find attractive.

Our stock price may fluctuate as a result of a variety of factors, many of which are beyond our control. In addition to the other risk factors contained or incorporated by reference herein, these factors include:

- Actual or anticipated quarterly fluctuations in our operating results and financial condition;
- Changes in expectations as to future financial performance or buy/sell recommendations of securities analysts;
- Speculation in the press or investment community regarding stock prices generally or relating to our reputation or the financial services industry;

Strategic actions by us or our competitors, such as acquisitions, restructurings, dispositions or financings;

Fluctuations in the stock price and operating results of our competitors;

Sales of our equity or equity-related securities;

Proposed or adopted regulatory changes or developments;

Anticipated or pending investigations, proceedings or litigation that involve or affect us;

Changes in global financial markets and global economies and general market conditions, such as interest or foreign exchange rates, stock, commodity or real estate valuations or volatility and other geopolitical, regulatory or judicial events; and

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General market conditions and, in particular, developments related to market conditions for the financial services industry.

The trading volume in our common stock may be low, and the sale of a substantial number of shares in the public market could depress the price of our stock and make it difficult for you to sell your shares.

Our common stock is currently traded on the NYSE MKT. An active trading market for our common stock may not develop or be sustained after the offering. Our common stock is thinly traded and has less liquidity than the average trading market for many other publicly traded companies, with volume averaging approximately 5,296 shares per day over the nine months ended September 30, 2016. Thinly traded stocks can be more volatile than stock trading in an active public market. General market declines or market volatility in the future, especially in the financial institutions sector of the economy, could adversely affect the price of our common stock, and the current market price may not be indicative of future market prices. Therefore, our stockholders may not be able to sell their shares at the volume, prices or times that they desire.

We may issue additional equity or equity related securities, or engage in other transactions which dilute our book value or affect the priority of the common stock, which may adversely affect the market price of our common stock.

Our board of directors may determine from time to time that we need to raise additional capital by issuing additional shares of our common stock or other securities. We are not restricted from issuing additional shares of common stock, including securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. Because our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings, or the prices at which such offerings may be affected. Such offerings could be dilutive to common stockholders. New investors also may have rights, preferences and privileges, including with respect to the receipt of dividends, that are senior to, and that adversely affect, our then current common stockholders. If we raise additional capital by selling debt securities, upon liquidation, holders of our debt securities, and lenders with respect to other borrowings, will receive distributions of our available assets prior to the holders of our common stock. Additional equity offerings may dilute the holdings of our existing stockholders or reduce the market price of our common stock, or both. Holders of our common stock are not entitled to preemptive rights or other protections against dilution.

We may reduce or eliminate the cash dividend on our common stock.

Holders of our common stock are only entitled to receive such cash dividends as our board of directors may declare out of funds legally available for such payments. Although we have historically declared cash dividends on our common stock, we are not required to do so and may reduce or eliminate our common stock cash dividend in the future. This could adversely affect the market price of our common stock. As a bank holding company, our ability to declare and pay dividends is dependent on certain federal regulatory considerations including the guidelines of the Federal Reserve Board regarding capital adequacy and dividends. See Market for Common Stock and Our Dividend Policy for more information.

If we fail to pay interest on or otherwise default on our subordinated debt, we will be prohibited from paying dividends or distributions on our common stock.

As of September 30, 2016, we had $11.3 million of junior subordinated debentures outstanding. The agreements under which the subordinated debentures were issued prohibit us from paying any dividends on our common stock or making any other distributions to our shareholders at any time when there shall have occurred and be continuing an event of default under the applicable agreement. Events of default generally consist of, among other things, our failure to pay any principal or interest on the subordinated debentures, as applicable,

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when due, our failure to comply with certain agreements, terms and covenants under the agreement (without curing such default following notice), and certain events of bankruptcy, insolvency or liquidation relating to us.

If an event of default were to occur and we did not cure it, we would be prohibited from paying any dividends or making any other distributions to our shareholders or from redeeming or repurchasing any of our common stock, which would likely have a material adverse effect on the market value of our common stock. Moreover, without notice to or consent from the holders of our common stock, we may enter into additional financing arrangements that may limit our ability to purchase or to pay dividends or distributions on our common stock.

An investment in our common stock is not an insured deposit and is not guaranteed by the FDIC, so you could lose some or all of your investment.

Our common stock is not a bank deposit and, therefore, is not insured against loss by the Federal Deposit Insurance Corporation or any other public or private entity. Investment in our common stock is inherently risky for the reasons described in this Risk Factors section, elsewhere in this prospectus supplement and the accompanying prospectus, and the additional documents and information incorporated by reference, and is subject to the same market forces that affect the common stock in any company. As a result, if you acquire our common stock, you may lose some or all of your investment.

Our certificate of incorporation and bylaws as well as certain banking laws may have an anti-takeover effect.

Provisions of our certificate of incorporation and bylaws and federal banking laws, including regulatory approval requirements, could make it more difficult for a third party to acquire us, even if doing so would be perceived to be beneficial to our shareholders. The combination of these provisions may inhibit a non-negotiated merger or other business combination or make such a transaction more expensive, which, in turn, could adversely affect the market price of our common stock. See Description of the Securities Description of Common Stock Provisions of Our Certificate of Incorporation, Our Bylaws and Federal Law Affecting Our Shareholders in the accompanying prospectus.

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MARKET FOR COMMON STOCK AND OUR DIVIDEND POLICY

Our common stock is listed on the NYSE MKT under the symbol EVBN. As of January 17, 2017, we had 4,300,634 shares of common stock outstanding, held of record by approximately 1,227 shareholders of record. The actual number of common shareholders is greater than the number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

The following table sets forth, for the periods indicated, the high and low sales prices per share for the common stock as reported on the NYSE MKT and the cash dividends paid per common share, for the periods shown.

Quarter Ended	High	Low	Dividend Paid
March 31, 2017 (through January 17, 2017)	$ 36.10	$ 32.00	
December 31, 2016	$ 37.67	$ 25.90	
September 30, 2016	$ 27.87	$ 24.41	$ 0.38
June 30, 2016	$ 25.48	$ 22.87	
March 31, 2016	$ 26.10	$ 23.55	$ 0.38
December 31, 2015	$ 25.75	$ 22.85	
September 30, 2015	$ 24.95	$ 22.75	$ 0.36
June 30, 2015	$ 25.06	$ 23.75	
March 31, 2015	$ 25.75	$ 23.26	$ 0.36
December 31, 2014	$ 25.50	$ 22.75	
September 30, 2014	$ 23.75	$ 22.80	$ 0.34
June 30, 2014	$ 23.70	$ 22.06	
March 31, 2014	$ 24.87	$ 20.58	$ 0.31

The amount of future dividends, if any, will be determined by our board of directors and will depend on our earnings, financial condition and other factors considered by the board of directors to be relevant. In addition, the payment of cash dividends on the common stock will depend upon the ability of the Bank to declare and pay dividends to us. The Bank s ability to pay dividends will depend primarily upon its earnings, financial condition, and need for funds, as well as applicable governmental policies. Even if we have earnings in an amount sufficient to pay dividends, the Bank s board of directors may determine to retain earnings for the purpose of funding growth. The Bank generally pays a dividend to us to provide funds for: debt service on the subordinated debentures, a portion of the proceeds of which were contributed to the Bank as capital; dividends that we pay to our shareholders; stock repurchases; and other expenses.

There are various legal limitations with respect to the Bank s ability to pay dividends to us and our ability to pay dividends to shareholders. Under the New York Business Corporation Law, we may pay dividends on our outstanding shares except if we are insolvent or would be made insolvent by the dividend. Under federal banking law, the prior approval of the Federal Reserve Board and the Office Comptroller of the Currency (the OCC) may be required in certain circumstances prior to the payment of dividends by us or the Bank. A national bank may generally declare a dividend, without approval from the OCC, in an amount equal to its year-to-date net income plus the prior two years net income that is still available for dividend. The OCC has the authority to prohibit a national bank from paying dividends if such payment is deemed to be an unsafe or unsound practice. In addition, as a depository institution the

deposits of which are insured by the FDIC, the Bank may not pay dividends or distribute any of its capital assets while it remains in default on any assessment due to the FDIC. The Bank currently is not (and never has been) in default under any of its obligations to the FDIC.

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The Federal Reserve Board has issued a policy statement regarding the payment of dividends by bank holding companies. In general, the Federal Reserve Board s policy provides that dividends should be paid only out of current earnings and only if the prospective rate of earnings retention by the bank holding company appears consistent with the organization s capital needs, asset quality and overall financial condition. The Federal Reserve Board has the authority to prohibit us from paying dividends if such payment is deemed to be an unsafe or unsound practice.

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USE OF PROCEEDS

We expect to receive net proceeds from this offering of approximately $12.9 million (or $14.8 million if the underwriters exercise their option to purchase additional shares in full) after deducting the underwriting discount and estimated expenses payable by us. We intend to use the net proceeds generated by this offering to support our organic growth and for other general corporate purposes, including contributing capital to the Bank.

CAPITALIZATION

The following table shows our capitalization as of September 30, 2016 on an actual basis and on an as adjusted basis to give effect to the receipt of the net proceeds from this offering.

	As of September 30, 2016	
	Actual	As Adjusted
	(dollars in thousands) (unaudited)	
Stockholders Equity		
Common stock, $0.50 par value per share (10,000,000 shares authorized; 4,287,400 shares outstanding at September 30, 2016 and 4,687,400 shares outstanding as adjusted)[(1)]	2,147	2,347
Capital Surplus	43,983	56,643
Treasury stock at cost (2,822 shares at September 30, 2016)	(69)	(69)
Retained earnings	50,294	50,294
Accumulated other comprehensive income (loss), net of income tax	(1,157)	(1,157)
Total Stockholders Equity	$ 95,198	$ 108,058
Capital Ratios		
Tier 1 capital to risk-weighted assets	10.82%	12.21%
Total capital to risk-weighted assets	12.07	13.46
Tier 1 capital to average assets	9.55	10.64

(1) The number of common shares to be outstanding after the offering is based on actual shares outstanding as of September 30, 2016, and assumes that 400,000 shares of common stock are sold in the offering and that the underwriters option to purchase additional shares is not exercised. In addition, the number of common shares to be outstanding after this offering excludes 261,930 shares subject to outstanding compensatory stock options having a weighted average exercise price of $18.74 per share; and 157,403 shares reserved for issuance pursuant to our dividend reinvestment and stock purchase plan.

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DESCRIPTION OF OUR COMMON STOCK

Please refer to Description of Securities Common Stock in the accompanying prospectus for a summary description of our common stock being offered hereby, including the following: dividends, voting rights, liquidation events, no preemptive or redemption rights, and anti-takeover effects of certain provisions of our certificate of incorporation, our bylaws and federal and state laws affecting our shareholders.

We are authorized to issue 10,000,000 shares of common stock, par value $0.50 per share. As of January 17, 2017, we had 4,300,634 shares of common stock outstanding. As of January 17, 2017, there were also 251,702 shares of common stock subject to outstanding compensatory stock options having a weighted average exercise price of $18.66 per share; and 147,262 shares of common stock reserved for issuance pursuant to our dividend reinvestment and stock purchase plan.

UNDERWRITING

We are offering the shares of our common stock described in this prospectus supplement in an underwritten offering through Sandler O Neill & Partners, L.P. and Hovde Group, LLC. We have entered into an underwriting agreement with Sandler O Neill & Partners, L.P., on behalf of the underwriters, with respect to the common stock being offered. Subject to the terms and conditions contained in the underwriting agreement, the underwriters have agreed to purchase, at the public offering price less the underwriting discount set forth on the cover page of this prospectus supplement, all of the shares of common stock being offered by this prospectus supplement.

The underwriting agreement provides that the underwriters obligations to purchase shares of our common stock depend on the satisfaction of the conditions contained in the underwriting agreement, including:

- the representations and warranties made by us are true and our agreements have been performed;
- there is no material adverse change in or affecting our business, financial condition, stockholders equity, liquidity, results of operations or prospects; and
- we deliver customary closing documents.

Subject to these conditions, the underwriters are committed to purchase and pay for all shares of our common stock offered by this prospectus supplement, if any such shares are taken. However, the underwriters are not obligated to take or pay for the shares of our common stock covered by its purchase option described below, unless and until such option is exercised.

Purchase Option. We have granted the underwriters an option, exercisable no later than 30 days after the date of the underwriting agreement, to purchase up to an aggregate of 60,000 additional shares of common stock at the public offering price less the underwriting discount set forth on the cover page of this prospectus supplement. We will be obligated to sell these shares of common stock to the underwriters to the extent such option is exercised.

Commissions and Expenses. The underwriters propose to offer our common stock directly to the public at the public offering price set forth on the cover page of this prospectus supplement and to dealers at the public offering price less a concession not in excess of $1.1550 per share. After the public offering of our common stock, the underwriters may

change the offering price, concessions and other selling terms. The underwriters will be reimbursed for out-of-pocket expenses (including attorney s fees up to $100,000).

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The following table shows the per share and total underwriting discount that we will pay to the underwriters and the proceeds we will receive before expenses. These amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares of our common stock.

	Per Share	Total Without Exercise of Purchase Option	Total With Exercise of Purchase Option
Public offering price	$ 35.00	$ 14,000,000	$ 16,100,000
Underwriting discount	$ 1.925	$ 770,000	$ 885,500
Proceeds to us before expenses	$ 33.075	$ 13,230,000	$ 15,214,500

We estimate that the total expenses of this offering, exclusive of the underwriting discount, will be approximately $370,000, and are payable by us.

Indemnity. We have agreed to indemnify the underwriters, and persons who control the underwriters, against certain liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments that the underwriters may be required to make in respect of these liabilities.

Lock-Up Agreement. We, and each of our directors and executive officers, have agreed, for a period of 90 days after the date of this prospectus supplement, not to, without the prior written consent of the underwriters, directly or indirectly offer, pledge, sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock, file, or cause to be filed, any registration statement under the Securities Act of 1933 with respect to any of the foregoing or enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of our common stock, whether such transaction would be settled by delivery of common stock or other securities, in cash or otherwise.

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions and syndicate covering transactions.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares of common stock over-allotted by the underwriters is not greater than the number of shares that it may purchase in its purchase option. In a naked short position, the number of shares involved is greater than the number of shares in its purchase option. The underwriters may close out any short position by exercising its purchase option and/or by purchasing shares in the open market.

Syndicate covering transactions involve purchases of common stock in the open market after this offering has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which it may purchase shares through exercise of its purchase option. If the underwriters sell more shares than could be covered by exercise of its purchase option and, therefore, has a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in this offering.

These stabilizing transactions and syndicate covering transactions may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our

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common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the market price of our common stock. These transactions may be effected on the NYSE MKT, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making. In connection with this offering, the underwriters and selected dealers, if any, who are qualified market makers on the NYSE MKT, may engage in passive market making transactions in our common stock on the NYSE MKT in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 permits passive market making activity by the participants in this offering. Passive market making may occur before the pricing of this offering or before the commencement of offers or sales of our common stock. Each passive market maker must comply with applicable volume and price limitations and must be identified as a passive market maker. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for the security. If all independent bids are lowered below the bid of the passive market maker, however, the bid must then be lowered when purchase limits are exceeded. Net purchases by a passive market maker on each day are limited to a specified percentage of the passive market maker s average daily trading volume in the common stock during a specified period and must be discontinued when that limit is reached. The underwriters and other dealers are not required to engage in passive market making and may end passive market making activities at any time.

Our Relationship with the Underwriters. The underwriters and their affiliates are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and some of its affiliates have performed and expect to continue to perform financial advisory and investment banking services for us in the ordinary course of their respective businesses, and may have received, and may continue to receive, in the future, compensation for such services.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Our common stock is being offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of certain legal matters by counsel for the underwriters and other conditions.

TRANSFER AGENT

The Transfer Agent for our common stock is Computershare Trust Company, N.A., Canton, Massachusetts.

LEGAL MATTERS

The validity of the shares of common stock offered hereby and selected other legal matters in connection with the offering will be passed upon for us by the law firm of Luse Gorman, PC, Washington, D.C. Kilpatrick, Townsend & Stockton LLP, Washington, D.C., will pass upon certain legal matters for the underwriters.

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EXPERTS

The consolidated financial statements of Evans Bancorp, Inc. incorporated in this prospectus supplement by reference to Evans Bancorp, Inc. s Annual Report on Form 10-K for the year ended December 31, 2015 have been so incorporated in reliance on the report of KPMG LLP, an independent registered public accounting firm, given upon their authority as experts in accounting and auditing.

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PROSPECTUS

$50,000,000

Evans Bancorp, Inc.

Debt Securities

Common Stock

Warrants

Purchase Contracts

Units

We may offer and sell from time to time up to $50.0 million of unsecured debt securities, which may consist of notes, debentures, or other evidences of indebtedness; shares of common stock; purchase contracts; warrants to purchase other securities; and units consisting of any combination of the above securities. This prospectus provides you with a general description of the securities listed above. Each time we offer any securities pursuant to this prospectus, we will provide you with a prospectus supplement, and, if necessary, a pricing supplement, that will describe the specific amounts, prices and terms of the securities being offered. These supplements may also add, update or change information contained in this prospectus. To understand the terms of the securities offered, you should carefully read this prospectus with the applicable supplements, which together provide the specific terms of the securities we are offering.

Our common stock is traded on the NYSE MKT under the symbol EVBN.

This prospectus may be used to offer and sell securities only if accompanied by the prospectus supplement and any applicable pricing supplement for those securities.

You should read this prospectus and any supplements carefully before you invest. Investing in our securities involves a high degree of risk. See the section entitled Risk Factors, on page 3 of this prospectus, in any prospectus supplement and in the documents we file with the Securities and Exchange Commission that are incorporated in this prospectus by reference for a discussion of certain risks and uncertainties you should consider.

These securities are not deposits or obligations of a bank or savings association and are not insured or guaranteed by the Federal Deposit Insurance Corporation or any other governmental agency.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined that this prospectus or any prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 22, 2016

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IMPORTANT NOTICE ABOUT INFORMATION PRESENTED IN THIS PROSPECTUS AND THE ACCOMPANYING PROSPECTUS SUPPLEMENT

We may provide information to you about the securities we are offering in three separate documents that progressively provide more detail:

- this prospectus, which provides general information about Evans Bancorp, Inc. and the securities being registered, some of which may not apply to your securities;
- a prospectus supplement, which describes the terms of a particular issuance of securities, some of which may not apply to your securities and which may not include information relating to the prices of the securities being offered; and
- if necessary, a pricing supplement, which describes the pricing terms of your securities.

If the terms of your securities vary among the pricing supplement, the prospectus supplement and the prospectus, you should rely on the information in the following order of priority:

- the pricing supplement, if any;
- the prospectus supplement; and
- this prospectus.

We include cross-references in this prospectus and the prospectus supplement to captions in these materials where you can find further related discussions. The following Table of Contents and the Table of Contents included in the prospectus supplement provide the pages on which these captions are located.

Unless indicated in the applicable prospectus supplement, we have not taken any action that would permit us to publicly sell these securities in any jurisdiction outside the United States . If you are an investor outside the United States , you should inform yourself about and comply with any restrictions as to the offering of the securities and the distribution of this prospectus.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the SEC) utilizing a shelf registration process. Under this shelf registration process, we may from time to time offer and sell the debt securities, common stock, warrants, purchase contracts, or units consisting of a combination of any of the securities described in this prospectus in one or more offerings, up to a total dollar amount of $50.0 million. This prospectus provides you with a general description of the securities covered by it. Each time we offer these securities, we will provide a prospectus supplement and, if necessary, a pricing supplement, that will contain specific information about the terms of the offer. The prospectus supplement and any pricing supplement may also add, update or change information contained in this prospectus. You should read this prospectus, the prospectus supplement and any pricing supplement together with the additional information described under the heading Where You Can Find More Information.

Unless otherwise indicated or unless the context requires otherwise, all references in this prospectus to Evans Bancorp, the Company, we, us, our or similar references mean Evans Bancorp, Inc. and references to the Bank Evans Bank.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC s public reference room at 100 F Street, N.E. , Room 1580, Washington, D.C. 20549 . You should call 1-800-SEC-0330 for more information on the public reference room. Our SEC filings are also available to you on the SEC s Internet site at http://www.sec.gov.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC s Internet site.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference information into this prospectus. This means that we can disclose important information to you by referring you to another document that we file separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus, except for any information that is superseded by information that is included directly in this document or in a more recent incorporated document.

This prospectus incorporates by reference the documents listed below that we have previously filed with the SEC.

SEC Filings	Period or Filing Date (as applicable)
Annual Report on Form 10-K	Year ended December 31, 2015, as amended on March 23, 2016
Current Reports on Form 8-K (in each case other than those portions furnished under Item 2.02 or 7.01 of Form 8-K)	February 4, 2016 February 17, 2016
The description of our common stock set forth in the registration statement on Form 10 (No. 000-18539) and any amendment or	April 30, 1999

report filed with the SEC for the purpose of updating this description

In addition, we also incorporate by reference all future documents that we file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of our initial registration statement relating to the securities covered by this prospectus until the completion of the distribution of such securities. These documents include periodic reports, such as annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K (other than current reports furnished under Items 2.02 or 7.01 of Form 8-K), as well as proxy statements.

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The information incorporated by reference contains information about us and our financial condition and is an important part of this prospectus.

You can obtain any of the documents incorporated by reference in this document through us, or from the SEC through the SEC s Internet site at *www.sec.gov* . Documents incorporated by reference are available from us without charge, excluding any exhibits to those documents, unless the exhibit is specifically incorporated by reference as an exhibit in this prospectus. You can obtain documents incorporated by reference in this prospectus from us by requesting them in writing or by telephone from us at:

Corporate Secretary

Evans Bancorp, Inc.

One Grimsby Drive

Hamburg, New York 14075

(716) 926-2000

In addition, we maintain a corporate website, *www.evansbank.com* . We make available, through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. This reference to our website is for the convenience of investors as required by the SEC and shall not be deemed to incorporate any information on the website into this Registration Statement.

We have not authorized anyone to give any information or make any representation about us that is different from, or in addition to, those contained in this prospectus or in any of the materials that we have incorporated into this prospectus. If anyone does give you information of this sort, you should not rely on it. If you are in a jurisdiction where offers to sell, or solicitations of offers to purchase, the securities offered by this document are unlawful, or if you are a person to whom it is unlawful to direct these types of activities, then the offer presented in this document does not extend to you. The information contained in this document speaks only as of the date of this document unless the information specifically indicates that another date applies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make statements in this prospectus and the documents incorporated into it by reference that are considered forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995 (the PSLRA). Such forward-looking statements, in addition to historical information, involve risk and uncertainties, and are based on the beliefs, assumptions and expectations of management of the Company. Words such as expects, believes, should, plans, anticipates, will, potential, could, intend, may, outlook, predict, project, would, estima variation of such similar expressions are intended to identify such forward-looking statements. Forward-looking statements speak only as of the date they are made. Because forward-looking statements are subject to assumptions and uncertainties, actual results or future events could differ, possible materially, from those that we anticipated in our

forward-looking statements and future results could differ materially from historical performance.

Our forward-looking statements are subject to the following principal risks and uncertainties:

- changes in economic conditions including an economic recession that could affect the value of real estate collateral and the ability for borrowers to repay their loans;
- the timing and amount of revenues that we may recognize;
- increased competition among depository and other financial institutions;
- inflation and changes in the interest rate environment (including changes in the shape of the yield curve) that reduce our margins or fair value of financial instruments;
- our ability to enter new markets successfully and capitalize on growth opportunities;
- changes in consumer spending, borrowing and savings habits;
- legislative and regulatory changes, including increases in Federal Deposit Insurance Corporation (FDIC) insurance rates;

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monetary and fiscal policies of the federal government, including the impact of the current government effort to restructure the U.S. financial and regulatory system;
changes in tax policies, rates and regulations of federal, state and local tax authorities;
changes in interest rates; deposit flows;
the cost of funds; demand for loan products and other financial services; competition;
changes in the quality and composition of the Bank s loan and investment portfolios;
changes in management s business strategies;
changes in accounting principles, policies or guidelines;
changes in real estate values; and
a variety of other matters which, by their nature, are subject to significant uncertainties.

We provide greater detail regarding some of these factors in our Form 10-K for the year ended December 31, 2015, including the Risk Factors section of that report and in our other filings we make with the SEC. Our forward-looking statements may also be subject to other risks and uncertainties, including those that we may discuss elsewhere in other documents we file with the SEC from time to time.

You should not place undue reliance on these forward-looking statements, which reflect our expectations only as of the date of this prospectus. We do not assume any obligation to revise forward-looking statements except as may be required by law.

RISK FACTORS

Before making an investment decision, you should carefully consider the risks described under Risk Factors in the applicable prospectus supplement and in our most recent Annual Report on Form 10-K, and in our updates to those Risk Factors in our Quarterly Reports on Form 10-Q, together with all of the other information appearing in this prospectus or incorporated by reference into this prospectus, the prospectus supplement or any applicable pricing supplement, in light of your particular investment objectives and financial circumstances. In addition to those risk factors, there may be additional risks and uncertainties of which management is not aware or focused on or that management deems immaterial. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment.

OUR COMPANY

We are a New York corporation formed in 1988 to become the holding company for Evans Bank. We are registered as a bank holding company under the Bank Holding Company Act of 1956, as amended. Our primary business is the operation of our subsidiaries: (1) Evans Bank, N.A., which provides a full range of banking services to consumer and commercial customers in Western New York; and (2) Evans National Financial Services, LLC (ENFS), which owns 100% of the membership interests in The Evans Agency, LLC (TEA), which sells various premium-based insurance policies on a commission basis. At December 31, 2015, we had total assets of $939 million, net loans and leases of $761 million, deposits of $803 million and total stockholders equity of $91 million.

Evans Bank is a nationally chartered bank that has its headquarters at One Grimsby Drive, Hamburg, NY, and a total of 13 full-service banking offices in Erie County and Chautauqua County, New York. The Bank offers deposit products, which include checking and NOW accounts, savings accounts, and certificates of deposit, as its principal source of funding. The Bank s deposits are insured up to the maximum permitted by the Bank Insurance Fund (the Insurance Fund) of the Federal Deposit Insurance Corporation (FDIC). The Bank offers a variety of loan products to its customers, including commercial and consumer loans and commercial and residential mortgage loans.

As is the case with banking institutions generally, the Bank s operations are significantly influenced by general economic conditions and by related monetary and fiscal policies of banking regulatory agencies, including the Federal Reserve Board (FRB) and FDIC. The Bank is also subject to the supervision, regulation and examination of the Office of the Comptroller of the Currency of the United States of America (the OCC).

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TEA is a property and casualty insurance agency headquartered in Hamburg, New York, with offices located throughout Western New York. TEA is a full-service insurance agency offering personal, commercial and financial services products. For the year ended December 31, 2015, TEA had total revenue of $ 7 million. TEA s primary market area is Erie, Chautauqua, Cattaraugus and Niagara counties. Most lines of personal insurance are provided, including automobile, homeowners, boat, recreational vehicle, landlord, and umbrella coverage. Commercial insurance products are also provided, consisting of property, liability, automobile, inland marine, workers compensation, bonds, crop and umbrella insurance. TEA also provides the following financial services products: life and disability insurance, Medicare supplements, long term care, annuities, mutual funds, retirement programs and New York State Disability.

Our principal executive offices are located at One Grimsby Drive, Hamburg, New York 14075, and our telephone number is (716) 926-2000.

Additional information about us and our subsidiaries is included in documents incorporated by reference in this prospectus. See Where You Can Find More Information on page 1 of this prospectus.

CONSOLIDATED RATIOS OF EARNINGS TO FIXED CHARGES

Our consolidated ratios of earnings to fixed charges were as follows for the periods presented:

	Years Ended December 31,				
	2015	2014	2013	2012	2011
Ratios of Earnings to Fixed Charges:					
		11			

The use of any of our C-Scan Cap, C-Scan Track or C-Scan View could result in product liability or similar claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability or similar claims related to the manufacturing, marketing and sale of medical devices. The medical device industry has historically been litigious, and we face financial exposure to product liability or similar claims if the use of any of our C-Scan Cap, C-Scan Track or C-Scan View were to cause or contribute to injury or death, including, without limitation, harm to the body caused by the procedure or inaccurate diagnoses from the procedure that could affect treatment options. There is also the possibility that defects in the design or manufacture of any of these products might necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration, and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

Our C-Scan system is a complex medical device that requires training for qualified personal and care for data analysis.

Our C-Scan system is a complex medical device that requires training for qualified personal, including physicians, and care for data analysis. Although our distributors will be required to ensure that our C-Scan system is prescribed only by trained clinicians, the

potential for misuse of our C-Scan system still exists due to its complexity. Such misuse could result in adverse medical consequences for patients that could damage our reputation, subject us to costly product liability litigation and otherwise have a material adverse effect on our business, financial condition and results of operations.

We depend on third parties to manage our clinical studies and trials, perform related data collection and analysis, and to enroll patients for our clinical trials, and, as a result, we may face costs and delays that are beyond our control.

We rely on third parties, such as third-party clinical research organizations, clinical investigators and clinical sites, to manage our clinical trials and perform data collection and analysis, and to enroll patients for our clinical trials. Although we have and expect to continue to have contractual arrangements with these third parties, we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on such third parties does not relieve us of our regulatory responsibilities. If such third parties fail to comply with applicable regulatory requirements, the clinical data generated in our clinical trials may be deemed unreliable and regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, which would delay the regulatory approval process. Furthermore, we may not be able to control the amount and timing of resources that these parties devote to our studies and trials or the quality of these resources. If these third parties fail to properly manage our studies and trials or enroll patients for our clinical trials, we will be unable to complete them at all or in a satisfactory or timely manner, which could delay or prevent us from obtaining regulatory approvals for, or achieving market acceptance of, our product.

In addition, termination of relationships with third parties may result in delays, inability to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional clinical sites involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new clinical site commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We intend to sell our products in the United States, Europe and Japan and, if we are unable to manage our operations in these territories, our business, financial condition and results of operations could be materially adversely affected.

Our headquarters and substantially all of our operations and employees are presently located in Israel, but we intend to market our products in the United States, Europe and Japan. Accordingly, we are subject to risks associated with international operations, and our international sales and operations will require significant management attention and financial resources. In addition, our international sales and operations will subject us to risks inherent in international business activities, many of which are beyond our control and include, among others:

- foreign certification, registration and other regulatory requirements;
- customs clearance and shipping delays;
- import and export controls;
- trade restrictions;
- multiple and possibly overlapping tax structures;
- difficulty forecasting the results of our international operations and managing our inventory due to our reliance on third-party distributors;
- differing laws and regulations, business and clinical practices, licensures, government and private third-party payor reimbursement policies and patient preferences;
- differing standards of intellectual property protection among countries;
- difficulties in staffing and managing our international operations;
- difficulties in penetrating markets in which our competitors' products are more

established;

- currency exchange rate fluctuations and foreign currency exchange controls and tax rates; and

- political and economic instability, war or acts of terrorism.

If we are unable to manage our international operations effectively, our business, financial condition and results of operations could be materially adversely affected.

If we lose our key personnel or are unable to attract and retain additional personnel, our business and ability to compete will be harmed.

Our success relies upon the continued service and performance of the principal members of our management and research and development team. In order to implement our business strategy, we will need to retain our key personnel with expertise in the areas of research and development, clinical testing, government regulation, manufacturing, finance, marketing and sales. Our product development plans depend in part on our ability to retain engineers with expertise in a variety of technical fields. The loss of a number of these persons or our inability to attract and retain qualified personnel could harm our business and our ability to compete.

Substantially all of our operations are currently conducted at a single location near Haifa, Israel, and any disruption at our facility could materially adversely affect our business, financial condition and results of operations.

Substantially all of our operations are currently conducted at a single location near Haifa, Israel. We take precautions to safeguard our facility, including obtaining insurance coverage and implementing health and safety protocols. However, a natural or other disaster, such as a fire, flood or an armed conflict involving Israel (as detailed further under “Risks Related to Our Operations

in Israel"), could damage or destroy our facility and our manufacturing equipment or inventory, cause substantial delays in our operations and otherwise cause us to incur additional unanticipated expenses. In addition, the insurance we maintain against fires, floods and other natural disasters and the war and terrorism insurance we maintain may not be adequate to cover our losses in any particular case. Damage to our facility or our other property or to any of our suppliers' facilities and properties, whether located in Israel or elsewhere, due to fire, a natural disaster or casualty event or an armed conflict or terrorist attack, could materially adversely affect our business, financial condition and results of operations, with or without insurance.

A security breach or disruption or failure in a computer or communications systems could adversely affect us.

Our operations depend on the continued and secure functioning of our computer and communications systems and the protection of electronic information (including sensitive personal information as well as proprietary or confidential information) stored in computer databases maintained by us or by third parties. Such systems and databases are subject to breach, damage, disruption or failure from, among other things, cyber-attacks and other unauthorized intrusions, power losses, telecommunications failures, fires and other natural disasters, armed conflicts or terrorist attacks. We may be subject to threats to our computer and communications systems and databases of unauthorized access, computer hackers, computer viruses, malicious code, cyber-crime, cyber-attacks and other security problems and system disruptions. Unauthorized persons may attempt to hack into our systems to obtain personal data relating to clinical trial participants or employees or our confidential or proprietary information or of third parties or information relating to our business and financial data. If, despite our efforts to secure our systems and databases, events of this nature occur, we could expose clinical trial participants or employees to financial or medical identity theft, lose clinical trial participants or employees or have difficulty attracting new clinical trial participants or employees, be exposed to the loss or misuse of confidential information or business and financial data, have disputes with clinical trial participants or employees, suffer regulatory sanctions or penalties under applicable laws, incur expenses as a result of a data privacy breach, or suffer other adverse consequences including legal action and damage to our reputation.

We have and will continue to incur significant costs as a result of operating as a public company in the United States, and our management is required to devote substantial

time to compliance initiatives.

As a public company whose securities are traded in the United States, we have and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, as well as rules and regulations implemented by the U.S. Securities and Exchange Commission and the NASDAQ Stock Market, impose various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Changes in the laws, rules and regulations affecting public companies would result in increased costs to us as we respond to their requirements. These rules and regulations could make it more difficult or more expensive for us to obtain certain types of insurance, including director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantial costs to obtain or maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount or timing of additional costs we may incur in order to comply with such requirements.

We are required to develop and maintain proper and effective internal controls over financial reporting. We may not complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may have one or more material weaknesses, which may adversely affect investor confidence in our company and, as a result, the value of our securities.

Section 404 of the Sarbanes-Oxley Act requires the management of public companies to conduct an annual review and evaluation of their internal controls and to obtain an attestation report from their registered public accounting firm regarding the effectiveness of

internal controls. We were first required to perform the annual review and evaluation of our internal controls in connection with our annual report on Form 20-F for the year ended December 31, 2015. However, so long as we qualify as a smaller reporting company and/or emerging growth company, which we expect to, we will be exempt from the auditors' attestation requirement under Section 404 of the Sarbanes-Oxley Act. We would no longer qualify as a smaller reporting company if the market value of our public float exceeded $75 million as of the last day of our second fiscal quarter in any fiscal year following the date of our initial public offering. We would no longer qualify as an emerging growth company at such time as described in the risk factor below.

To maintain the effectiveness of our disclosure controls and procedures and our internal control over financial reporting, we expect that we will need to continue enhancing existing, and implement new, financial reporting and management systems, procedures and controls to manage our business effectively and support our growth in the future. The process of evaluating our internal control over financial reporting requires an investment of substantial time and resources, including by our Chief Financial Officer and other members of our senior management. The determination and any remedial actions required could divert internal resources and take a significant amount of time and effort to complete and could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. During the evaluation and testing process, if we identify one or more additional material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our securities to decline.

While we currently qualify as an “emerging growth company” under the JOBS Act, we will cease to be an emerging growth company on or before the end of 2020, and at such time our costs and the demands placed upon our management will increase.

We will continue to be deemed an emerging growth company until the earliest of (i) the last day of the fiscal year in which our annual gross revenues exceed $1 billion (as indexed for inflation); (ii) the last day of the fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt; or (iv) the date on which we are deemed to be a ‘large accelerated filer,’ as defined by the U.S. Securities and Exchange Commission, which

would generally occur upon our attaining a public float of at least $700 million. Once we lose emerging growth company status, we expect the costs and demands placed upon our management to increase, as we will be required to comply with additional disclosure and accounting requirements, particularly if we also no longer qualify as a smaller reporting company.

Risks Related to Regulations

If we are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals, CE Certificates of Conformity, or equivalent third country approvals for our C-Scan system or future products or product enhancements, our ability to commercially distribute and market our products could suffer.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities and notified bodies. The process of obtaining regulatory clearances or approvals, CE Certificates of Conformity, or equivalent third country approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals, CE Certificates of Conformity, or equivalent third-country approvals on a timely basis, if at all. In particular, we expect to eventually generate a portion of our revenues from sales of our C-Scan system and future products in the United States, the European Union, or third countries. Before a new medical device, or a new use of, or claim for, an existing product can be marketed in the United States, it must first receive clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDA approval of a premarket approval application, or PMA, unless an exemption applies. The FDA will clear marketing of a low to moderate risk medical device through the 510(k) process if sufficiently similar predicate devices have previously been cleared via this pathway. In the 510(k) clearance process, the FDA must only determine that the proposed device is “substantially equivalent” to a device

legally on the market, known as a “predicate” device, with respect to intended use/indications for use, technological characteristics and principles of operation in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence.

High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on the data obtained in clinical trials. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

In instances where a device is novel and there is no suitable predicate device, but that device is deemed to be of low to moderate risk, the FDA can reclassify the device to class I or class II via de novo reclassification. This process involves the submission of a reclassification petition, and the FDA accepting that "special controls" are adequate to ensure the product's performance and safety. The FDA now allows "direct" de novo reclassification petitions, a mechanism by which a sponsor can directly submit a detailed de novo reclassification petition as the device's initial submission without having to first receive a not substantially equivalent, or NSE, decision on a 510(k) submission.

These processes can be expensive and lengthy. FDA's 510(k) clearance process usually takes between 6 to 9 months, but it can last longer. Direct de novo reclassification typically takes at least 9 to 12 months from filing to clearance. The PMA pathway is much more costly and uncertain than the 510(k) clearance process or de novo reclassification, and generally takes at least 12 to 18 months, or even longer, from the time the application is filed with FDA to ultimate approval.

We are not aware of any legally marketed predicate device upon which FDA could base a determination of substantial equivalence

under a 510(k) clearance process. Our strategy therefore is to submit a direct de novo reclassification petition for our C-Scan system. To support this petition, our objective is to demonstrate that the device poses a low to moderate risk to patients. We cannot assure you that FDA will not demand that we obtain PMA approval of our C-Scan system.

FDA can delay, limit or deny clearance or approval of an application for many reasons, including, among others:

- we may not be able to demonstrate to FDA's satisfaction that our products are safe and effective for their intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval;
- in the case of a PMA submission, that the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA's 510(k) clearance, de novo reclassification, or PMA approval processes and policies, or the adoption of new regulations may require additional data.

We may not obtain the necessary regulatory clearances, approvals, CE Certificates of Conformity or equivalent third country approvals to market our C-Scan system or future products in the United States or elsewhere. Any delay in, or failure to receive or maintain, clearance, approval or CE Certificates of Conformity for our C-Scan system or other products under development could prevent us from generating revenue from these products or achieving profitability.

There is no guarantee that the FDA will grant de novo reclassification or PMA approval of our C-Scan system and failure to obtain necessary 510(k) clearances or approvals for our future products would adversely affect our ability to grow our business.

Our C-Scan system and some of our future products will require FDA clearance of a

510(k), de novo reclassification, or may require FDA approval of a PMA. The FDA may not approve or clear our C-Scan system or our future products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance, de novo reclassification or PMA for our C-Scan system or any other future product, new intended uses or modifications to these products once they are cleared or approved for marketing.

Our strategy is to submit a direct de novo reclassification petition for our C-Scan system. A de novo reclassification generally applies where there is no predicate device and the FDA believes the device poses a low to moderate risk. De novo reclassifications can either be submitted in lieu of a 510(k) notice, such as in our case, or after a 510(k) notice has been filed and found NSE. If a 510(k) notice is found NSE, a de novo petition must be submitted within 30 days from the receipt of the NSE determination.

To support our direct de novo reclassification petition, our objective is to demonstrate that the device poses a low to moderate risk to patients. If the FDA determines that our C-Scan system is not a candidate for de novo reclassification, it will require approval of the device for market through the PMA process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided or even request new data that may require us to conduct additional tests. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. The FDA's review of a PMA could significantly delay our plans to get to market. There is also no guarantee that the FDA would approve a PMA. Failure to receive clearance or approval for our C-Scan system or future products would have an adverse effect on our ability to expand our business.

If we or our future distributors do not obtain and maintain the necessary regulatory clearances or approvals, or CE Certificates of Conformity, or equivalent third country approvals in a specific country or region, we will not be able to market and sell our C-Scan system or future products in that country or region.

We intend to market our C-Scan system in a number of international markets. To be able to market and sell our C-Scan system in a specific country or region, we and/or our distributors must comply with the regulations of that country or region. While the regulations of some countries do not impose barriers to marketing and selling part or all of our products or only require notification, others require that we and/or our distributors obtain the approval of a specified regulatory authorities or that we obtain CE Certificates of Conformity from a Notified Body. We are engaged with Dekra Certification as our Notified Body for such purposes. These regulations, including the requirements for approvals or CE Certificates of Conformity, and the time required for regulatory review, vary from country to country. Obtaining regulatory approvals or CE Certificates of Conformity is expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals or CE Certificates of Conformity for our C-Scan system or any future products in each country or region in which we plan to market such products. If we modify our C-Scan system or any future products, we or our distributors may need to apply for new regulatory approvals or our Notified Body may need to review the planned changes before we are permitted to sell them. We may not meet the quality and safety standards required to maintain the authorizations or CE Certificates of Conformity that we or our distributors have received. If we or our distributors are unable to maintain our authorizations or CE Certificates of Conformity in a particular country or region, we will no longer be able to sell our C-Scan system or any future products in that country or region, and our ability to generate revenues

will be materially and adversely affected.

Our C-Scan system may be considered a drug-device combination product because of the preparatory use of iodinated oral contrast medium to provide a coating for colonic imaging. We cannot be sure how the FDA or the competent regulatory authorities of foreign countries will regulate this product. The review of combination products is often more complex and more time consuming than the review of products under the jurisdiction of only one center within the FDA.

Our C-Scan system may be considered a combination product because of the preparatory use of iodinated oral contrast medium to provide a coating for colonic imaging. A combination product is the combination of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are combined or mixed and produced as a single entity; packaged together in a single package or as a unit; or a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication or effect. For a combination product, the FDA must determine which center or centers within the FDA will review the product and under what legal authority the product candidate will be reviewed. The combination product's primary mode of action is used to determine which center within the FDA has primary regulatory jurisdiction over the product. The other centers within the agency also may provide consulting or collaborative reviews of the product as necessary. We believe that we will put forth a reasonable argument to the FDA that our C-Scan system should be regulated as a device and or a combination product with a device primary mode of action. However, we cannot be sure as to whether the FDA will treat our C-Scan system as a device or a combination product. The review of combination products is often more complex and more time consuming than the review of a product under the jurisdiction of only one

center within the FDA. In the case of the system, should the FDA determine that the iodinated oral contrast medium is not being used in accordance with its approved labeling, the Center for Drug Evaluation and Research may take a prominent role it its regulation. If the FDA does not approve or clear our C-Scan system, or any future products, in a timely fashion, or at all, our business and financial condition will be adversely affected.

Similar obstacles may be encountered in foreign countries should our C-Scan system be considered as a combination product.

If the indications for use or instructions for use for which the iodinated oral contrast medium is approved are not sufficiently broad to support its use prior to the ingestion of our capsules, the FDA or the competent regulatory authorities in the EU Member States and other foreign countries may consider that contrast agent is being used off-label.

Ingestion of our C-Scan system requires the preparatory use of iodinated oral contrast medium to provide a coating for colonic imaging. We cannot be sure that the indications for which iodinated oral contrast medium are approved in the United States, the EU Member States or in other countries is sufficiently broad to cover such use. If the FDA or the competent regulatory authorities in the EU Member States and in other countries consider that iodinated oral contrast medium is not approved for the purpose for which it is used with the system, we may be considered to promote the off-label use of the iodinated oral contrast medium. Because the promotion of off-label use of drugs or medicinal products is prohibited in the United States, the EU Member States and in other countries, we could face both related issues with the FDA and/or the competent authorities of the EU Member States and/or other countries. In these circumstances, the FDA and/or the competent regulatory authorities in the EU Member States and/or other countries may require us to obtain appropriate regulatory approvals for the

iodinated oral contrast medium prior to marketing our C-Scan system with such substances. Under such circumstances, should we fail to obtain approval of the contrast agent for use with our C-Scan system, in a timely fashion, or at all, our business and financial condition will be adversely affected.

If we are unable to successfully complete clinical trials with respect to our C-Scan system, we may be unable to receive regulatory approvals or clearances, CE Certificates of Conformity or equivalent third-country approvals for our C-Scan system and/or our ability to achieve market acceptance of our C-Scan system will be harmed.

The development of medical devices typically includes pre-clinical studies. Certain other devices require the submission of data generated from clinical trials, which can be long, expensive and uncertain processes, subject to delays and failure at any stage. The data obtained from the studies and trials may be inadequate to support regulatory clearances or approvals, or to obtain CE Certificates of Conformity or equivalent third-country approval, or to allow market acceptance of the products being studied. Our C-Scan system technology is currently undergoing clinical development and clinical trials. To date, we have performed clinical studies with several versions of our C-Scan system and with several versions of our non-scanning capsules.

The development of sufficient and appropriate clinical protocols to demonstrate safety, clinical performance and clinical effectiveness are required, and we may not adequately develop such protocols to support clearance, approval, or to obtain CE Certificates of Conformity or equivalent third country approval. The clinical trials that were conducted using prior versions of our C-Scan system, were conducted under differing protocols and used groups of patients different from those we intend to study in future clinical trials. Further, the FDA, the competent regulatory authorities of other countries, or our Notified Body in the EU may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or they may change the data collection requirements or data analysis applicable to our clinical trials.

The commencement or completion of any of our clinical studies or trials may be delayed or halted, or be inadequate to support regulatory clearance, approval or product acceptance, or to obtain CE Certificates of Conformity or equivalent third country approval, for numerous reasons, including, among others:

- patients do not enroll in the clinical trial at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- undetected capsule retention in patients
- patients experience adverse side effects, including related to excessive radiation exposure as a result of capsule malfunction or break down;
- patient death during a clinical trial, even though their death may be unrelated to our product;
- FDA, institutional review boards, or IRBs, or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or

place a clinical trial on hold;

- IRBs, Ethics Committees and third-party clinical investigators may delay or reject our trial protocol and Informed Consent Form;

- third-party clinical investigators decline to participate in a study or trial or do not perform a study or trial on our anticipated schedule or consistent with the investigator agreements, study or trial protocol, good clinical practices or other FDA or IRBs, Ethics Committees, or any other applicable requirements;

- third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the study or trial protocol or investigational or statistical plans;

- regulatory inspections of our studies, trials or manufacturing facilities may require us to, among other things, undertake corrective action or suspend or terminate our studies or clinical trials;

- changes in governmental regulations or administrative actions;

- we may not be able to develop our C-Scan system at the rate or to the stage we desire:

- the interim or final results of the study or clinical trial are inconclusive or unfavorable as to safety or efficacy;

- a regulatory agency or our Notified Body concludes that our trial design is or was inadequate to demonstrate safety and efficacy; and

- If we do not continue to retain a permit to employ Jewish employees on Saturdays and Jewish holidays to conduct our clinical trials, as required under the Israeli Hours of Work and Rest Law, 1951, and we are unsuccessful in employing only non-Jewish employees on Jewish rest days and holidays, we may be compelled to cease or halt our clinical trials during Saturdays and Jewish holidays, which

could decrease our clinical capacity.

The results of pre-clinical and clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA, the competent regulatory authorities of EU Member States, other third country regulatory entities, or our Notified Body may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance, approval, or CE Certificate of Conformity of our products. The data we collect from our non-clinical testing, our pre-clinical studies and other clinical trials may not be sufficient to support regulatory clearance, approval or to obtain CE Certificates of Conformity.

If the third parties on which we rely to conduct our clinical trials and clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval, CE Certificates of Conformity, or equivalent third country approval for, or commercialize, our C-Scan system or future products.

We do not have the ability to independently conduct our clinical trials for our C-Scan system and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain CE Certificates of Conformity, regulatory clearance, approval for, or successfully commercialize, our C-Scan system or future

products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The results of our current or future clinical trials may not support our product candidate requirements or intended use claims or may result in the discovery of adverse side effects.

Even if our current or future clinical trials are completed as planned, we cannot be certain that their results will support our product requirements or intended use claims, which could inhibit our marketing strategies, or that the FDA, foreign authorities or our Notified Body will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our C-Scan system, or any future products, are safe and effective for the desired or proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our C-Scan system, or any future products, and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

Even if our C-Scan system or future products are cleared or approved by regulatory authorities or if we obtain CE Certificates of Conformity from our Notified Body, modifications to our C-Scan system or future products may require new regulatory clearances or approvals, new CE Certificates of Conformity, or may require us to recall or cease marketing it until the necessary clearances, approvals or CE Certificates of

Conformity are obtained.

Once cleared, approved or marketed, modifications to our C-Scan system or future products may require new regulatory approvals, clearances, including CE Certificates of Conformity from our Notified Body, 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We may make modifications to our C-Scan system in the future that we believe do not or will not require additional clearances or approvals. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all.

Any modification to a PMA-approved device must either be approved in a PMA Supplement, or if the modification does not impact the device's safety or effectiveness, described in a 30-Day Notice or in the device's Annual Report. The FDA may not approve a modification described in a PMA Supplement, in which case the modified device cannot be marketed. The FDA can also disagree that a change described in a 30-Day Notice or Annual Report is appropriately described in either filing, and request that the company file a PMA Supplement and/or request that the company cease marketing the modified device until the PMA Supplement is approved.

Similar rules also apply in foreign jurisdictions. In the European Union, or EU, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EU of any planned substantial changes to our quality C-Scan system or changes to our devices which could affect compliance with the Essential Requirements laid down in Annex I to the Council Directive 93/42/EEC concerning medical devices, or Medical Devices Directive, or the devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the products' conformity with the Essential Requirements laid down in Annex I to the Medical Devices Directive or the conditions for the use of the device. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum

to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive.

If the Notified Body or relevant regulatory authorities disagree with our assessments and require modifications to an existing CE Certificate of Conformity, the preparation of a new CE Certificates of Conformity or new regulatory clearances or approvals for modifications, we may be required to recall and to stop marketing the modified devices.

Obtaining clearances and approvals, or new or amended CE Certificates of Conformity for device modifications can be a time-consuming process, and delays in obtaining required future clearances, approvals, or CE Certificates of Conformity could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could harm our future growth.

Even if our C-Scan system and future products are cleared or approved by regulatory authorities or if we obtain CE Certificates of Conformity from our Notified Body, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, our products could be subject to restrictions or withdrawal from the market.

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities associated with any product for which we obtain clearance or approval CE Certificates of Conformity, or equivalent third country approval will be subject to continuous regulatory review, oversight and periodic inspections by the FDA other domestic and foreign regulatory authorities and our Notified Body. In particular, we and certain of our suppliers are required to comply with the FDA’s Quality System Regulations, or QSR, as well as current good manufacturing practices, or cGMP. In the EU, we will also be subject to the quality system requirements laid down in

the Annexes to the Medical Devices Directive. Such compliance can be facilitated by, among other things, a certificate of compliance with ISO 13485:2003. Through compliance with the ISO 13485:2003 standard, we will benefit from a presumption of conformity with the relevant quality system requirements laid down in the Annexes to Medical Devices Directive. These regulations and standards govern the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval, CE Certificates of Conformity, or equivalent third country approval. Regulatory authorities, such as the FDA, and our Notified Body enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations falling within the competence of the FDA and other regulatory authorities or our Notified Body, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, corporate integrity agreements, consent decrees and civil penalties;

- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- suspension or withdrawal of our CE Certificates of Conformity;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur, our reputation would be harmed, our product sales and profitability would suffer and we may not be able to generate revenue. Furthermore, our key suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, or if we obtain CE Certificates of Conformity, such clearance or approval, or CE Certificates of Conformity may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If FDA or the competent regulatory authorities of foreign countries determines that our promotional materials, labeling, training or other

marketing or educational activities constitute the promotion of an unapproved use or the promotion of an intended purpose not covered by our CE mark, they could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse side effects or adverse side effects of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension or withdrawal of regulatory approvals or CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties, all of which would adversely affect our business, financial condition and operating results and prospects.

If we fail to maintain necessary regulatory clearances or CE Certificates of Conformity for our C-Scan system and indications in our target foreign markets, if clearances or approvals, or CE Certificates of Conformity for future products and indications are delayed or not issued, or if there are regulatory changes in our existing or future target markets, our commercial operations could be harmed.

Our C-Scan system is a medical device that is subject to extensive regulations that are intended to assure its safety, effectiveness and compliance with applicable consumer laws. If we fail to obtain and maintain these regulatory approvals or clearances, or CE Certificates of Conformity, our ability to sell our C-Scan system and generate revenues will be materially harmed.

These laws and regulations relate to the design, development, testing, manufacturing, storage, labeling, packaging, content and language of the instructions for use of the device, sale, promotion, distribution, importing and exporting, shipping, post-sale surveillance and recall from our C-Scan system's markets, and all countries in which we intend to sell our C-Scan system apply some form of regulations of this kind. Most notably, we must comply with the Medical Devices Directive and are subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. In the EU, compliance with the requirements set forth in the Medical Devices Directive, including the Essential Requirements set forth in its Annex I thereto, is a prerequisite to be able to affix the CE mark of conformity to our medical devices. Without such CE mark, our products cannot be marketed or sold in the EU. To demonstrate compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer can

make an EC Declaration of Conformity based on self-assessment of the conformity of its products with the Essential Requirements laid down in Annex I to the Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body. The Notified Body would typically audit and examine the products' Technical File, which we must create, and the quality system for manufacture, design and final inspection of our devices before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements laid down in Annex I to the Medical Devices Directive or the quality system requirements laid down in the other Annexes to the Directive. Following the issuance of this CE Certificate of Conformity, we can draw up an EC Declaration of Conformity and affix the CE mark to the products covered by this CE Certificate of Conformity and by the EC Declaration of Conformity. Other countries outside the EU also accept the CE mark as a certification of quality, efficacy and safety of medical devices and an element of related authorization of the products in their territory.

We will be subject to annual audits by a Notified Body under the Medical Devices Directive. During this audit, the third-party assessor or Notified Body will examine the maintenance and implementation of our quality control system, device post-marketing vigilance system and any changes or modifications made to our products.

On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the EU. These proposals are intended to strengthen the medical devices rules in the EU. On October 22, 2013, the European Parliament voted in favor of an amended draft of the Regulation. The proposed text is currently being discussed by the Council of the European Union. These adopted or expected regulatory changes may adversely affect our business, financial condition and results of operations or restrict our operations.

Our failure to comply with radiation safety or radio frequency regulations in a specific country or region could impair our ability to commercially distribute and market our C-Scan system in that country or region.

Our C-Scan system includes a small X-ray source and wireless radio frequency transmitter and receiver, and is therefore subject to equipment authorization requirements in a number of countries and regions. In the United States, the EU and Japan, authorities often require advance clearance of all radiation and radio frequency devices before they can be sold or marketed in these jurisdictions, subject to limited exceptions. Modifications to the approved C-Scan system design and specifications may require new or further regulatory clearances or approvals before we are permitted to market and sell a modified C-Scan system. If we are unable to obtain any required clearances or approvals from the authorities responsible for the radiation as well as the radio frequency regulations in these and other jurisdictions, the sale or use of our C-Scan system could be prevented in these countries. Any such action could negatively affect our business, financial condition and results of operations.

Our C-Scan system may in the future be subject to product recalls 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 or a public health/safety issue. 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 injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated 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 deficiencies and issues. Once marketed, recalls of any of our products, including our C-Scan system, would divert managerial and financial resources and have an adverse effect on our business, financial condition and results of operations. FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require us to notify the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action against us based on our failure to report the recalls when they were conducted.

If our C-Scan system or future products cause or contribute to a death or a serious injury, or malfunction in such a way that causes or contributes to a death or serious injury, we

will be subject to medical device reporting regulations, which can result in corrective actions or enforcement actions from regulatory authorities.

Under FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of our device (or any similar future product) were to recur. If we fail to investigate and report these events to FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, including any legal action taken against us, will require us to devote sufficient time and capital to the matter, distract management from operating our business, and may harm our reputation and financial results.

In addition, we must also comply with the EU Medical Device Vigilance System (MEDDEV 2.12/1 rev.8), which is intended to protect the health and safety of patients, users and others by establishing reporting procedures and reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents (which are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, may lead to or may have led to the death of a patient, or user or other persons or to a serious deterioration in such person’s state of health) must be reported by manufacturers through a Manufacturer’s Incident Reports to competent authorities within periods of time specified in the MEDDEV 2.12/1 rev. 8. Such incidents are evaluated and, where appropriate, information

is disseminated between the competent authorities of the EU Member States. The MEDDEV 2.12/1 rev. 8 is also intended to facilitate a direct, early and harmonized establishment of Field Safety Corrective Actions, or FSCAs, across the EU Member States in which the device is being marketed. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification, exchange, or destruction. FSCAs must be reported by the manufacturer or the manufacturer's European Authorized Representative, to its customers and/or the end users of the device through a Field Safety Notice. FSCAs must also be reported to the competent authorities of the EU Member States.

Our business is subject to complex environmental legislation that may increase our costs and our risk of noncompliance.

Our research and development and manufacturing processes involve the handling of potentially harmful radioactive and other hazardous materials. We are subject to local laws and regulations governing the use, shipping, handling, storage and disposal of these materials, and we incur expenses related to compliance with these laws and regulations. If we are found to have violated environmental, health and safety laws, whether as a result of human error, equipment failure or other causes, we could be held liable for damages, penalties and costs of remedial actions which could materially adversely affect our business, financial condition and results of operations. In the future, we could be subject to additional environmental requirements or existing environmental laws could become more stringent, which could lead to greater compliance costs and increasing risks and penalties associated with violations. For example, changes to, or restrictions on, permitting requirements or processes, hazardous or radioactive material storage or handling might require an unplanned capital investment or relocation. If we fail to comply with existing or new environmental laws or regulations, our business, financial condition and results of operations could be materially adversely affected.

If we are unable to achieve reimbursement and coverage from government and private third-party payors for procedures using our C-Scan system, or if reimbursement is insufficient to create an economic benefit for purchasing or using our C-Scan system when compared to alternative procedures, demand for our products may not grow at the rate we expect.

The demand for our C-Scan system will depend significantly on the eligibility of the procedures performed using our C-Scan system for reimbursement through government-sponsored healthcare payment

systems and private third-party payors. Reimbursement practices vary significantly from country to country and within some countries, by region, and we must obtain reimbursement approvals on a country-by-country and/or region-by-region basis. In general, the process of obtaining reimbursement and coverage approvals has been longer outside of the United States. We may not be able to obtain reimbursement approvals in a timely manner or at all and existing reimbursement and coverage policies may be revised from time to time by government and private third-party payors. If physicians, hospitals and other healthcare providers are unable to obtain sufficient coverage and reimbursement from government and private third-party payors for procedures using our C-Scan system, if reimbursement is, or is perceived by our customers to be, insufficient to create an economic incentive for purchasing or using our C-Scan system, or if such reimbursement does not adequately compensate physicians and health care providers compared to the other procedures they offer, demand for our products may not grow at the rate we expect.

Federal and state privacy laws, and equivalent laws of third countries, may increase our costs of operation and expose us to civil and criminal sanctions.

The Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations that have been issued under it, to which we refer collectively as HIPAA, and similar laws outside the United States, contain substantial restrictions and requirements with respect to the use and disclosure of individuals' protected health information. The HIPAA privacy rules prohibit "covered entities," such as healthcare providers and health plans, from using or disclosing an individual's protected health information, unless the use or disclosure is authorized by the individual or is specifically required or permitted under the privacy rules. Under the HIPAA security rules, covered entities must establish administrative, physical and technical safeguards to protect the

confidentiality, integrity and availability of electronic protected health information maintained or transmitted by them or by others on their behalf. While we do not believe that we are a covered entity under HIPAA, many of our customers are covered entities subject to HIPAA. Such customers may require us to enter into business associate agreements, which will obligate us to safeguard certain health information we obtain in the course of our relationship with them, restrict the manner in which we use and disclose such information and impose liability on us for failure to meet our contractual obligations.

In addition, under The Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which was signed into law as part of the U.S. stimulus package in February 2009, certain of HIPAA's privacy and security requirements are now also directly applicable to "business associates" of covered entities and subject them to direct governmental enforcement for failure to comply with these requirements. We may be deemed as a "business associate" of some of our customers. As a result, we may be subject as a "business associate" to civil and criminal penalties for failure to comply with applicable privacy and security rule requirements. Moreover, HITECH created a new requirement obligating "business associates" to report any breach of unsecured, individually identifiable health information to their covered entity customers and imposes penalties for failing to do so.

In addition to HIPAA, most U.S. states have enacted patient confidentiality laws that protect against the disclosure of confidential medical information, and many U.S. states have adopted or are considering adopting further legislation in this area, including privacy safeguards, security standards, and data security breach notification requirements. These U.S. state laws, which may be even more stringent than the HIPAA requirements, are not preempted by the federal requirements, and we are therefore required to comply with them to the extent they are applicable to our operations.

These and other possible changes to HIPAA or other U.S. federal or state laws or regulations, or comparable laws and regulations in countries where we conduct business, could affect our business and the costs of compliance could be significant. Failure by us to comply with any of the standards regarding patient privacy, identity theft prevention and detection, and data security may subject us to penalties, including civil monetary penalties and in some circumstances, criminal penalties. In addition, such failure may damage our reputation and adversely affect our ability to retain customers and attract new customers.

The protection of personal data, particularly patient data, is subject to strict laws and regulations in many countries. The collection and use of personal health data in the EU is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. This Directive imposes a number of requirements, including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual EU Member States and the security and confidentiality of the personal data. The Data

Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the US. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties and harm our business. We may incur extensive costs in ensuring compliance with these laws and regulations, particularly if we are considered to be a data controller within the meaning of the Data Protection Directive.

The adoption of healthcare reform and deficit reduction measures in the United States may adversely affect our business and financial results.

On March 23, 2010, President Obama signed into law major healthcare reform legislation under the Patient Protection and Affordable Care Act of 2010, or the PPACA, which was modified on March 30, 2010 by the enactment of the Health Care and Education Reconciliation Act of 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the device industry. The PPACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Under the PPACA, it is expected that expanded healthcare coverage will be made available to millions of Americans. The increased costs to the U.S. government from the PPACA are expected to be funded through a combination of payment reductions for providers over time and several new taxes. The PPACA imposes, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013, resulting in an anticipated cost to the medical device industry of up to $20 billion over the next decade. We likely will be subject to the excise

tax with respect to our C-Scan system if it is approved for sale in the United States. The PPACA also limits the rate of growth in Medicare payments to providers and authorizes certain voluntary demonstration projects beginning no later than 2013 around development of bundling payments for acute, inpatient hospital services, physician services, and post-acute services for episodes of hospital care. In addition, the PPACA provides for the establishment of an Independent Payment Advisory Board, or IPAB, that, beginning in 2014, could recommend changes in Medicare payments to physicians and other providers that would take effect unless Congress passes an alternative measure to achieve the same amount of savings. The IPAB has not yet been created. The PPACA also increases fraud and abuse penalties and expands the scope and reach of the Federal Civil False Claims Act and government enforcement tools, which may adversely impact healthcare companies.

The U.S. Supreme Court heard a constitutional challenge to the PPACA and in June 2012 held that the PPACA is constitutional. However, states are allowed to opt out of the expansion of eligibility criteria for Medicaid under the PPACA and many states have chosen to do so, causing many uninsured patients to remain without coverage. In addition to the PPACA, the effect of which cannot presently be quantified given its recent enactment, various healthcare reform proposals have also emerged at the state level. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or the effect any future legislation or regulation will have on us. However, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, and could adversely affect our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Insurers may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals, all of which may adversely affect our business, financial condition and results of operations, possibly materially.

In addition to healthcare reform, other deficit reduction measures could affect reimbursement for our device and related procedures. For example, beginning April 1, 2013, Medicare payments for all items and services have been reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. These cuts will remain in effect until 2024 unless Congress enacts legislation to cancel or delay the cuts. These payment reductions, or similar efforts to reduce Medicare spending to control the federal deficit, could adversely affect our business by reducing reimbursement to the providers who purchase and use our devices

and perform related procedures.

The implementation of the reporting and disclosure obligations of the Physician Payment Sunshine Act's provisions relating to healthcare reform could adversely affect our business. A health care reform provision, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, has imposed new reporting and disclosure requirements for drug and device manufacturers with regard to payments or other transfers of value made to certain practitioners (including physicians, dentists and teaching hospitals), and for such manufacturers and for group purchasing organizations, with regard to certain ownership interests held by physicians in the reporting entity. On February 1, 2013, the Centers for Medicare and Medicaid Services, or CMS, released the final rule to implement the Physician Payment Sunshine Act. As required under the Physician Payment Sunshine Act, CMS will publish information from these reports on a publicly available website, including amounts transferred and physician, dentist and teaching hospital identities.

The final rule implementing the Physician Payment Sunshine Act is complex, ambiguous, and broad in scope. If we participate in federal healthcare programs, meaning our product is reimbursed by a federal healthcare program such as Medicare, Medicaid, or Children’s Health Insurance Program, our product would be considered a “covered device.” Within 180 days of becoming “covered,” we would be required to collect and report detailed information regarding certain financial relationships we have with physicians and teaching hospitals. The Physician Payment Sunshine Act preempts similar state reporting laws, although we may be required to report under certain of such state laws. Our compliance with the new final rule imposes additional costs on us and requires additional resources including dedicated personnel with experience and expertise in this area. Failure to comply may expose us to federal and/or state enforcement

action and fines.

If we fail to comply with the U.S. federal Anti-Kickback Statute and similar state and third-country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third-country programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. PPACA, among other things, clarified that a person or entity needs not to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws similar to the federal Anti-Kickback Statute, and some of these laws are even broader than the federal Anti-Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti-Kickback

Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

All of our financial relationships with healthcare providers, purchasers, formulary managers, and others who provide products or services to federal healthcare program beneficiaries are potentially governed by the federal Anti-Kickback Statute and similar state laws. We believe our operations are in compliance with the federal Anti-Kickback Statute and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

There are other federal and state laws that may affect our ability to operate, including the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Moreover, we may be subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government healthcare benefit programs. Moreover, there are analogous state laws. Violations of these laws can result in substantial criminal, civil or administrative

penalties, damages, fines and exclusion from participation in federal healthcare programs.

Similar restrictions are imposed by the national legislation of many third countries in which our medical devices will be marketed. Moreover, the provisions of the Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more aggressive and frequent investigations and enforcement by both the U.S. Securities and Exchange Commission and the Department of Justice. A determination that our operations or activities violated United States or foreign laws or regulations could result in imposition of substantial fines, interruption of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. In addition, lawsuits brought by private litigants may also follow as a consequence.

If the U.S. Nuclear Regulatory Commission, or NRC, or other nuclear regulatory commissions around the world, would take the position that a system containing radioactive material cannot be passed in excreta into the sanitary sewer system without limitation, we may be subject to further regulations and patients may be required to retrieve our C-Scan system after use.

As our C-Scan system includes an ingestible capsule with a radioactive source, we must address NRC regulations in addition to FDA requirements as well as regulations of other nuclear regulatory commissions in jurisdictions in which we intend to commercialize our C-Scan system. Our C-Scan system is loaded with the X-ray source, sealed and then ingested by the

patient. Although the NRC places conditions and limitations on the disposal of radioactive material in the sanitary sewer, such conditions and limitations do not apply to radioactive material contained in the excreta of individuals that are undergoing medical diagnosis or therapy with radioactive material. However, there is no assurance that the NRC or other regulatory commissions worldwide will take a similar position in relation to our C-Scan system and we may face limitations by the NRC or other nuclear regulatory commissions in jurisdictions in which we intend to commercialize our C-Scan system in relation to the disposal of our C-Scan Cap in the sanitary system, such as requiring patients to retrieve our C-Scan system after use, which could make our C-Scan system less attractive.

Our failure to comply with the necessary regulatory approval regarding the use of radioactive materials could significantly impair our ability to develop, manufacture and/or sell our C-Scan system.

The manufacture of our C-Scan system requires the use and storage of radioactive materials. In order to use such materials in the development and manufacture of our C-Scan system in Israel, we are required to obtain a permit from the Israeli Commissioner for Environmental Radiation, or the Commissioner, pursuant to the Israeli Pharmaceutical Regulations (Radioactive Elements and By-Products), 5740–1980. Should we fail to comply with the conditions of our currently existing permit, the Commissioner would have authority to cancel our permit. Should the Commissioner determine that our activities or facilities constitute a danger to the health and well-being of a person, the public or the environment, the cancellation of our permit could be immediate and without prior notice. Furthermore, we cannot guarantee the annual renewal of our permit and/or annual renewal subject to identical conditions, as the approval of an annual application and the conditions thereof are at the discretion of the Commissioner. Similar requirements and regulations may apply to the manufacture of our C-Scan system in other countries. Cancellation of or failure to renew our permit could have materially adverse consequences on our ability to manufacture and sell our products and therefore on our ability to continue our business and operations.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights, our competitive position could be harmed.

Our success and ability to compete depends in large part upon our ability to protect our intellectual property. Although we have patents issued in Israel, Europe, United States, Japan, China, India, Hong Kong, and Australia, we continue to file and prosecute in

many of the same countries and additional countries such as Canada, Brazil and South Korea. We face several risks and uncertainties in connection with our intellectual property rights, including, among others:

- pending and future patent applications may not result in the issuance of patents or, if issued, may not be issued in a form that will be advantageous to us;
- our issued patents may be challenged, invalidated or legally circumvented by third parties;
- our patents may not be upheld as valid and enforceable or prevent the development of competitive products;
- the eligibility of certain inventions related to diagnostic medicine, more specifically diagnostic methods and processes, for patent protection in the United States has been limited recently which may affect our ability to enforce our issued patents in the United States or may make it difficult to obtain broad patent protection going forward in the United States;
- for a variety of reasons, we may decide not to file for patent protection on various improvements or additional features; and
- intellectual property protection and/or enforcement may be unavailable or limited in some countries where laws or law enforcement practices may not protect our proprietary rights to the same extent as the laws of the United States, the European Union, Canada or Israel.

Consequently, our competitors could develop, manufacture and sell products that directly compete with our products, which could decrease our sales and diminish our ability to compete. In addition, competitors could attempt to develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property does not adequately protect us from our competitors' products and methods, our competitive position could be materially adversely affected.

Because the medical device industry is litigious, we are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our C-Scan system.

There is a substantial amount of litigation over patent and other intellectual property rights in the medical device industry. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. We are presently unaware of any other parties' valid patents and proprietary rights which our evolving product designs would infringe. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe. In addition, our competitors or other parties may assert that our C-Scan system and the methods it employs may be covered by patents held by them. If our C-Scan system infringes a valid patent, we could be prevented from manufacturing or selling it unless we can obtain a license or redesign the product to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and could divert

our management's attention from operating our business.

The steps we have taken to protect our intellectual property may not be adequate, which could have a material adverse effect on our ability to compete in the market.

In addition to patents, we rely on confidentiality, non-compete, non-disclosure and assignment of inventions provisions, as appropriate, with our employees, consultants and, to some extent, our distributors, to protect and otherwise seek to control access to, and distribution of, our proprietary information. These measures may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation, for the following reasons:

- the agreements may be breached, may not provide the scope of protection we believe they provide or may be determined to be unenforceable;
- we may have inadequate remedies for any breach;
- proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

Specifically with respect to non-compete agreements, under current United States and Israeli law, we may be unable to enforce these agreements, in whole or in part, and it may be difficult for us to restrict our competitors from gaining the expertise that our former employees gained while working for us. For example, Israeli courts have recently required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the

employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or its intellectual property. If we cannot demonstrate that harm would be caused to us, we may be unable to prevent our competitors from benefiting from the expertise of our former employees. In addition, some states in the United States, such as California, have laws which severely restrict the use of non-compete undertakings.

If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it could harm our ability to protect our rights and could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, although our employees and consultants have agreed to assign to us all rights to any intellectual property created in the scope of their employment or engagement with us and most of our current employees and consultants, have agreed to waive their economic rights with respect to our intellectual property, we cannot assure you that such claims will not be brought against us by current or former employees or consultants, despite their contractual representations and obligations toward us, or by any of the medical and/or governmental institutions that employ or engage such consultants, claiming alleged rights to our intellectual property or demanding remuneration in consideration for assigned intellectual property rights, which could result in litigation and adversely affect our business, financial condition and results of operations.

Third-party claims of infringement or other claims against us could require us to redesign our C-Scan system, seek licenses, or engage in future costly intellectual property litigation, which could negatively affect our future business and financial performance.

Substantial litigation over intellectual property rights exists in the medical device industry in general and in the medical imaging or screening sectors in particular. We expect that we may be subject to third-party infringement claims as our revenues increase, the number of competitors grows and the functionality of products and technology in different industry segments converges. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe.

In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers,

cause product shipment delays, prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology in a timely and cost-effective manner, our ability to generate significant revenues may be substantially harmed and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition or results of operations.

We may also become involved in litigation in connection with our brand name rights. We do not know whether others will assert that our brand name infringes their trademark rights. In addition, names we choose for our products may be claimed to infringe names held by others. If we have to change the names we use, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

Third parties may challenge the validity of our issued patents or challenge patent applications in administrative proceedings before various patent offices which, if successful, could negatively affect our future business and financial performance.

Various patent offices, including in the United States and Europe, provide administrative proceedings by which a third party can challenge the validity of an issued patent or challenge an application that is being examined absent any threat of

litigation. In some instances, including in the United States, the administrative proceedings provide a more efficient and favorable forum to challenge our patents which may lead to more opportunities for competitors to do so, particularly smaller competitors with limited resources. Moreover, the standards utilized in these administrative proceedings, at least in the United States, provide certain legal advantages versus challenging the validity of a patent in a district court. If a third party is successful in one of these administrative proceedings, the patent will no longer be enforceable in the corresponding jurisdiction. With this loss in patent rights, we will not be able to prevent third parties from offering identical or similar competing products which may result in lower profits and a less substantial market share.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent and related litigation against third parties, such as infringement suits or interference proceedings. Any lawsuits that we initiate could be expensive, take significant time and divert our management's attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being issued. In addition, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, including attorney fees, if any, may not be commercially valuable. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

We rely on trademark protection to distinguish our products from the products of our competitors; however, if a third party is entitled to use or trademark we could be forced to rebrand, which could result in loss of brand recognition and our ability to distinguish our products may be impaired, which could adversely affect our business.

We rely on trademark protection to distinguish our products from the products of our competitors. We have registered the "CHECK CAP" and "C-Scan" trademarks and

design logos in the United State and European Union. In jurisdictions where we have not registered our trademarks and logos and are using them, and as permitted by applicable local law, we rely on common law trademark protection. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks, and may be able to use our trademarks in jurisdictions where they are not registered or otherwise protected by law. If our trademarks are successfully challenged or if a third party is using confusingly similar or identical trademarks in particular jurisdictions before we do, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. If others are able to use our trademarks, our ability to distinguish our products may be impaired, which could adversely affect our business. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We may not be able to enforce covenants not to compete at all or, we may be unable to enforce them for the duration contemplated in our employment contracts and may, therefore, be unable to prevent competitors from benefiting from the expertise of some of our former employees involved in research and development activities.

We currently have non-compete agreements with substantially all of our employees who are involved in research and development, all of whom are located in Israel. These agreements prohibit our employees, if they cease working for us, from directly competing with us or working for our competitors for a limited period of time following termination of employment. In many jurisdictions, courts are increasingly refusing to enforce restrictions on competition by former employees or have interpreted them narrowly. For example, in Israel, where all of our employees reside, courts have required employers seeking to enforce non-compete undertakings of a former employee to

demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or its intellectual property. If we cannot demonstrate that harm would be caused to us, an Israeli court may refuse to enforce our non-compete restrictions or reduce the contemplated period of non-competition such that we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

Risks Related to Our Operations in Israel

Our principal offices, research and development facilities and some of our suppliers are located in Israel and, therefore, our business, financial condition and results of operation may be adversely affected by political, economic and military instability in Israel.

Our principal offices, research and development facilities are located in northern Israel. In addition, substantially all of our employees and officers, and certain of our directors, are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations.

During the Second Lebanon War of 2006, between Israel and Hezbollah, a militant Islamic movement, rockets were fired from Lebanon into Israel, including into the Haifa area, where our facility is located, causing casualties and major disruption of economic activities in northern Israel. An escalation in tension and violence between Israel and the militant Hamas movement (which controls the Gaza Strip) and other Palestinian Arab groups, culminated with Israel's military campaign in Gaza in December 2008, in November 2012 and again in July and August 2014 in an endeavor to prevent continued rocket attacks against Israel's southern towns, as well as other tension and violence between Israel and Palestinian Arab groups and individuals. It is unclear whether any negotiations that may occur between Israel and the Palestinian Authority will result in an agreement. In addition, Israel faces threats from more distant neighbors, in particular, Iran, an ally of Hezbollah and Hamas.

Popular uprisings in various countries in the Middle East and North Africa are affecting the political stability of those countries. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and these countries. Furthermore, several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in the region continue or intensify. Such restrictions may seriously limit our ability to sell our products to customers in those countries. Similarly, Israeli corporations are limited in conducting business with entities from several countries. Parties with whom we may do business could decline to travel to Israel during periods of heightened unrest or tension. In addition, the political and security situation in Israel may result in parties with whom we may have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. In addition, any hostilities involving Israel could have a material adverse effect on our facilities including our corporate office or on the facilities of our local suppliers, in which event all or a portion of our inventory may be damaged, and our ability to deliver products to customers could be materially adversely affected.

Furthermore, the war and terrorism insurance we maintain may not be adequate to cover our losses associated with armed conflicts and terrorist attacks. Although the Israeli government in the past covered the reinstatement value of certain damages that were caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

Our operations could also be disrupted by the obligations of personnel to perform military service. As of February 15, 2017, we had 57 employees and independent contractors, all of whom were based in Israel other than our Chief Executive Officer. Some of these employees may be called upon to perform up to 54 days in each three year period (and in the case of military officers, up to 84 days in each three year period) of military reserve duty until they reach the age of 40 (and in some cases, depending on their specific military profession up to 45 or even 49 years of age) and, in certain emergency circumstances, may be called to immediate and unlimited active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists and it is possible that there will be similar large-scale military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of employees related to military service, which could materially adversely affect our business and results of operations.

Any hostilities involving Israel, terrorist activities or political instability in the region or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturns in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our revenues to decrease and adversely affect our share price.

Pursuant to the terms of the Israeli government grants we received for research and development expenditures, we are obligated to pay certain royalties on our revenues to the Israeli government. The terms of the grants require us to satisfy specified conditions and to make additional payments in addition to repayment of the grants upon certain events.

We have received grants from the Government of the State of Israel through NATI (formerly known as the OCS) for the financing of a portion of our research and development expenditures pursuant to the Research Law and related regulations and guidelines. As of December 31, 2016, we had received funding from NATI in the aggregate amount of $5.1 million. As of December 31, 2016, we had not paid any royalties to NATI and had a contingent obligation to NATI in the amount of $5.3 million. We may apply for additional NATI grants in the future. However, as the funds available for NATI grants out of the annual budget of the State of Israel have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

Under the terms of the Research Law as currently in effect, products developed with NATI grants are required to be manufactured in Israel and technology developed thereunder may not be transferred outside of Israel (including by way of license), unless prior approval is received from NATI, which we may not receive. In addition, payment of additional amounts would be required if manufacturing is moved outside of Israel, in

which case the royalty repayment rate is increased and the royalty ceiling can reach up to three times the amount of the grants received, and if NATI developed know-how is transferred outside of Israel, the royalty ceiling can reach up to six times the amount of grants received (plus interest). We are currently considering whether it would be possible to assemble the capsule without the X-ray source in Israel, and have the X-ray source subsequently assembled into our C-Scan system at a reactor or cyclotron site or at a distribution center outside Israel. Even following the full repayment of any NATI grants, we must nevertheless continue to comply with the requirements of the Research Law and related regulations and guidelines. The foregoing restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with NATI funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to NATI.

A significant amendment to the Research Law entered into effect on January 1, 2016, under which NATI, a statutory government corporation, was established, which replaced the OCS. Under such amendment, NATI is authorized to establish rules concerning the ownership and exploitation of NATI-funded know-how (including with respect to restrictions on transfer of manufacturing activities and NATI-funded know-how outside of Israel), which may differ from the restrictive laws, regulations and guidelines as currently in effect (and which shall remain in effect until such rules have been established by NATI). No such rules have been published to date by NATI and we cannot predict or estimate the changes (if any) that may be made to this legislation (including with respect to the acquisition of a NATI-funded entity or the transfer of

NATI-funded technology).

If we fail to comply with any of the conditions and restrictions imposed by the Research Law and related regulations and guidelines, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

Your rights and responsibilities as a shareholder are governed by Israeli law, which differ in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our amended articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S. based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company or prevent any other power granted to a shareholder under the company's articles of association, has a duty of fairness toward the company. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

It may be difficult to enforce a judgment of a U.S. court against us, certain of our officers and directors or the Israeli experts named in this Annual Report in Israel or the United States, to assert U.S. securities laws claims in Israel or to serve process on certain of our officers and directors and these experts.

We are incorporated in Israel. All but one of our executive officers who is also a director,

two of our directors and our Israeli experts, reside in Israel, and substantially all of our assets and a substantial portion of the assets of these persons are located in Israel. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws on the grounds that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court.

Provisions of Israeli law and our amended articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, us, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a full tender offer for all of a public company’s issued and outstanding shares can only be completed if the acquirer receives

positive responses from the holders of at least 95% of the issued share capital and the approval of a majority of the offerees that do not have a personal interest in the tender offer, unless at least 98% of the company's outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), may, at any time within six months following the completion of the tender offer, petition an Israeli court for an appraisal right, to alter the consideration for the acquisition. In addition, a statutory merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

We may become subject to claims for payment of compensation for assigned service inventions by our current or former employees, which could result in litigation and adversely affect our business.

Under the Israeli Patents Law, 5727-1967, or the Patents Law, inventions conceived by an employee during the scope of his or her employment are regarded as "service inventions" and are owned by the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. Section 134 of the Patents Law provides that if no agreement between an employer and an employee exists that prescribes whether, to what extent, and on what conditions the employee is entitled to remuneration for his or her service inventions, then such matters may, upon application by the employee, be decided by a government-appointed compensation and royalties committee established under the Patents Law, or the Committee. Although our employees have agreed to assign to us all rights to any intellectual property created in the scope of their employment and most of our current employees, including all those involved in the development of our intellectual property, have agreed to waive their economic rights with respect to service inventions, we cannot assure you that claims will not be brought against us by current or former employees demanding remuneration in consideration for assigned service inventions. If any such claims were filed, we could potentially be required to pay remuneration to our current or former employees for such assigned service inventions, or be forced to litigate such claims, which could negatively affect our business.

Risks Related to the Company

For as long as we are an "emerging growth company," we will not be required to comply with certain reporting requirements that apply to other public companies. We cannot predict whether the reduced disclosure requirements applicable to emerging growth companies

will make our securities less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of certain exemptions from reporting requirements applicable to other public companies that are not emerging growth companies. These include: (i) not being required to comply with the auditor attestation requirements for the assessment of our internal controls over financial reporting provided by Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act; (ii) not being required to comply with any requirements adopted by the Public Company Accounting Oversight Board, or PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer; (iii) not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the U.S. Securities and Exchange Commission determines otherwise, (iv) not being required to provide certain disclosure regarding executive compensation required of larger public companies; and (v) not being required to hold a non-binding advisory vote on executive compensation or seek shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years from the end of our current fiscal year, although, if the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of any June 30 before the end of that five-year period, we would cease to be an emerging growth company as of the following December 31. We cannot predict if investors will find our securities less attractive if we choose to rely on these exemptions. If some investors find our securities less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our securities and the price for our securities may be more volatile. Further, as a result of these

scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to security holders of such companies.

We are a foreign private issuer and, as a result, we are not be subject to U.S. proxy rules and are subject to the Securities Exchange Act of 1934 reporting obligations that, to some extent, are more lenient and less frequent than those applicable to a U.S. issuer.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act as a foreign private issuer. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. We intend to furnish quarterly reports to the SEC on Form 6-K for so long as we are subject to the reporting requirements of Section 13(g) or 15(d) of the Exchange Act, although the information we furnish may not be the same as the information that is required in quarterly reports on Form 10-Q for U.S. domestic issuers. In addition, while U.S. domestic issuers that are not large accelerated filers or accelerated filers are required to file their annual reports on Form 10-K within 90 days after the end of each fiscal year, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year. Foreign private issuers are also exempt from the

Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. Although we intend to make interim reports available to our shareholders in a timely manner, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer, we are permitted, to follow, and follow certain home country corporate governance practices instead of otherwise applicable NASDAQ requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the Listing Rules of the NASDAQ Stock Market for domestic U.S. issuers. For instance, we follow home country practice in Israel with regard to, among other things, director nomination procedures, the approval of compensation of officers, and quorum requirements at general meetings of our shareholders. In addition, we intend to follow our home country law instead of the Listing Rules of the NASDAQ Stock Market that require us to obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or greater interest in the company, and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on NASDAQ may provide less protection to you than what is accorded to investors under the Listing Rules of the NASDAQ Stock Market applicable to domestic U.S. issuers.

If we lose our status as a foreign private issuer under the SEC’s rules, our compliance costs will increase.

We would lose our foreign private issuer status if more than 50 percent of our outstanding voting securities are directly or indirectly held of record by residents of the United States and if a majority of our directors or executive officers are U.S. citizens or residents and we fail to meet additional requirements necessary to avoid

loss of foreign private issuer status. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs for us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We would also be required to follow U.S. proxy disclosure requirements, including the requirement to disclose more detailed information about the compensation of our senior executive officers on an individual basis. We may also be required to modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

Exchange rate fluctuations between the U.S. dollar and the NIS and the Euro and inflation may negatively affect our earnings and we may not be able to hedge our currency exchange risks successfully.

The dollar is our functional and reporting currency. However, a significant portion of our operating expenses, including personnel and facilities related expenses, are incurred in NIS. As a result, we are exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or, if the NIS instead devalues relative to the U.S. dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. The Israeli rate of inflation has not had a material adverse

effect on our financial condition during the years 2016, 2015 and 2014. In addition, we expect to incur operating expenses denominated in Euros, and therefore, our operating results are also subject to fluctuations due to changes in the U.S. dollar/Euro exchange rate. Given our general lack of currency hedging arrangements to protect us from fluctuations in the exchange rates of the NIS, the Euro and other foreign currencies in relation to the U.S. dollar (and/or from inflation of such foreign currencies), we may be exposed to material adverse effects from such movements. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar.

We have never declared or paid a dividend and currently do not intend to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our securities.

We have never declared and do not anticipate paying cash dividends on our ordinary shares in the foreseeable future. Our board of directors has discretion to declare and pay dividends on our ordinary shares and will make any determination to do so based on a number of factors, such as our operating results, financial condition, current and anticipated cash needs and other business and economic factors that our board of directors may deem relevant. In addition, we are only permitted to pay dividends out of "profits" (as defined by the Israeli Companies Law, 1999, or the Israeli Companies Law), provided that there is no reasonable concern that the dividend distribution will prevent us from meeting our existing and foreseeable obligations, as they become due. If we do not pay dividends, our ordinary shares may be less valuable because a return on your investment will only occur if the trading price of our securities appreciates. Further, you should not rely on an investment in us if you require dividend income from your investments.

If securities or industry analysts do not publish research or reports about us or our business or publish unfavorable research about us or our business, the price of our securities and their trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our securities, the price of our securities would likely decline. We do not have control over these analysts and we do not have commitments from them to continue to write research reports about us or our business. The price of our ordinary shares

could decline if one or more equity research analysts downgrade our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Our stock price has and may be subject to fluctuation, and purchasers of our securities could incur substantial losses.

Our stock price has been subject to considerable fluctuation since our initial public offering in February 2015, with the closing price per share having varied from a low of $0.97 to a high of $5.88, and may be subject to fluctuation in the future. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities at or above the purchase price. The market price for our ordinary shares on the NASDAQ Capital Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, among others:

- we may not be able to develop our C-Scan system at the rate or to the stage we desire;
- inability to obtain the approvals necessary to commence further clinical trials;
- unsatisfactory results of clinical trials;
- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the medical device industry in general;
- achievement of expected product sales and profitability or our failure to meet expectations;

- our commencement of, or involvement in, litigation;
- any major changes in our board of directors or management;

- legislation in the United States relating to the sale or pricing of medical device;
- future substantial sales of our ordinary shares;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts; or
- the trading volume of our ordinary shares.

In addition, the stock market in general, and NASDAQ Stock Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. Further, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly.

The trading market for our ordinary shares is not always active, liquid and orderly, which may inhibit the ability of our shareholders to sell ordinary shares.

Prior to our initial public offering in February 2015, there was no public market for our ordinary shares. Since that time, the trading market for our ordinary shares has not always been active, liquid or orderly. The lack of an active market at times may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital by selling shares.

We have broad discretion in how we use the net proceeds from our initial public offering and concurrent private placement and our August 2016 registered direct offering, and we may not use these proceeds effectively.

Our management has broad discretion as to the application of the net proceeds of our initial public offering and concurrent private placement and our August 2016 registered direct offering. Our shareholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase our profitability or our market value.

Risks Related to Taxation

There is a risk that we could be treated as a domestic (U.S.) corporation for U.S. federal income tax purposes by reason of the transactions related to our acquisition of all of the business operations and substantially all of the assets of Check-Cap LLC on May 31, 2009 (hereinafter sometimes referred to as the "reorganization").

Section 7874(b) of the Internal Revenue Code of 1986, as amended, or the Code, generally provides that a foreign corporation (i.e., a corporation created or organized under the laws of a jurisdiction outside of the United States) would be treated as a domestic (U.S.) corporation for U.S. federal income tax purposes if, pursuant to a plan or a series of related transactions, (1) the foreign corporation acquires, directly or indirectly, substantially all of the assets of a domestic corporation (or substantially all of the properties constituting a trade or business of a domestic partnership), (2) after the acquisition, the former shareholders of the acquired corporation by reason of holding shares of the acquired corporation (or, in the case of an acquisition with respect to a domestic partnership, the former partners of the domestic partnership by reason of holding a capital or profits interest in the domestic partnership) own at least 80% of the stock (by vote or value) of the acquiring corporation, and (3) after the acquisition, the expanded affiliated group that includes the acquiring corporation does not have substantial business activities in the foreign country in which, or under the laws of which, the acquiring

corporation is created or organized when compared to the total business activities of such expanded affiliated group. On the basis of analysis of the relevant facts and circumstances and the relevant law (including the temporary regulations under Section 7874 applicable at the time of the reorganization), it was determined that the third condition described in the preceding sentence was not met with respect to the reorganization and, therefore, that the inversion tax rules of Section 7874(b) would not apply to treat us as a domestic corporation for U.S. federal income tax purposes. However, since this determination was made on the basis of all of the relevant facts and circumstances, and it is not clear which facts and circumstances the Internal Revenue Service, or the IRS, may consider more important than others, this conclusion is not free from doubt.

If Section 7874(b) were to apply to the reorganization (and we were to be treated as a domestic corporation for U.S. federal income tax purposes), then, among other things, (i) we would be subject to U.S. federal income tax on our worldwide taxable income (if and when we have taxable income); (ii) certain payments (e.g., interest and dividends) that we make (or have made) to our foreign investors may be (or may have been) subject to U.S. withholding taxes; (iii) we may be subject to significant penalties for the failure to file certain tax returns and reports, including reports with respect to our foreign bank accounts; and (iv) the U.S. unitholders of Check-Cap LLC would not have been subject to U.S. federal income tax on royalties that are deemed to be paid to them under Section 367(d) of the Code as a result of the reorganization. As discussed under Item 5B "Operating and Financial Review and Prospects – Liquidity and Capital Resources – Application of Critical Accounting Policies and Estimates – Royalties provision – Reimbursement liability to Check-Cap LLC unitholders," and Item 5F "Operating and Financial Review and Prospects-Tabular Disclosure of Contractual Obligations," as part of the reorganization, we committed to reimburse the unitholders of Check-Cap LLC for any tax burdens that may be imposed on them due to the reorganization, including royalties that are deemed to be paid to the U.S. unitholders under Section 367(d) of the Code.

Prospective investors are urged to consult their own advisors on these issues. The balance of this discussion, including the discussion under Item 10E "Additional Information – Taxation – U.S. Federal Income Taxation," assumes that we will be and have been treated as a foreign corporation for U.S. federal income tax purposes.

We may be eligible for tax benefits from government programs, which require us to meet certain conditions, including regarding the location of our property, plant and equipment and manufacturing in Israel. We can provide no assurance that we would

continue to be eligible for such benefits and/or that any such benefits will not be terminated in the future.

Our manufacturing facilities in Israel may qualify as a "Benefited Enterprise" under the Israeli Law for Encouragement of Capital Investments, 1959, or the Investment Law, which would entitle us to receive certain tax benefits. In order to be eligible for such benefits, we would be required to meet certain conditions, including the making of a minimum capital investment in our productive assets and the carrying on of a required portion of our manufacturing in Israel. The amount of the benefit will be determined in accordance with various conditions, including the location of our property, plant and equipment and the location of certain of our sub-contractors. If we cease to meet the required conditions for eligibility, the tax benefits could be cancelled and we could be required to pay increased taxes or to refund the amounts of the benefits received with interest and penalties. We can provide no assurance as to the amount of future capital investment in our productive assets, our future manufacturing location and the future location of our property, plant and equipment and certain of our sub-contractors, and therefore, we cannot provide assurance that we will be eligible for such tax benefits or assurance as to the amount of such tax benefits. Even if we continue to meet the relevant requirements, the tax benefits that Benefited Enterprises receive may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we would be required to pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. See Item 10E "Additional Information—Taxation— Israeli Tax Considerations and Government Programs—Law for the Encouragement of Capital Investments, 5719-1959" for additional information concerning these tax benefits.

There is a risk that we may be classified as a passive foreign investment company, or PFIC, which could result in adverse U.S. federal income tax consequences to U.S. investors.

In general, we will be treated as a PFIC for any taxable year in which either (1) at least 75% of our gross income (including our pro rata share of the gross income of our 25% or more-owned corporate subsidiaries) is passive income or (2) at least 50% of the average value of our assets (including our pro rata share of the assets of our 25% or more-owned corporate subsidiaries) is attributable to assets that produce, or are held for the production of, passive income. Passive income generally includes dividends, interest, rents, royalties, and gains from the disposition of passive assets. If we are determined to be a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder (as defined in Item 10E “Additional Information - Taxation—U.S. Federal Income Taxation—General”) of our securities, the U.S. Holder may be subject to increased U.S. federal income tax liability upon a sale or other disposition of our securities or the receipt of certain excess distributions from us and may be subject to additional reporting requirements. We have not performed an analysis of our PFIC status for our taxable year ended December 31, 2016. In addition, our actual PFIC status for our current taxable year or any subsequent taxable year is uncertain and will not be determinable until after the end of such taxable year. Accordingly, there can be no assurance with respect to our status as a PFIC for our taxable year ended December 31, 2016 or any subsequent taxable year.

U.S. investors are urged to consult their own tax advisors regarding the possible application of the PFIC rules. For more information, see Item 10E “Additional Information—Taxation—U.S. Federal Income Taxation—U.S. Holders—Passive Foreign Investment Company Rules.”

There is a risk that a holder of Long Term Incentive Warrants will recognize ordinary compensation income on the exercise of the Long Term Incentive Warrants, which may result in U.S. federal and Israeli income tax liability to such holder without the receipt of cash.

While not free from doubt, the Long Term Incentive Warrants may be treated for U.S. federal and Israeli income tax purposes as compensatory warrants (i.e., warrants issued to compensate an original purchaser of units in our initial public offering for holding the ordinary shares underlying the units for a certain period of time after the closing date of our initial public offering). Based on this characterization, a holder may recognize ordinary compensation income for U.S. federal and Israeli income tax purposes on the exercise of the Long Term Incentive Warrants, as described under Item 10E “Additional Information—Taxation—Israeli Tax Considerations and Government Programs—Taxation of our Shareholders—Taxation of Non-Israeli Shareholders upon Exercise of Long Term Incentive Warrants” and Item 10E “Additional Information—Taxation—U.S. Federal Income Taxation—U.S. Holders—Exercise of Long Term Incentive Warrants” and “Non-U.S. Holders.” Such compensation income may result in U.S. federal or Israeli income tax liability to such holder without the receipt of cash. Holders of Long Term Incentive Warrants are urged to consult their own tax advisors with respect to the U.S. federal and Israeli income tax consequences that may arise with respect to the Long Term Incentive Warrants.

ITEM 4. INFORMATION ON OUR COMPANY

A. History and Development of the Company

Our History

Our legal and commercial name is Check-Cap Ltd. We were formed as a company in Israel on April 5, 2009. On May 31, 2009, we acquired all of the business operations and substantially all of the assets of Check-Cap LLC, a Delaware limited liability company formed in December 2004. On May 15, 2015, we formed our wholly-owned subsidiary Check-Cap US, Inc., a Delaware corporation.

On February 24, 2015, we successfully completed an initial public offering in the United States and the listing of our securities on the NASDAQ Capital Market.

We are subject to the provisions of the Israeli Companies Law. Our principal executive offices are located at Check-Cap Building, 29 Abba Hushi Avenue, P.O. Box 1271, Isfiya, 3009000, Israel. Our telephone number is +972-4-8303400 and our website is located at www.check-cap.com (the information contained therein or linked thereto shall not be considered incorporated by reference in this annual report). Our U.S. agent is Puglisi & Associates, located at 850 Library Avenue, Suite 204, Newark, Delaware 19711.

Principal Capital Expenditures

For a discussion of our capital expenditures, see Item 5 “Operating and Financial Review and Prospects—Liquidity and Capital Resources.”

B. Business Overview

Our Company

We are a clinical stage medical diagnostics company engaged in the development of a capsule-based system that utilizes ultra-low-dose X-rays to generate structural information on the endoluminal surface of the colon that may be used for screening of the colon to detect polyps, masses and CRC. While CRC is the second leading cause of death from cancer for both sexes combined in the United States and is preventable with early screening and intervention, according to the National Health Interview Survey, in 2015, only 63% of Americans over the age of 50 reported being current with CRC screening recommendations. Unlike other screening modalities that are designed for direct visualization and imaging of the internal colon, such as optical colonoscopy, CTC and other capsule-based technologies, our C-Scan system is designed to function without any cathartic preparation of the colon, and to transit the gastrointestinal tract by natural motility while the patient continues his or her normal daily routine. Furthermore, the C-Scan system does not require fasting prior to or during capsule transit. Our C-Scan system is comprised of three main components: (1) C-Scan Cap, an ingestible X-ray scanning capsule; (2) C-Scan Track, a biocompatible unit worn on the patient's back for capsule control, tracking and data recording; and (3) C-Scan View, a PC-based, standalone application used to process and display structural information of the colon. We believe that this solution will be attractive to both physicians and patients, with the potential to increase the number of people completing CRC screening.

Our C-Scan Cap will be swallowed and propelled by natural motility through the gastrointestinal tract and excreted naturally with no need for retrieval for data collection. Unlike other existing CRC screening methods, this process should not disrupt a patient's normal activities or require fasting. Our C-Scan Cap employs ultra-low-dose

X-rays, which allow the C-Scan system to image the interior lining of the colon even when surrounded by intestinal content. As such, we believe that patients using our C-Scan system will not be required to undergo any prior bowel preparation. The Radiation Safety Division of the Soreq Nuclear Research Center found, as set forth in its report of November 2010 that was prepared at our request and based on the information provided by us and the relevant methods and principles known at such time, or the Report, that the radiation dose to the patient in the proposed screening procedure utilizing the scanning device developed by us at that time in routine operation and normal conditions is low relative to the radiation dose involved in conventional imaging procedures using X-rays (such as fluoroscopy and CT) and is also low when compared to the radiation dose involved in established screening procedures such as mammography, all as more fully described in the Report.

Our C-Scan Cap is being designed to transmit position, motility and the data it collects to the C-Scan Track that will be worn on the patient's back. The external data recorder is being designed to enable the transfer of the data to our C-Scan View application to allow physicians to analyze the data collected by our C-Scan Cap. The C-Scan Track is being designed to provide the physician with accurate localization data aligned with a reconstructed image. We intend for physicians to be able to review the colon's inner images in less time than is required to perform an optical colonoscopy.

Colonic polyps are tissue growths that occur on the lining of the colon. Polyps in the colon are common, and certain types of polyps may become cancerous over time. In the event that polyps are identified by our C-Scan system, the patient may be advised to undergo a subsequent traditional colonoscopy procedure to examine, remove and biopsy the polyps. For those patients who require a subsequent colonoscopy, concerns regarding pain, discomfort and embarrassment may still remain. We do not, however, believe that

these concerns will make the use of our C-Scan system any less attractive to physicians and patients. Although patients who are initially screened utilizing a traditional colonoscopy could avoid the need for a second colonoscopy if polyps are discovered, we believe that our C-Scan system will still be attractive to physicians and patients as a large number of patients who are screened will not require a subsequent colonoscopy. Published data from a multi-center CT colonography screening study of 2,531 asymptomatic adults published in The New England Journal of Medicine in 2008 showed that if all patients with a lesion measuring 5mm or more on CT colonography were referred for colonoscopy, the colonoscopy-referral rate would have been 17%.

We initiated our first clinical studies in 2010, consisting of two single-center feasibility studies with non-scanning (no X-ray source) capsules for the purposes of measuring gastrointestinal tract activity, colon contractions and associated capsule motility, and shortening capsule transit time.

In 2013, we initiated a multi-center prospective clinical feasibility study, designed to allow for the recruitment of 100 subjects, to establish clinical proof of concept, safety and functionality of our C-Scan system in patients eligible for CRC screening. Analysis conducted on the first 66 capsules swallowed by participants showed that 65 of 66 capsules swallowed were naturally eliminated, without major or minor side effects, after 62±40.7 hours. The average calculated radiation exposure was 0.06 ± 0.04 mSv (similar to a single chest radiograph). Both pedunculated and sessile polyps were detected in several patients and validated later by colonoscopy.

In the first quarter of 2017, we initiated enrollment in a multi-center study of the C-Scan system in support of CE Mark submission. This prospective study, designed to demonstrate the safety and clinical performance of the C-Scan system, will evaluate polyp detection as compared to colonoscopy.

To date, we have achieved key product development milestones, including the ability of our C-Scan system to reconstruct the human colon and to identify polyps. Following our certification to ISO 13485:2003 by our Notified Body, successful completion of our current multi-center clinical study and achievement of compliance with the requirements of the Medical Devices Directive, we plan to submit during the first half of 2017 a request for CE marking for the marketing and sale of our C-Scan system in the European Union. We expect to initiate post-marketing studies in Europe following CE marking for the purpose of collecting additional evidence of clinical effectiveness and clinical utility to support market adoption. Subject to clinical results, regulatory approvals, available capital and engagement with strategic partners, we anticipate launching our C-Scan system commercially in Europe during 2018.

We conducted a pre-submission meeting with the FDA in December 2016 for the purpose of receiving feedback on the regulatory pathway

for our system in the United States. We also sought feedback on a proposed protocol for a feasibility or pilot study, the primary purposes of which is to establish the safety of the C-Scan system and evaluate user compliance and satisfaction. Subject to required approvals, we plan on initiating such a study in 2017. Following successful completion of the pilot study and receipt of required approvals, we plan to initiate during 2018, a pivotal study in the United States to (i) demonstrate device safety as evidenced by a lack of device-related serious adverse events; and (ii) provide efficacy data concerning our C-Scan system's performance. We anticipate that FDA approval for the pivotal study will be subject to our providing sufficient clinical data from previous clinical studies, which may include the multi-center clinical feasibility study, the multicenter safety and clinical performance study, and U.S. pilot study. However, there can be no assurance that we will receive approvals for the pilot and/or pivotal studies to be conducted in the United States.

We also intend to pursue clinical trials for regulatory approvals in Japan and China in parallel to the U.S. pivotal study, subject to available capital and engagement with strategic partners. Pivotal studies are expected, among other things, to compare polyps identified by our C-Scan system with the polyps identified by traditional optical colonoscopy. These clinical findings may be analyzed in comparison with results obtained from FOBTs and FITs.

Following and subject to the successful completion of our pivotal trial, our current strategy is to submit a direct de novo reclassification petition, which we anticipate submitting in 2019, for initial FDA approval for the marketing of our C-Scan system in the United States. Direct de novo reclassification typically takes at least 9 to 12 months from filing to clearance. If the FDA determines that our C-Scan system is not a candidate for de novo reclassification, it will require approval of the device for market through the PMA process. The PMA pathway is much more

costly and uncertain than the 510(k) clearance process or de novo reclassification, and generally takes at least 12 to 18 months, or even longer, from the time the application is filed with FDA to ultimate approval.

We have submitted patent applications covering our technology in the United States, member states of the European Patent Organisation, Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan and South Korea. We have been granted patents for our core patent by the U.S. Patent and Trademark Office as well as from the European Patent Office, Australia, China, Hong Kong, Israel, India and Japan. We also filed patent applications describing the use of our technology in several other medical applications.

Since our formation, we have not generated any revenue. We do not anticipate generating any revenue for the foreseeable future and we do not yet have any specific launch dates for our product. We incurred net losses of $8.8 million in 2016, $12.3 million in 2015 and $610,000 in 2014. As of December 31, 2016, we had an accumulated deficit of $42.9 million and a total shareholders' equity of $10.4 million.

Our Solution

CRC screening can reduce the incidence of and mortality from the disease by detecting polyps at an earlier, more treatable stage. CRC is one of the few cancers that can be prevented through screening because pre-cancerous polyps, from which colon cancers often develop, can be identified and removed. Today, there is a range of options for CRC screening in the average-risk population, with current technology falling into two general categories: (i) structural exams, such as optical colonoscopy (which is currently regarded as the “gold standard” for CRC screening), sigmoidoscopy, CTC and optical capsules (all of which require aggressive bowel preparation), which are invasive exams that enable physicians to visualize the colon for abnormalities; and (ii) stool and serum based tests, such as FOBTs, FITs, stool DNA, and blood tests, which test for blood in stool and irregularities in blood and DNA. Notwithstanding the many CRC screening alternatives, despite the fact that the tests are encouraged by clinicians and insurers and the clinical value of screening for CRC, a large portion of the population is still reticent to go for CRC screening and are not satisfied with the currently available alternatives.

We believe that our C-Scan system could represent a potential breakthrough in CRC screening by providing structural information on the endoluminal surface of the colon without the discomfort and embarrassment experienced by some patients undergoing a traditional optical colonoscopy and other currently available screening methods by offering the following benefits:

- eliminating the need for fasting and prior bowel preparation, which would differentiate our system from every other currently available structural screening exam;

- providing patients with a procedure that requires them to swallow our C-Scan Cap and small amounts of a contrast agent, thereby minimizing any disruption to their normal

activities;

- eliminating the need to sedate patients;

- obviating the requirement for the insufflation (the forcing of air into the gastrointestinal tract) of patients; and

- providing digital reporting, storage and remote consulting capabilities.

Although our C-Scan system utilizes radiation that is less than one mSv, we believe that the potential risks associated with such radiation exposure are low compared to the potential risks associated with other procedures such as perforation, bleeding or sedation related effects (optical colonoscopy and sigmoidoscopy) and dehydration and damage to kidneys. Unlike FOBTs, FITs and stool DNA tests, our capsule-based imaging modality generates structural information on the colon, which could assist in the detection of pre-cancerous polyps. We therefore do not believe that the ultra-low-dose radiation in our capsule will make our C-Scan system less attractive to physicians and patients than other less-effective products that do not employ any radiation.

We believe that gastroenterologists will adopt our technology and encourage the use of our capsule. This may increase the number of people undergoing CRC screening and may cause more people with polyps to obtain a polypectomy – a therapeutic procedure during which polyps are removed.

Our goal is to become a leading supplier of CRC screening technology and to establish our technology as a leading CRC screening method. Key elements of our strategy include:

- obtaining CE marking for the marketing and sale of our C-Scan system in the European Union, followed by obtaining regulatory approvals for the sale of our C-Scan system initially in the United States and Japan;

- In Europe and Japan, we intend to offer our C-Scan system as an imaging and screening tool for the general population. In the United States, we may choose to first obtain regulatory clearance/approval for our C-Scan system in a screening sub-population, and after we have conducted more extensive clinical studies in the United States, we would anticipate applying to the FDA for the use of our C-Scan system as a primary screening tool;

- obtaining government and private third-party reimbursement for our technology;

- improving and enhancing our existing technology portfolio and developing new technologies; and

- successfully marketing our product to establish a large customer base.

Our Technology

Our technology is based on an ingestible capsule (C-Scan Cap), which is swallowed by the patient and propelled by natural motility through the gastrointestinal tract. Our capsule transmits information to a receiving device (C-Scan Track) worn on the patient’s body that stores the information for off-line analysis. Our C-Scan Cap consists of an X-ray source and several X-ray detectors. The X-ray source is contained in a rotating radiation shield, enabling the generation of 360-degree angular scans. The collection of successive angular scans is intended to enable the virtual reconstruction of a portion of the colon’s inner surface. During movement of our capsule longitudinally through the colon, successive images of portions of the colon enable the three-dimensional reconstruction of the colon. Our C-Scan system is also intended to enable identification of polyps, masses, and colorectal cancers which protrude inward into the colon, through the detection of irregularities in the topography of the colon's inner surface.

Our C-Scan system is intended to be prescribed to patients by physicians.

Immediately prior to capsule ingestion, patients will swallow 15ml of iodinated oral contrast medium, combined with oral fiber, and continue to do so with normal daily meals in order to enhance the contrast of the colon surface. The capsule is propelled by natural motility through the gastrointestinal tract. During transit, information is transmitted to the C-Scan Track, which stores the information for off-line analysis. After our C-Scan Cap is expelled from a patient's body, the C-Scan Track data will be downloaded into our workstation (C-Scan View) through which physicians will utilize our data viewer software application to analyze the data collected by our C-Scan system. Our proprietary software is being designed to process the data and produce a two and three-dimensional visualization of the colon's inner surface. A physician will then analyze the visualization to determine whether any anatomical anomalies are present on the inner surface of the colon.

Our C-Scan system consists of the following three main subsystems that together enable the generation of high-resolution 3D imaging of the colon's inner surface, further described below: (i) an ultra-low-dose X-ray based colon scanning capsule (C-Scan Cap); (ii) C-Scan Track; and (iii) a PC-based standalone application (C-Scan-View).

C-Scan Cap

C-Scan Cap is an X-ray scanning capsule, designed to measure, collect and transmit structural information, and is comprised of the following components:

- X-ray Source – Including radioactive material sealed in a cylindrical housing.

- Collimator – Radiation shield around the source, which absorbs most of the radiation. Several radial holes enable emission of radiation in defined directions.

- X-ray Sensor – Comprised of several solid state X-ray detectors for measuring the scattered radiation intensity.

- Tilt Sensor – Indication of capsule motion (3D acceleration).

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- Rotation Motor – For rotating the collimator and X-ray Source.
- Compass sensor – Indication of true north (reference coordinate system).
- Source Concealment Mechanism – Conceals the source inside the radiation shield.
- R-T – Radio frequency transceiver device to communicate with the receiver.
- Batteries – Electrical power supply for the capsule.
- Memory – Data storage. The capsule should be able to store up to an hour of measured data.
- C-Scan Track Coil – Transmits a continuous electromagnetic filed utilized by an external localization system to track 3D position.

Image for illustration purpose only

C-Scan Track

C-Scan Track is a small, disposable system of biocompatible stickers which are designed to automatically track the imaging capsule's positioning and orientation throughout the gastrointestinal tract transit, control the capsule scan mechanism through an embedded scan control algorithm or SCA, capture imaging data from the capsule through radio frequency communication to a non-volatile memory device, and enable data retrieval, through either wired or wireless communication, to an external processor.

The C-Scan Track is comprised of the following components:

- Sticker Housings – Biocompatible and water-resistant stickers and housing integrating all functional components, attached to the patient's back, enabling five days of continuous operation.
- Recorder – Consists of receiver electronics embedded software and nonvolatile memory.

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- Antennas – Radio frequency antennas are embedded into the sticker housings and used to communicate with the capsule.
- Activation/Deactivation Circuit – Used to activate/deactivate the C-Scan Track through a specialized protocol.
- UI Indicators – Provides user with vocal, light or vibration indication as required.
- PCB – Electronics' printed circuit boards.
- Microcontroller – Runs embedded software, logic that manages the C-Scan Track and SCA.
- RF Transceivers – Several transceivers used to communicate with the capsule.
- TILT/Compass Sensors – To determine the patient's body movements.
- Batteries – Electrical power supply for the C-Scan Track.
- Memory – Non-volatile data storage to store data acquired by the system.

Image for illustration purpose only
C-Scan View

C-Scan View is a specialized, user friendly, personal computer-based software package designed to retrieve and process clinical data from the C-Scan Track and to reconstruct and produce 3D visualization of the colon's inner surface. The C-Scan Track is comprised of the following software components:

- Communication Driver Software – to communicate with the C-Scan Track and retrieve collected data following procedure completion.
- Data Processing Software – to process and reconstruct clinical data into a 3D structure.

- Data Display and Management Software – includes the following functions:

  3D visualization of the reconstructed colon surface.

  Annotation tools.

  Registration of patient and capsule data and management of the patient database.

  Report – to enable generation of clinical results report out.

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C-Scan System Non-Clinical, Pre-Clinical and Clinical History

We have developed and validated our capsule-based imaging modality for providing structural information on colonic polypoid lesions and masses for CRC screening. Below is a summary of the validation tests carried out by us in the laboratory, in phantoms, animals and humans, which were designed to evaluate this new imaging modality's performance and potential clinical value.

Non-Clinical and Pre-Clinical Testing

Imaging Performance Testing

The C-Scan Cap transmits data as it transits the colon. This data consists of imaged slices perpendicular to the capsule's longitudinal axis; slices are then reconstructed by the C-Scan View to produce 2D and 3D images of the inner surface of the colon. Following are performance measurements of the capsule imaging.

- Modulation Transfer Function, or MTF. The capsule was moved along a longitudinal-edge phantom setup in 3mm steps. The figure below shows a typical raw signal after filtering for peak detection. The same test was carried out using an angular-edge phantom setup, which demonstrated similar results to those shown below. These tests do not take into account noise characteristics.

Image for illustration purpose only

For each position of the capsule in the phantom, the mean signal intensity (peak) was measured, the result of which is shown in the right figure below. Resulting line spread function, or LSF, which is the differential of the curve in the left figure below.

Image for illustration purpose only

The graphs above demonstrate that the existing design of our C-Scan system can detect objects of approximately 2-3mm when noise is not taken into account.

Resolution Limit: Estimation of the Smallest Visible Object Size. In order to estimate the size of the smallest visible object, both spatial resolution and noise characteristics must be taken into account. The graph below presents the estimated MTF of our C-Scan system. Noise analysis indicates MTF 1/3 for minimum visibility, which demonstrates that the smallest visible object that can be detected with the existing design of our C-Scan system (in the conditions used, which included a colon diameter of 30mm) is of approximately 5-6 mm (see graph below).

Image for illustration purpose only

Image Reconstruction

Two main characteristics of our C-Scan system contribute to the image reconstruction performance:

- The number of photons hitting the detector per time frame.
- The angular spread of the photon beam coming out of the capsule collimator.

Based on the laboratory tests performed with the previous version of our C-Scan system, polyps of 6 mm and larger should be visible and 10 mm polyps and larger are expected to be detected at high sensitivity. To further enhance the visibility of 6 mm - 9 mm polyps, a new design of the collimator was

successfully tested in a prototype version of our C-Scan Cap, which is expected to enable 2.5 times the number of photons to be detected by the detectors, allowing the implementation of an image enhancement algorithm, which is expected to improve the imaging performance.

Animal Testing and Tissue Equivalent Phantom Image Reconstruction

The physics of our imaging modality was tested in the laboratory on phantoms with tissue equivalent material and in animals to ensure that laboratory conditions mimic real life clinical scenarios.

Following the initial proof of concept, we performed a series of studies in order to evaluate the feasibility and preliminary safety of our technology. All studies were performed in pigs ranging from 60 to 90 kg. Pigs, which are commonly used in gastrointestinal studies, were selected as the animal model for preliminary evaluation of our C-Scan system based on the resemblance of the porcine colon size and morphology to the human colon. However, there are marked differences between the colon of pigs and that of humans. The pig colon is much longer and as a larger diameter, in addition to other anatomical differences. In the pig model, the pressure waves of peristalsis are believed to be more frequent and shorter than in humans. As a result, we believe that colon content movement is substantially slower and more frequent in pigs than in humans. In these studies, we did not intend to collect statistically significant data; hence, the tests were repeated a limited number of times until adequate data was collected.

The first test was performed to demonstrate imaging proof-of-concept using a wired C-Scan system. This technology included all the basic features intended to be included in the clinical C-Scan system, but on a larger scale due to the use of off-the-shelf components. The subsequent studies used versions of the C-Scan system that integrated most of the imaging components, software and electronics of the C-Scan system that we used with humans. Since off-the-shelf components were used, the animal capsules were larger and heavier than the version of our C-Scan system that are used clinically.

Raw data from an animal colon showing a decrease in X-ray florescence, or XRF,

photon signals and an increase in Compton backscattering, or CMT, signals corresponding to the position of a polyp that was detected when our C-Scan Cap passed over the polyp is shown in the image below. These two signals are combined in order to form a three dimensional image below.

Image for illustration purpose only

The animal studies conducted to date demonstrate that our technology provides sufficient resolution, in these studies, for the detection of 10 mm polyps which is the size of clinically significant polyps. The animal studies also demonstrated that 5 mm polyps can be detected, though with lower resolution than 10 mm polyps in the first animal capsule. Animal health was maintained throughout the studies. No adverse effects related to passage of our capsule were noted.

The capsules evaluated in the animal studies were significantly larger than the capsules that we are using with humans. The differences in anatomy, physiology, and capsules may have several effects on the data compared to use in the human population. Motility of the capsules through the digestive C-Scan system was slow due to the specific shape of the porcine gastrointestinal tract. In addition, because of the size of the capsule, it was retained in the stomach for many hours and even days. Accordingly, the animal model required that normal ingestion be replaced by direct insertion of the capsule into the small bowel. In order to simplify the development and animal testing, we used Tungsten radiation source with long half-life (120 days).

Following the success of the animal testing, a series of in-vitro tests were conducted to simulate different clinical scenarios in the laboratory using a miniaturized human capsule. Polyps were created and reconstruction of the laboratory phantoms with a human capsule was generated to assess the ability to detect polyps as the capsule advances in the colon. The in-vitro tests demonstrated the imaging capabilities of our imaging technology. Below is the reconstruction of a laboratory phantom image.

Image for illustration purpose only

Polyp Detection Analysis

Laboratory tests were carried out to estimate the capsule's ability to detect polyps in phantoms and demonstrate sensitivity and specificity of such detection. Below is an example of the reconstruction of a scan composed of three slices: XRF, CMT and a fused (combined) image.

Receiver Operating Characteristics

Standard receiver operating characteristics, or ROC, curves were generated from phantom data with 8 mm polyp in a 30 mm barrel phantom with 3% iodine concentration mimicking the colon contents. CMT, XRF and fused (combined) data were analyzed based on 2D slices that were generated and standard deviation indicator. There were a few cases where the noise in the phantoms was high enough to generate polyp false positive condition separately for each data type, especially in CMT. However, fusion of CMT and XRF data contributed to noise reduction and enabled to demonstrate 100% true positive and 0% false positive.

Clinical Trials

We initiated our first clinical study at University Hospital, Hamburg, Germany in 2010. The purpose of this study was to monitor and record the colon contractions and the associated motility of the capsule in the colon. This study was conducted with a passive capsule that contained no X-ray source or detectors. It included several electronic components of the C-Scan system and had similar dimensions to the current capsule. 63 healthy volunteers were enrolled and no adverse events were reported.

We completed a limited, single-center, feasibility study at Rambam Medical Center, Haifa, Israel to assess the motility of a non-scanning capsule in healthy subjects. The objective of the study was optimizing the daily routine of the subjects in order to shorten the transit time of our capsule. 15 subjects participated and swallowed a capsule with the same weight and dimensions as our current capsule. No adverse events were reported and all capsules were retrieved. A structured daily routine determined the timing of the following: capsule ingestion, the subjects' daily meals, the contrast agent ingestion and one evening dose of 10 mg of Bisacodyl, and all subjects continued their regular active lifestyles (such as work and exercise). The average transit time of the

capsule in the 15 subjects was approximately 38 ± 19 hours, which is comparable to the average transit time of our capsule in subjects participating in the multi-center feasibility study, in which the participants do not ingest a daily dose of Bisacodyl, and participants are released to their homes and continue their regular lifestyles during the study.

A 10 subject clinical proof-of-concept study, conducted at Tel Aviv Sourasky Medical Center in Israel and using a prior version of our C-Scan system, did not identify any material safety or feasibility issues. The study demonstrated the applicability of our C-Scan system to the human colon, generating images of the colon without any prior bowel preparation. All subjects ingested the capsule easily with smooth passage within the designated transit time, on average, within 48-72 hours. There were no reported device-related adverse events. Mild effects on bowel movements were noted, which were determined to be related to the contrast agent and passed within one to two days after the capsule excretion. Estimated total radiation exposure was calculated using standard established factors for calculating effective radiation exposure, such as the duration of the capsule inside the body, and was based on the activity of the radiation source inside the C-Scan Cap and radiation energy, both of which were measured for each case study. The average calculated exposure for the entire procedure in the 10-case study, from ingestion of the capsule to excretion, was 0.03 mSv (STD 0.007 mSv). This level of radiation exposure is similar to a single chest X-ray (approximately 0.06mSv) and two orders of magnitude less than a CTC.

The 10-subject study constituted the initial phase of a multi-center, prospective clinical feasibility study to establish the safety, functionality and preliminary efficacy of our C-Scan system in patients eligible for CRC screening, by comparing results from the clinical feasibility study with those from non-invasive, low-sensitivity FOBTs and FITs, as well as from optical colonoscopies. The feasibility study has been designed to allow for the recruitment of 100 subjects. The study is being conducted at multiple centers in Israel, with the potential to be conducted at a single site in the Netherlands. The clinical feasibility study will evaluate the image resolution generated by the capsule in a human colon without cathartic preparation, will assess polyp imaging in various shapes and in different segments of the colon, and will evaluate the safety of the device in terms of total and segmental transit time and analyze the effects of the presence of polyps and variable colon dimensions on these parameters. The study will also seek to create a clinical atlas of images that will enable comparisons between images acquired by different CRC screening modalities. During the feasibility study we will collect data regarding the overall imaging of the colon's internal surfaces during the passage of the capsule to support the development of a correlation map of polyps identified through our imaging system with polyps imaged by optical colonoscopy and CTC. Additionally, the feasibility study will measure total radiation exposure and the distribution of contrast material within the colon.

Analysis conducted on the first 66 capsules swallowed by participants enrolled in the multi-center, prospective clinical feasibility study showed that 65 of 66 capsules swallowed were naturally eliminated, without major or minor side effects, after 62±40.7 hours. The average calculated radiation exposure was 0.06 ± 0.04 mSv (similar to a single chest radiograph). Image reconstructions allowed 2D/3D views of the colonic wall and lumen with the typical contour of different segments (hepatic flexure, triangular shape of the transverse

colon). Both pedunculated and sessile polyps were detected in several patients and validated later by colonoscopy.

In the first quarter of 2017, we initiated enrollment in a multi-center study of the C-Scan system in support of CE Mark submission. This prospective study, designed to demonstrate the safety and clinical performance of the C-Scan system, will evaluate polyp detection as compared to colonoscopy.

Research and Development

Our research and development strategy is centered on developing our C-Scan system. Our research and development team is located at our facilities in Isfiya, Israel, and consists of 51 employees and independent contractors as of February 15, 2017 and is supported by highly experienced consultants.

We have received grants from the Government of the State of Israel through NATI (formerly known as the OCS) for the financing of a portion of our research and development expenditures pursuant to the Research Law and related regulations and guidelines. As of December 31, 2016, we had received funding from NATI in the aggregate amount of $5.1 million and had a contingent obligation to NATI in the amount of $5.3 million. As of December 31, 2016, we had not paid any royalties to NATI. We may apply for additional NATI grants in the future. However, as the funds available for NATI grants out of the annual budget of the State of Israel have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

We incurred approximately $5.5 million, $5.8 million and $2.8 million in research and development expenses, net (after deducting participation by others and government grants) for the years ended December 31, 2016, 2015 and 2014, respectively. For additional information, see “Management’s

Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview— Research and Development Expenses, Net."

Intellectual Property

An important part of our competitive strategy is to seek, when appropriate, protection for our products and proprietary technology through a combination of U.S. and foreign patents, trademarks, trade secrets and non-disclosure and confidentiality, assignment of invention and other contractual arrangements with our employees, consultants and suppliers. These measures, however, may not be adequate to protect our technology from unauthorized disclosure, third-party infringement or misappropriation as these parties may breach these agreements, and we may not have adequate remedies for any such breach. We intend to prosecute and defend our proprietary technology. The primary test for patent protection eligibility includes novelty, non-obviousness and usefulness.

We submit applications under the Patent Cooperation Treaty, or PCT, which is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in each of the member states. Although a PCT application is not itself examined and cannot issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

As of December 31, 2016, we had 23 granted patents (not including separate validations in Europe) and 37 pending patent applications worldwide relating to various elements and functions of our products and related enhancements. We have submitted patent applications covering our technology in the United States, member states of the European Patent Organisation, Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan and South Korea. We have received patent grants for our core patent by the United States Patent and Trademark Office as well as from the European Patent Office, Australia, China, Hong Kong, Israel, India and Japan. We also filed patent applications describing the use of our technology in several other medical applications.

Our registered U.S. Patent Number 7,787,926 discloses an ingestible capsule with a radiation source and radiation detectors that, when used in conjunction with a radio opaque contrast agent, is adapted to detect clinically relevant findings in the colon. Utilizing X-ray fluorescence and Compton back scatterings, the capsule is able to measure the distance between the capsule and the colon wall and to distinguish between gas, intestinal contents, and clinically significant findings in the gastrointestinal tract.

A second PCT patent application (PCT/IL2008/000163), which is pending in several countries in the national-phase and granted in Europe and Hong Kong, discloses additional features such as a rotating collimator and improved scanning mechanisms, the capability to determine

tissue density to differentiate between different types of polyps, as well as the capability to determine capsule movement in the colon. Another PCT application (PCT/IL2011/000462), which is pending in several countries in the PCT national-phase, discloses a number of alternate fail safe concealment mechanisms that can be utilized in the capsule to ensure that the X-ray source is blocked when the capsule is not scanning and is open when it is scanning, allowing the capsule to image the colon. The fail-safe feature ensures that in the event of power failure, the radiation source is blocked and X-rays do not escape. Recently the application filed in Australia has been granted and the application filed in Europe has been allowed.

In another PCT patent application (PCT/IL2008/000765), which was granted in the United States, Europe, Israel and Japan, we disclose an imaging catheter that utilizes X-ray fluorescence, Compton back scattering and electron back scattering. The imaging catheter is designed for use in cardiac applications as well as intra-operative imaging applications such as imaging inside blood vessels where optical imaging cannot be performed because of obscuring circumstances.

While our policy is to obtain patents by application, to maintain trade secrets and to seek to operate without infringing on the intellectual property rights of third parties, technologies related to our business have been rapidly developing in recent years. Additionally, patent applications that we may file may not result in the issuance of patents, and our issued patents and any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot predict the extent of claims that may be allowed or enforced in our patents nor be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications that also claim technology or therapeutics to which we have rights, we may have to partake in proceedings

to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us. Moreover, because of the extensive time required for clinical development and regulatory review of a product we may develop, it is possible that, before our C-Scan system can be commercialized, related patents will have expired or will expire a short period following commercialization, thereby reducing the advantage of such patent. Loss or invalidation of certain of our patents, or a finding of unenforceability or limited scope of certain of our intellectual property, could have a material adverse effect on us. See “Item 3D “Key Information - Risk Factors— Risks Related to Our Intellectual Property.”

In addition to patent protection, we rely on trade secrets, including unpatented know-how, technology innovation, drawings, technical specifications and other proprietary. We also rely on protection available under trademark laws, and hold registered trademarks for the “CHECK-CAP” and “C-Scan” marks and design logos in the United States and Europe. Applications for additional marks and design logos are pending in the United States and Europe.

Competition

Competition for our C-Scan system comes from traditional well-entrenched manufacturers of tests and equipment for CRC screening, such as colonoscopy, sigmoidoscopy, CTC, optical capsule endoscopy, FOBTs and FITs. The principal manufacturers of equipment for optical colonoscopy and sigmoidoscopy include Olympus, Pentax, Hoya and Fuji Film. The principal manufacturers of equipment for CTC include General Electric Healthcare Systems, Siemens Medical Solutions, Philips Medical Systems Ltd. and Toshiba Corporation. The principal manufacture of equipment for optical capsule endoscopy includes Medtronic plc. All of these companies have substantially greater financial resources than we do, and they have established reputations as well as worldwide distribution channels for providing medical instruments to physicians.

Several companies have developed or are developing non-invasive technologies based on stool, serum, or molecular diagnostics (from blood and other bodily fluids), or MDx, tests that are used to indicate the presence of CRC and polyps in the colon. These companies include Polymedco, Exact Sciences and Epigenomics AG.

Procedures for bowel cleansing that are less onerous are constantly being developed, which could make our entry into the market more difficult. For instance, bowel cleansing initiated by the ingestion of pills or food-substitute diet regimes rather than through drinking large amounts of distasteful liquids may be viewed as an improvement to the cleansing process, but other screening methods may be even more palatable to patients.

Sales and Marketing

Our goal is to establish our position as a leading player in the CRC screening market. Although we do not currently generate revenues, we expect to generate revenues

through sales of our C-Scan system following demonstration of acceptable clinical safety and effectiveness and obtaining required regulatory approvals and licensures.

Because we are still in the clinical and development stage, we are subject to certain challenges, including, among others, that:

- our technology has been tested on a limited basis and therefore we cannot assure the product's clinical value;
- we need to receive CE Mark of conformity for the C-Scan system in the European Union and obtain the requisite regulatory approvals in the United States, Japan and other markets where we plan to focus our commercialization efforts;
- we need to raise an amount of capital sufficient to complete the development of our technology, obtain the requisite regulatory approvals and commercialize our current and future products;
- we need to obtain reimbursement coverage from third-party payors for procedures using our C-Scan system;
- we need to increase our manufacturing capabilities; and
- we need to establish and expand our user base while competing against other sellers of capsule endoscopy systems as well as other current and future CRC screening technologies and methods.

Our ability to operate our business and achieve our goals and strategies is subject to numerous risks as described more fully in "Risk Factors."

Subject to our receipt of regulatory approvals, available capital, and engagement with strategic partners, we expect to commercialize our C-Scan system during 2018 in selected markets in Europe. We intend to target major markets in Europe. In these markets, we are planning to work with strategic partners and/or local distributors who are active in the gastroenterology field and who have already demonstrated excellent performance in introducing new and innovative technologies.

In Europe and Japan, we intend to offer our C-Scan system as an imaging and screening tool for the general population. In the United States, we may choose to first obtain regulatory clearance/approval for our C-Scan system in a screening sub-population, and after we have conducted more extensive clinical studies in the United States, we would anticipate applying to the FDA for the use of our C-Scan system as a primary screening tool.

Subject to the successful completion of our clinical trials and the receipt of our initial FDA clearance/approval, we expect to launch the product in the U.S. market, where we will consider setting up our own sales force or aligning with a strategic partner. Initially, we are planning to sell our C-Scan system to the private sector. Simultaneously, we will work intensively to obtain reimbursement by Medicare and private insurers within the shortest possible time frame.

Subject to local regulatory approval, we also intend to market our C-Scan system in key markets in Asia. Initial efforts will focus in Japan in view of its developed CRC screening market.

Manufacturing and Suppliers

Our manufacturing operations are conducted at a facility located in Isfiya, Israel. We lease approximately 900 square meters at this facility under a lease agreement expiring on May 31, 2022. We have the right to terminate the agreement at any time, upon as least 60

days prior written notice. We currently have sufficient space to manufacture our C-Scan system for the clinical studies but have limited resources, facilities and experience in commercially manufacturing large quantities of our C-Scan system, external receiver and software application to meet the demand we expect from our expanded commercialization efforts. We expect to face certain technical challenges as we increase manufacturing capacity, including, among others, logistics associated with the handling of radioactive materials, equipment design and automation, material procurement, lower than expected yields and increased scrap costs, as well as challenges related to maintaining quality control and assurance standards. Our production objective is to establish a scalable capacity in order to meet such expanded demand for our C-Scan system and market expansion. If we are unable to scale our manufacturing capabilities to meet market demand, our growth could be limited and our business, financial condition and results of operations could be materially adversely affected.

We are continuing to upgrade and expand our production system and capacity and developing supply chain systems to support production for clinical trials and to meet standards for CE marking. Our current capacity was built to accommodate our clinical phase. We have integrated a product life management system to enable overall life cycle tracking and documentation including full configuration management control and manufacturing documentation.

During the clinical testing phase in Europe, we are planning to conduct both the assembling of our C-Scan system and the insertion of the X-ray source at our facilities. In July 2016, we entered into an agreement with GE Healthcare to develop and demonstrate proof of principle of the process for high-volume manufacturing for the production of the X-ray source and its assembly into our capsule. Subject to successful completion, GE and we may discuss a collaboration for the establishment

of a high-volume manufacturing facility and the distribution of the C-Scan system.

We do not currently have any sales. We are planning to develop a scale-up plan to meet our expected commercial supply needs. We are also working on a plan to expand our manufacturing capacity to support the expected larger clinical volume and subsequent higher volumes expected in the early commercialization stage. We are considering, among other options, the expansion of our assembly line in Israel, the buildup of new assembly lines in the United States and Europe, and alternative sources for the key capsule components (such as the motor, X-ray detectors, electrical components and PCBs). All of the facilities in which manufacturing and assembly of our products will be conducted will need to comply with applicable regulations and standards for medical devices.

We have received grants from Government of the State of Israel through NATI (formerly known as the OCS) for the financing of a portion of our research and development expenditures pursuant to the Research Law and related regulations and guidelines. Under the terms of the Research Law as currently in effect, products developed with NATI grants are required to be manufactured in Israel and the technology developed thereunder may not be transferred outside of Israel (including by way of license), unless prior approval is received from NATI, which we may not receive (and any such approval would be subject to increased royalty repayment rates and increased royalties). We are currently considering whether it would be possible to assemble the capsule without the X-ray source in Israel, and have the X-ray source subsequently assembled into our C-Scan system at a reactor or cyclotron site or at a distribution center outside Israel. Even following the full repayment of any NATI grants, we must nevertheless continue to comply with the requirements of the Research Law and regulations and guidelines thereunder. The foregoing restrictions may impair our ability to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. A significant amendment to the Research Law entered into effect on January 1, 2016, under which NATI, a statutory government corporation, was established and replaced the OCS. Under such amendment, NATI is authorized to establish rules concerning the ownership and exploitation of NATI-funded know-how (including with respect to restrictions on transfer of manufacturing activities and NATI-funded know-how outside of Israel, which may differ from the restrictive laws, regulations and guidelines as currently in effect (and which shall remain in effect until such rules have been established by NATI). See “Risk Factors – Risks Related to Our Operations in Israel.”

We currently depend on single source suppliers for some of the components necessary for the production of our C-Scan system. For example, for the current version

of the C-Scan system used in clinical trials, we currently have a single supplier for the motor used to rotate the collimated X-ray source in our C-Scan system and for each of the specially designed X-ray detectors, X-ray source and batteries used in our C-Scan system. There are a limited number of manufacturers worldwide who are capable of manufacturing the motor and the specially designed X-ray detectors and X-ray source that we currently use in our C-Scan system. In addition, the ASIC residing in our C-Scan system is currently manufactured for us by a single FAB. However, there are many alternative FABs worldwide and the design of our current ASIC could be adapted in the event it became necessary to use an alternative FAB. Furthermore, we do not currently have written contracts with any of such suppliers. While our current suppliers have been able to supply the required quantities of such components to date, if the supply of these components is disrupted or terminated or if our current suppliers are unable to supply required quantities of components, we may not be able to find alternative sources for these key components in a timely manner. Although we are planning to maintain strategic inventory of key components, the inventory may not be sufficient to satisfy the demand for our C-Scan system if such supply is interrupted, or subject to risk of loss due to catastrophic events such as a fire at our storage facility. As a result, we may be unable to meet the demand for our C-Scan system, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. If we are required to change the manufacturer of any of these key components, there may be a significant delay in locating a suitable alternative manufacturer. In addition, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with FDA and other applicable quality standards and with all applicable regulations and guidelines. The delays associated with the identification of a new manufacturer could delay our ability to manufacture our C-Scan system in a timely manner or within budget. Furthermore, in the

event that the manufacturer of a key component of our C-Scan system ceases operations or otherwise ceases to do business with us, we may not have access to the information necessary to enable another supplier to manufacture the component. The occurrence of any of these events could harm our ability to meet demand for our C-Scan system in a timely manner or within budget.

Environmental Health and Safety Matters

We are subject to environmental health and safety laws and regulations in Israel, governing, among other things, the use of radioactive materials, including the Israeli Work Safety Regulations (Occupational Safety and Health of Ionizing Radiation Practitioners) 1992-5753 and Women Employment Regulations (Work with Ionizing Radiation), 1979-5739. Our current research and development activities require, and our currently contemplated commercial activities will require, permits from various governmental authorities including, Israel's Ministry of Environmental Protection, Israel's Ministry of Health and local municipal authorities. Failure to obtain or maintain any such permits could have a material adverse effect on our business, financial condition and results of operations. The Ministry of Environmental Protection and the Ministry of Health conduct periodic inspections in order to review and ensure our compliance with the various regulations.

These laws, regulations and permits could potentially require expenditure by us for compliance or remediation. If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to radioactive materials) or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted.

U.S. Government Regulation

Our C-Scan system is a medical device subject to extensive regulation by FDA and other U.S. federal and state regulatory bodies. To ensure that medical products distributed in the United States are safe and effective for their intended use, FDA has imposed regulations that govern, among other things, the following activities that we or our partners perform and will continue to perform:

- product design and development;
- product testing;
- validation and verifications;
- product manufacturing;
- product labeling;

- product storage, shipping and handling;
- premarket clearance or approval;
- advertising and promotion;
- product marketing, sales and distribution; and
- post-market surveillance reporting death or serious injuries and medical device reporting.

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, before we can commercially distribute medical devices in the United States, we must obtain, depending on the type of device, either prior 510(k) clearance or PMA approval from the FDA. The FDA classifies medical devices into one of three classes:

- Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;
- Class II devices, generally requiring 510(k) premarket clearance before they may be commercially marketed in the United States; and
- Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring the submission of a PMA approval supported by clinical trial data.

510(k) Clearance Pathway

To obtain 510(k) clearance, we must submit a premarket notification, or 510(k) notice, demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications. The FDA's 510(k) clearance pathway takes approximately between 6 to 9 months, but it can take significantly longer. FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, require premarket approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), or a premarket approval, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

De Novo Reclassification

If the FDA finds that there is no suitable predicate device for our C-Scan system, it will automatically be considered a class III device. However, in instances where a device

is novel and there is no suitable predicate device, but that device is deemed to be of low to moderate risk, the FDA can reclassify the device to class I or class II via de novo reclassification. This process involves the submission of a reclassification petition, and the FDA's acceptance that “special controls” are adequate to ensure the product’s performance and safety.

The FDA now allows “direct” de novo reclassification petitions, a mechanism by which a sponsor can directly submit a detailed de novo reclassification petition as the device’s initial submission without having to first receive a not substantially equivalent, or NSE, decision on a 510(k) submission. The direct de novo pathway takes at least 9 to 12 months from submission of the petition to device clearance.

Our current strategy is to submit a direct de novo reclassification petition for our C-Scan system. To support a direct de novo reclassification petition, our objective is to demonstrate that the device poses a low to moderate risk to patients. If the FDA determines that our C-Scan system is not a candidate for de novo reclassification, it will require approval of the device for market through the PMA process.

Alternatively, if we seek 510(k) clearance and our device is found not substantially equivalent, or NSE, a de novo petition must be filed within 30 days from the receipt of the NSE determination. The request should include a description of the device, labeling for the device, reasons for the recommended classification and information to support the recommendation. The de novo process following an NSE determination has a 60-day review period, although it is typical for the review to take far longer. If the FDA classifies the device into class II, the company will then receive an approval order to market the device. This device type can then be used as a predicate device for future 510(k) submissions. However, if the FDA subsequently determines that the device will remain in the class III category, then the

device may not be marketed until the company has obtained an approved PMA.

Premarket Approval Pathway

A premarket approval application must be submitted if the device cannot be cleared through the 510(k) process or is found ineligible for de novo reclassification. The premarket approval application process is generally more costly and time consuming than the 510(k) process. A premarket approval application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use.

After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take at least 12 to 18 months, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New premarket approval applications or premarket approval application supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Premarket approval supplements often require the submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

Clinical trials are almost always required to support a premarket approval application or de novo reclassification petition and are sometimes required for a 510(k) premarket notification. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an IDE application with the FDA and obtain IDE approval prior to commencing the human clinical trials. The investigational device exemption application must be supported by appropriate data, such

as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The investigational device exemption application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a "non-significant risk" device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Future clinical trials of our motion preservation designs will require that we obtain an investigational device exemption from the FDA prior to commencing clinical trials and that the trial be conducted under the oversight of an institutional review board at the clinical trial site. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. A clinical trial may be suspended by the FDA or the investigational review board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient to obtain approval of our product. Similarly, in Europe the clinical study must be approved by the local ethics committee and in some cases, including studies of high-risk devices, by the Ministry of Health in the applicable country.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

- Quality System Regulation, or QSR, and current good manufacturing practices, or cGMP, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;

- approval of product modifications that affect the safety or effectiveness of one of our approved devices;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval restrictions or conditions, including post-approval study commitments;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

- FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

- regulations pertaining to voluntary recalls; and

- notices of corrections or removals.

We and our third-party manufacturers must register with the FDA as medical device manufacturers and must obtain all necessary state permits or licenses to operate our business. As manufacturers, we and our third-party manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations. We have not yet been inspected by the FDA.

Failure to comply with applicable regulatory requirements can result in enforcement action

by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Regulatory Pathway for our C-Scan System

We have established a clinical and regulatory strategy with our advisors and have conducted a pre-IDE meeting, now referred to as a pre-submission meeting, with FDA (an informal interaction to facilitate a clearer understanding of FDA's expectations). During this process, we received the FDA's feedback on our submission and our questions and we are planning to continue the dialogue with FDA before the submission of a formal request for the IDE that is necessary for us to conduct the U.S. pivotal clinical trial.

Our current strategy is to submit a direct de novo reclassification petition for our system. Although the FDA could require us to submit a PMA, we believe that the device could be considered for evaluation under the FDA's de novo reclassification provisions, which allow a novel device to be reclassified into class I or class II. To support this, our objective is to demonstrate that the device poses a low to moderate risk to patients.

We believe that important potential benefits of our C-Scan system for CRC screening are the elimination of the need for bowel preparation, the elimination of the need for conscious sedation, the minimally invasive, painless nature of the examination, and the ability to pursue normal daily activities immediately following the procedure. Furthermore, the C-Scan system is being designed to generate information from segments of the colon (e.g., cecum and ascending colon) that are difficult to access by conventional optical colonoscopy (i.e., incomplete colonoscopies) without the risks and discomforts of operative examination or other invasive methods. We believe these benefits will be attractive to a large number of patients from the target populations that so far refrained from any screening tests. Thus, we anticipate that our capsule will increase the public compliance to screening recommendation.

If FDA determines that our C-Scan system is not a candidate for de novo reclassification, it

will require approval of the device for market through the PMA process. Because of the technological characteristics of this device, the non-clinical tests (including lab and animals) and clinical data required may not be significantly different between de novo and PMA regulatory processes. We believe that under both scenarios, we will be required to conduct a multi-center clinical study to establish the safety and efficacy and to demonstrate sensitivity and specificity of our C-Scan system in several hundreds of patients.

FCC Clearance and Regulation

Because our C-Scan system includes a wireless radio frequency transmitter and receiver, it is subject to equipment authorization requirements in the United States. The U.S. Federal Communications Commission, or FCC, requires authorization of radio frequency devices before they can be sold or marketed in the United States, subject to limited exceptions. The authorization requirements are intended to confirm that the proposed products comply with FCC radio frequency emission, power level standards, and other technical requirements and will not cause interference. Our capsule is using the same frequency band as other approved capsules, and we expect that it will comply with the FCC's technical requirements, so it is expected that it will be authorized by the FCC as well.

Third-Party Coverage and Reimbursement

Coverage of and reimbursement for our C-Scan system and related procedures, after approval, will be subject to the requirements of various third-party payors, including government-sponsored healthcare payment systems and private third-party payors. Coverage policies and reimbursement methodologies vary significantly from program-to-program and may be subject to federal and state regulations. For example, the Medicare statute requires all items and services to be "reasonable and necessary for the diagnosis or treatment of illness or injury

or to improve the functioning of a malformed body member" in order to be covered. Medicare currently does not provide separate reimbursement for many devices, but may include payment for the device in the payment for the related procedure. Third-party payors' coverage and reimbursement policies, including their interpretations of whether an item or service is "reasonable and necessary" or experimental and their payment methodologies, are subject to change pursuant to legislation, regulation, or, in the case of private payors, negotiations with providers.

Fraud and Abuse Laws

In the United States, the healthcare industry is subject to extensive federal, state, and local regulation. Both federal and state governmental agencies subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices, by limiting the kinds of financial arrangements (including sales programs) we may have with hospitals, physicians and other potential purchasers of the medical devices. The laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between medical device manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Further, PPACA, among other things, clarified that a person or entity needs not to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny;

- The federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or

causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. In addition, PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Many medical device manufacturers and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to use the company's products. In addition, in recent years the government has pursued civil False Claims Act cases against a number of manufacturers for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Device manufacturers also are subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payor. Several states now require medical device manufacturers to report expenses relating to the marketing and promotion or require them to implement compliance programs or marketing codes. For example, California, Connecticut and Nevada mandate the implementation of corporate compliance

programs, while Massachusetts and Vermont impose more detailed restrictions on device manufacturers' marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare providers;

- The federal Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission. Violations of these laws can result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence; and

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires manufacturers of "covered products" (drugs, devices, biologics, or medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program) to track and publicly report payments and other transfers of value that they provide to U.S. physicians and teaching hospitals, as well as any ownership interests that U.S. physicians hold in applicable manufacturer. Applicable manufacturers must submit a report to the Centers for Medicare & Medicaid Services, or CMS, by the 90th day of each calendar year disclosing payments and transfers of value made in the preceding calendar year.

Violations of any of the laws described above or any other governmental regulations that apply to us, may cause us to be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, like Medicare and Medicaid, and the curtailment or restructuring of our operations.

Privacy Laws

HIPAA/HITECH and related U.S. federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under HIPAA.

These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their protected health information and limiting most use and disclosures of health information to the minimum degree reasonably necessary to accomplish the intended purpose. Because we intend to sell products, once approved, to persons and entities subject to HIPAA and are exposed to personally-identifiable health information in the course of our operations,

we also may be subject to certain elements of HIPAA, particularly as a business associate to covered entities, as well as similar state laws. HIPAA imposes civil and criminal penalties for violations of its provisions, which could be substantial. State privacy laws have their own penalty provisions which may be applicable.

NRC Regulatory Issues

As our C-Scan system includes an ingestible capsule with a radioactive source, the company must address NRC regulations, or relevant Agreement State regulations, in addition to FDA requirements. An Agreement State is a state that has signed an agreement with the NRC authorizing the state to regulate certain uses of radioactive materials within the state. Agreement State regulations are substantially similar to the NRC's regulations.

The capsule is loaded with the X-ray source, sealed and then ingested by the patient. The capsule is excreted naturally through the patient's system and is not intended to be recovered and therefore is disposed of in the sanitary sewer system. Although the NRC regulations in 10 CFR Part 20 place certain conditions and limitations on the disposal of radioactive material in the sanitary sewer, such conditions and limitations do not apply to radioactive material contained in excreta of individuals that are undergoing medical diagnosis or therapy with radioactive material. Our regulatory advisors have advised us that the NRC staff likely would take the position that a capsule containing radioactive material can be passed in excreta into the sanitary sewer system without limitation. If, however, the NRC were to find that our C-Scan system could not be passed in excreta into the sanitary sewer system without limitation pursuant to 10 CFR 20.2003(b) the NRC may place restrictions on the disposal of the C-Scan system in the sanitary sewer system.

An entity which manufactures, prepares, or transfers a medical capsule containing radioactive byproduct material needs to be licensed or covered by a license issued by the NRC or an Agreement State. An NRC or Agreement State licensee authorized to possess and/or distribute byproduct material can transfer the byproduct material only to another NRC, or Agreement State, approved entity or licensee. The NRC's regulations permit only individuals who are authorized users (e.g., individuals who meet certain training and experience criteria regarding the safe use of radioactive drugs) or persons working under the supervision of an authorized user to administer radioactive drugs for medical use.

The NRC regulations do exempt certain products from the NRC's regulations. Existing exemptions from licensing requirements for the use of byproduct material include exemptions for specific products (e.g., time pieces), exemptions for classes of products (e.g., gas or aerosol detectors), and broader materials exemptions for "exempt concentrations" and "exempt quantities" of radioactive material. These two broad materials exemptions specifically exclude the transfer of byproduct material contained in any food, drug, or product designed for ingestion by a human being. Capsules containing our X-ray source would not qualify as an "exempt quantity" because of their intended use (i.e., for ingestion) even though they may contain a smaller quantity of the source than the exempt quantities set forth in the regulations.

Accordingly, we will need to obtain the appropriate licenses from the NRC or an Agreement State prior to the clinical investigation and/or marketing of the device. We intend to engage a radiopharmaceutical company to manufacture our C-Scan Cap. The fact that another company will be manufacturing the capsule, however, does not exempt us from also obtaining radioactive materials licenses from the NRC or an Agreement State. Distribution activities are generally classified by the NRC as either

"distribution" or "redistribution", and both types of activities require a specific license. "Distribution" refers to the initial transfer from the manufacturing radiopharmacy, while "redistribution" refers to a subsequent transfer of the drug by an NRC licensee to an authorized user. In order to distribute the capsule commercially, we will need to obtain an NRC or Agreement State "medical distribution" radioactive materials license and may also need to obtain a radioactive materials license authorizing the possession of the radioactive material. Both types of licenses may be obtained by submitting a license application request to the NRC or an Agreement State. In the event that we develop the capsule outside the United States, we would be required to have one of our U.S. offices apply for and receive both the possession and medical distribution radioactive materials licenses. If we do not have an office in the United States, then we can contract with a company with a U.S. office to apply for and obtain these licenses, and that company would be the licensed U.S. distributor of the capsule.

We may be able to petition the NRC to carve out an exemption for the distribution licensing requirement to permit distribution to all health care professionals and not just those licensed by the NRC. This has been done successfully by other medical device companies. For example, Tri-Med, Inc. manufactures an ingestible capsule containing radioactive material for testing of H. Pylori. The company petitioned the NRC in 1994 for an exemption from the distribution licensing regulation. The NRC evaluated the petition and issued a proposed ruling for comments. After receiving comments on the proposed ruling, the NRC issued a final ruling, in 1997, providing for the exemption. This exemption is narrowly drawn, and specific to the distribution of a "radioactive drug containing one microcurie of carbon-14 urea to any person for 'in vivo' diagnostic use." In creating the exemption, the NRC noted the importance of bringing an inexpensive and effective diagnostic tool to a large number of people, along with the minimum radiation contained

in the capsule.

We may consider petitioning the NRC in a similar manner to make the device more widely available. As our C-Scan system imparts comparable radiation exposure to the Tri-Med device described above, and has the potential to be used widely for diagnosis, our C-Scan system may be a candidate for such an exemption.

Regulation in Europe, Japan and Other Countries

In the EU, a company that wishes to bring a medical device to market must CE mark the device following demonstration of conformity with the Essential Requirements laid down in Annex I to the Medical Devices Directive.

Compliance with these requirements entitles manufacturers to affix the CE mark of conformity to their medical devices, without which the medical devices cannot be commercialized in the EU. To demonstrate compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive and obtain the right to affix the CE mark of conformity to our medical devices, we and our products must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low-risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer can issue an EC Declaration of Conformity based on self-assessment of the conformity of its products with the Essential Requirements laid down in the Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by the competent authorities of a EU Member States to conduct conformity assessments. The Notified Body will typically audit and examine the Technical File that the manufacturer has created for the medical devices and the quality system for the manufacture, design and final inspection of the devices before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements laid down in Annex I to the Medical Devices Directive or the quality system requirements laid down in the other Annexes to the Directive. Following the issuance of this CE Certificate of Conformity, the manufacturer is required to draw up an EC Declaration of Conformity and to affix the CE mark to the products covered by this CE Certificate of Conformity and the EC Declaration of Conformity.

We will be required to demonstrate that our products comply with the Essential Requirements laid down in Annex I to the Medical Devices Directive through a conformity assessment procedure. We cannot be certain that we will be able to fulfill the quality and performance requirements laid down in Annex I to the Medical Devices

Directive and to obtain or maintain CE Certificates of Conformity for our products. If we are unable to obtain or maintain these CE Certificates of Conformity for our products, we will not be able to sell our products in any EU Member States nor in various other third countries where CE marking is accepted as evidence of compliance with relevant national laws.

In Japan, manufacturing and marketing medical devices are regulated by the Pharmaceutical Affairs Law, or PAL. In accordance with the PAL, manufacturers must obtain a license for manufacturing medical devices from the Ministry of Health, Labour and Welfare, or MHLW. A license is required for each manufacturing plant specified by an MHLW Ministerial Ordinance.

A licensed manufacturer is responsible only for manufacturing medical devices. In regard to the marketing of medical devices, the PAL specifies that a Marketing Authorization Holder, or MAH, licensed by MHLW is responsible for putting medical devices into marketplace. Licenses for marketing medical devices are divided into the following 3 types, which correspond to the classifications below:

- No. 1 type license for marketing – Specially controlled medical devices (Class III, IV)
- No. 2 type license for marketing – Controlled medical devices (Class II)
- No. 3 type license for marketing – General medical devices (Class I)

Generally, the process for obtaining marketing clearance for medical devices in Japan ranges from twelve months (for products with only very minor modifications from previously cleared product versions) to a few years in the case of a completely new device.

In order for us to market our products in countries other than the United States, the EU and Japan (which were described above), we

must obtain regulatory approvals and comply with extensive safety and quality regulations in these countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review varies from country to country. It is customary that once a product has been cleared for sales in the US and is CE marked in the EU, many other countries will follow. Failure to obtain regulatory approval or clearance in any foreign country in which we plan to market our product may harm our ability to generate revenue and harm our business.

Third-Party Reimbursement

Reimbursement in the United States

In the United States, healthcare providers that purchase medical devices generally rely on third-party payors, such as Medicare, Medicaid, private health insurance plans and health maintenance organizations, to reimburse all or a portion of the cost of the devices, as well as any related healthcare services utilizing the devices.

Coverage is not guaranteed simply because a product has received FDA clearance or approval. Medicare's general definition of a medically necessary service is one that is reasonable and necessary for the diagnosis or treatment of an illness or injury, or that improves the functioning of a malformed body member. In order to be eligible for reimbursement, a device must be proven to be cost-effective, demonstrating potential decrease in spending to the U.S. health economy.

According to various studies and publications, a key criterion for reimbursement for colon cancer screening is patient adherence (for instance, see "Cost-Effectiveness of Colonoscopy in Screening for CRC," Annals of Internal Medicine, October 17, 2000 vol. 133 no. 8 573-584). Adherence is strongly affected by patients' willingness to use the device as a screening tool for CRC. Several models have been designed to demonstrate the cost effectiveness of optical colonoscopy, CTC, fecal testing and optical capsule endoscopy. Today, several technologies achieved Medicare coverage for CRC Screening, including: FOBT / FIT, Flexible Sigmoidoscopy, Optical Colonoscopy and Barium Enema, and stool DNA.

In 2009, the Centers for Medicare and Medicaid Services issued a decision memorandum rejecting federal reimbursement for CTC screening for CRC. Their main argument for the decision was that based on available evidence, screening with

CTC would not necessarily result in cost saving, at least at current screening compliance rates. CTC was not seen as a tool which could potentially increase patients' adherence. This procedure involves bowel preparation, as well as insufflations of the colon and the exposure of patients to very significant amount of radiation.

An important European study (C. Hassan et al, "Cost Effectiveness of Optical capsule endoscopy," Endoscopy 2008, 40, 414-421) assessed the potential cost effectiveness of screening with optical capsule endoscopy and compared its cost-effectiveness with that of optical colonoscopy. Effectiveness of screening was measured in terms of life-years saved through prevention or down staging of CRC. The conclusion was that the cost effectiveness of capsule endoscopy in CRC screening will depend mainly on its ability to improve compliance in the general population.

Third-party payors in the United States began issuing coverage policies for optical capsule endoscopy in early 2002. Initially, all reimbursement policies provided coverage for optical capsule endoscopy of the small bowel only for the diagnosis of obscure gastrointestinal bleeding. Subsequently, reimbursement coverage has been expanded to include other diagnoses and as of December 31, 2012, approximately 220 million people in the United States are covered with most reimbursement policies providing coverage for a number of small bowel indications, including obscure gastrointestinal bleeding, suspected Crohn's disease, suspected small bowel tumors and other small bowel pathologies.

Currently, there is no optical capsule endoscopy reimbursement available for the colon in the United States, nor is there a CPT code for such capsule or related method of screening. There can be no assurance that coverage will be obtained in the near future or at all. Third-party payors may deny coverage if they determine that a procedure was not reasonable or necessary as determined by the

payor, was experimental or was used for an unapproved indication. During the past several years, the major third-party payors have substantially revised their reimbursement methodologies in an attempt to contain or reduce their healthcare reimbursement costs.

Coverage Outside the United States

In countries outside the United States, coverage for CRC screening is obtained from various sources, including governmental authorities, private health insurance plans, and labor unions. In some countries, private insurance systems may also offer payments for some therapies. Although not as prevalent as in the United States, health maintenance organizations are emerging in certain European countries. Coverage systems in international markets vary significantly by country and, within some countries, by region. Coverage approvals must be obtained on a country-by-country or region-by-region basis.

C. Organizational Structure

On May 15, 2015, we formed our wholly-owned subsidiary Check-Cap US, Inc., a Delaware corporation.

D. Property, Plants and Equipment

Our principal executive offices and operations are conducted at a facility located in Isfiya, Israel since June 1, 2009. We currently lease approximately 900 square meters at this facility under a lease agreement expiring on May 31, 2022, unless earlier terminated by us upon at least 60 days prior written notice. We believe that our current facilities are adequate to meet our current needs for the clinical phase of our development.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and related notes included in this Annual Report beginning on page F-1. The following discussion and analysis contain forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Item 3D “Key Information - Risk factors” and elsewhere in this Annual Report.

Overview

We are a clinical stage medical diagnostics company engaged in the development of a capsule-based system that utilizes ultra-low-dose X-rays to generate structural information on the endoluminal surface of the colon that may be used for screening of the

colon to detect polyps, masses and CRC. While CRC is the second leading cause of death from cancer for both sexes combined in the United States and is preventable with early screening and intervention, according to the National Health Interview Survey, in 2015, only 63% of Americans over the age of 50 reported being current with CRC screening recommendations. Unlike other screening modalities that are designed for direct visualization and imaging of the internal colon, such as optical colonoscopy, CTC and other capsule-based technologies, our C-Scan system is designed to function without any cathartic preparation of the colon, and to transit the gastrointestinal tract by natural motility while the patient continues his or her normal daily routine. Furthermore, the C-Scan system does not require fasting prior to or during capsule transit. Our C-Scan system is comprised of three main components: (1) C-Scan Cap, a ingestible X-ray scanning capsule; (2) C-Scan Track, a biocompatible unit worn on the patient's back for capsule control, tracking and data recording; and (3) C-Scan View, a PC-based, standalone application used to process and display structural information of the colon. We believe that this solution will be attractive to both physicians and patients, with the potential to increase the number of people completing CRC screening.

Check-Cap LLC was formed in 2004 as a Delaware limited liability company to develop a novel and superior solution for colon cancer screening. In 2009, all of the business operations and substantially all of the assets of Check-Cap LLC were transferred to Check Cap Ltd., a newly-incorporated Israeli company. Our offices are located near Haifa, in the northern part of Israel. Our management team includes an experienced group of executives in the business, research, clinical and regulatory fields. As of February 15, 2017, our research and development team consists of 51 experienced professionals (including employees and independent contractors) in the fields of physics, electronics, and software and mechanical engineering.

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Our C-Scan system is being designed to create a reconstructed three-dimensional image of the interior surface of the colon and to enable detection of clinically significant polyps with a high degree of sensitivity. Colonic polyps are tissue growths that occur on the lining of the colon. Polyps in the colon are extremely common and certain types of polyps can become cancerous over time.

Our C-Scan Cap will be swallowed and propelled by natural motility through the gastrointestinal tract and excreted naturally with no need for retrieval for data collection. Unlike other existing CRC screening methods, this process should not disrupt a patient's normal activities or require fasting. Our C-Scan Cap employs ultra-low-dose X-rays, which allow the C-Scan system to image the interior lining of the colon even when surrounded by intestinal content. As such, we believe that patients using our C-Scan system will not be required to undergo any prior bowel preparation. The Radiation Safety Division of the Soreq Nuclear Research Center found, as set forth in its report of November 2010 that was prepared at our request and based on the information provided by us and the relevant methods and principles known at such time, or the Report, that the radiation dose to the patient in the proposed screening procedure utilizing the scanning device developed by us at that time in routine operation and normal conditions is low relative to the radiation dose involved in conventional imaging procedures using X-rays (such as fluoroscopy and CT) and is also low when compared to the radiation dose involved in established screening procedures such as mammography, all as more fully described in the Report.

Our C-Scan Cap is being designed to transmit position, motility and the data it collects to the C-Scan Track that will be worn on the patient's back. The external data recorder is being designed to enable the transfer of the data to our C-Scan View to allow physicians to analyze the data collected by our C-Scan Cap. The C-Scan Track is being designed to provide the physician with accurate

localization data aligned with a reconstructed image. We intend for physicians to be able to review the colon's inner images in less time than is required to perform an optical colonoscopy.

In the event that polyps are identified by our C-Scan system, the patient may be advised to undergo a subsequent traditional colonoscopy procedure to examine, remove and biopsy the polyps. For those patients who require a subsequent colonoscopy, concerns regarding pain, discomfort and embarrassment may still remain. We do not, however, believe that these concerns will make the use of our C-Scan system any less attractive to physicians and patients. Although patients who are initially screened utilizing a traditional colonoscopy could avoid the need for a second colonoscopy if polyps are discovered, we believe that our C-Scan system will still be attractive to physicians and patients as a large number of patients who are screened will not require a subsequent colonoscopy. Published data from a multi-center CT colonography screening study of 2,531 asymptomatic adults published in The New England Journal of Medicine in 2008 showed that if all patients with a lesion measuring 5mm or more on CT colonography were referred for colonoscopy, the colonoscopy-referral rate would have been 17%.

For the past several years, we have focused on the research and development of our imaging technology. We initiated our first clinical studies in 2010, consisting of two single-center feasibility studies with non-scanning (no X-ray source) capsules for the purposes of measuring gastrointestinal tract activity, colon contractions and associated capsule motility, and shortening capsule transit time.

In 2013, we initiated a multi-center prospective clinical feasibility study, designed to allow for the recruitment of 100 subjects, to establish clinical proof of concept, safety and functionality of our C-Scan system in patients eligible for CRC screening. Analysis

conducted on the first 66 capsules swallowed by participants showed that 65 of 66 capsules swallowed were naturally eliminated, without major or minor side effects, after 62±40.7 hours. The average calculated radiation exposure was 0.06 ± 0.04 mSv (similar to a single chest radiograph). Both pedunculated and sessile polyps were detected in several patients and validated later by colonoscopy.

In the first quarter of 2017, we initiated enrollment in a multi-center study of the C-Scan system in support of CE Mark submission. This prospective study, designed to demonstrate the safety and clinical performance of the C-Scan system, will evaluate polyp detection as compared to colonoscopy.

To date, we have achieved key product development milestones, including the ability of our C-Scan system to reconstruct the human colon and to identify polyps. Following our certification to ISO 13485:2003 by our Notified Body, successful completion of our current multi-center clinical study and achievement of compliance with the requirements of the Medical Devices Directive, we plan to submit during the first half of 2017 a request for CE marking for the marketing and sale of our C-Scan system in the European Union. We expect to initiate post-marketing studies in Europe following CE marking for the purpose of collecting additional evidence of clinical effectiveness and clinical utility to support market adoption. Subject to clinical results, regulatory approvals, available capital and engagement with strategic partners, we anticipate launching our C-Scan system commercially in Europe during 2018.

We conducted a pre-submission meeting with the FDA in December 2016 for the purpose of receiving feedback on the regulatory pathway for our system in the United States. We also sought feedback on a proposed protocol for a feasibility or pilot study, the primary purposes of which is to establish the safety of the C-Scan system and evaluate user compliance and satisfaction. Subject to required approvals, we plan on initiating such a study in 2017. Following the successful completion of the pilot study and receipt of required approvals, we plan to initiate during 2018, a pivotal study in the United States to (i) demonstrate device safety as evidenced by a lack of device-related serious adverse events; and (ii) provide efficacy data concerning our C-Scan system's performance. We anticipate that FDA approval for the pivotal study will be subject to our providing sufficient clinical data from previous clinical studies, which may include the multi-center clinical feasibility study, the multicenter safety and clinical performance study, and U.S. pilot study. However, there can be no assurance that we will receive approvals for the pilot and/or pivotal studies to be conducted in the United States.

We also intend to pursue clinical trials for regulatory approvals in Japan and China in parallel to the U.S. pivotal study, subject to available capital and engagement with strategic partners. Pivotal studies are expected, among other things, to compare polyps identified by our C-Scan system with the polyps identified by traditional optical colonoscopy. These clinical findings may be analyzed in comparison with results obtained from FOBTs and FITs.

Following and subject to the successful completion of our pivotal trial, our current strategy is to submit a direct de novo reclassification petition, which we anticipate submitting in 2019, for initial FDA approval for the marketing of our C-Scan system in the United States. Direct de novo reclassification typically takes at least 9 to 12 months from filing to clearance. If the FDA determines that our C-Scan system is not a candidate for de

novo reclassification, it will require approval of the device for market through the PMA process. The PMA pathway is much more costly and uncertain than the 510(k) clearance process or de novo reclassification, and generally takes at least 12 to 18 months, or even longer, from the time the application is filed with FDA to ultimate approval.

We have submitted patent applications covering our technology in the United States, member states of the European Patent Organisation, Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan and South Korea. We have been granted patents for our core patent by the U.S. Patent and Trademark Office as well as from the European Patent Office, Australia, China, Hong Kong, Israel, India and Japan. We also filed patent applications describing the use of our technology in several other medical applications.

We have generated significant losses to date, and we expect to continue to generate losses for at least the next several years as we continue our investment in research and development and clinical trials in order to complete the development of our C-Scan system and to attain regulatory approvals, begin the commercialization efforts for our products, increase our marketing and selling expenses, and incur additional costs as a result of being a public company in the United States. The extent of our future operating losses and the timing of becoming profitable are highly uncertain, and we may never achieve or sustain profitability. As of December 31, 2016, we had accumulated losses of approximately $42.9 million.

On February 24, 2015, we consummated an initial public offering of 2,000,000 units, each consisting of one ordinary share and one half of a Series A Warrant to purchase one ordinary share. The price per unit sold in the initial public offering was $6.00. Each unit in the initial public offering was issued with one and one half Long Term Incentive Warrants. We granted the underwriters in the initial public offering a 45-day over-allotment

option to purchase up to 300,000 additional units (together with an accompanying 450,000 Long Term Incentive Warrants) from us to cover over-allotments. On March 6, 2015, the option to purchase additional 100,000 units was partially exercised. On March 18, 2015, the units were separated into one ordinary share and one-half of a Series A Warrant to purchase one ordinary share and the units ceased to exist. On April 6, 2015, the option to purchase additional 150,000 ordinary shares and 75,000 Series A Warrant was partially exercised. The aggregate offering price of the securities sold in the initial public offering (including the over-allotment option) was approximately $13.5 million. The total expenses of the offering, including underwriting discounts and commissions, were approximately $2.9 million (including certain warrants with value of $196,000 issued in connection with the IPO). The net proceeds we received from the initial public offering (including the over-allotment option) was approximately $10.8 million. Concurrently with our initial public offering, we consummated the private placement of 2,000,000 units in a private placement and received aggregate gross proceeds of $12,000,000 from the private placement.

On August 11, 2016, we consummated a registered direct offering of 643,614 ordinary shares at a price of $1.90 per share and pre-funded warrants to purchase 2,514,281 ordinary shares at a purchase price of $1.85 per pre-funded warrant. The pre-funded warrants had an exercise price of $0.05 per share, subject to certain adjustments and an expiration date of August 11, 2023, unless otherwise extended in accordance with the terms of the pre-funded warrants. We received gross proceeds from the registered direct offering of approximately $5.9 million (including proceeds from the exercise of 575,000 pre-funded warrants at the closing of the offering). As of December 31, 2016, additional pre-funded warrants to purchase an aggregate 1,649,281 ordinary shares had been exercised, for additional proceeds of $82,500. As of January 23, 2017, all of the remaining pre-funded warrants to purchase an aggregate 290,000 ordinary shares had been exercised, for additional proceeds of $14,500.

Our management has plans of increasing our research and development costs in 2017 to reach market in a timely manner. Such plans will increase the burn rate and our management expects that with such increased costs, existing cash will be sufficient to fund our projected operating requirements at least until December 31, 2017. Our management plans include additional fund raising in the next year, which management believe is probable. Nevertheless, we will require significant additional financing in the future to fund our operations if and when we progress with our clinical trials in Europe and the United States as well as other potential territories. If adequate additional financing on acceptable terms is not available to us on a timely basis during 2017, we believe that we would have the flexibility to downsize our operations such that our existing cash will be sufficient to fund our cash requirements until June 30, 2018. We have based these estimates on assumptions that may prove to be wrong and we may use our capital resources sooner than we currently expect.

For a more detailed description of our business and plans, see Item 4B “Information on Our Company – Business Overview.”

A. Operating Results

Financial Operations Overview

Revenue

We have not generated any revenue since our inception. To date, we have funded our operations primarily through equity financings, as well as from grants that we received from NATI (formerly known as the OCS). If our product development efforts result in clinical success, regulatory approval and the successful commercialization of our imaging system, we expect to generate revenue from sales of our C-Scan system.

Operating Cost and Expenses

Our operating costs and expenses are classified into two categories: research and development expenses and general and administrative expenses. For each category, the largest component is personnel costs, which consists of salaries, employee benefits and share-based compensation. Operating costs and expenses also include allocated overhead costs for depreciation of equipment. Operating costs and expenses are generally recognized as incurred. We expect personnel costs to continue to increase as we hire new employees to continue to grow our business.

Research and Development Expenses, Net

Research and development activities are central to our business model. We intend to increase our research and development operations in order to complete the development of our C-Scan system and to attain regulatory approvals.

Since 2014, we have spent approximately $14.2 million on research and development expenses as of December 31, 2016, of which $2.1 million was funded by government grants. Our total research and development expenses, net of participations in the years ended December 31, 2016, 2015 and 2014 were approximately $5.5 million, $5.8 million and $2.8 million, respectively. All research and development expenses are expensed as incurred. We expect research and development expenses to increase in absolute terms in the near term.

Research and development expenses consist primarily of costs incurred for our research activities, including:

- employee-related expenses for research and development staff, including salaries, benefits and related expenses, including share-based compensation and travel expenses;
- payments made to third-party contract research organizations, contract manufacturers, investigative sites and consultants;
- manufacturing development costs;
- costs associated with preclinical and clinical activities and regulatory operations;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities; and
- costs associated with obtaining and maintaining patents.

Our research and development expenses, net are net of grants we have received from the Government of Israel through NATI (formerly known as the OCS). Under the terms of the Research Law as currently in effect, in exchange for these grants, we are required to pay NATI royalties from our revenues up to an aggregate of 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant, plus interest at the rate of

12-month LIBOR. Pursuant to regulations under the Research Law, the rate of repayment ranges between 3% to 5% of revenues (or 6% with respect to certain limited programs and at an increased rate under certain circumstances). As of December 31, 2016, we had received funding from NATI (formerly the OCS) in the aggregate amount of $5.1 million. As of December 31, 2016, we had not paid any royalties to NATI and had a contingent obligation to NATI in the amount of $5.3 million. For additional information regarding the NATI grants, see Item 10E “Additional Information - Taxation - Israeli Tax Considerations and Government Programs - The Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Encouragement of Industrial Research and Development Law, 5744-1984).” There can be no assurance that we will continue to receive grants from the OCS in amounts sufficient for our operations, if at all.

As of December 31, 2016, we, together with Synergy Research Inc., or Synergy, had received funding from the BIRD Foundation of $127,000 for the funding of a project entitled “Collection & Analysis of Gastrointestinal Images for Diagnostic Adenomatic Polyps and Colorectal Cancer.” We shall not be receiving additional funding from the BIRD Foundation for such project, which is no longer active; however, we are considering applying to the BIRD Foundation for funding for related projects. Based on the aggregate expenses that we incurred for the project, we are required to refund to the BIRD Foundation an amount of approximately $12,000. As of December 31, 2016, we had not paid any royalties to the BIRD Foundation and had a contingent liability to the BIRD Foundation in the amount of $127,000. See Item 5B “Operating and Financial Review and Prospects — Liquidity and Capital Resources — Sources of Liquidity” for a description of the Cooperation and Project Funding Agreement with the BIRD Foundation and Synergy.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and other related costs, including share-based compensation expense, for persons serving as our executive, finance, legal, human resources and administrative personnel, professional service fees and other general corporate expenses, such as communication, office and travel expenses. We expect that our general and administrative expenses will continue to increase in the future as we incur additional general and administrative costs associated with being a public company in the United States, including compliance under the Sarbanes-Oxley Act of 2002 and rules promulgated by the U.S. Securities and Exchange Commission. These public company-related expense increases will likely include costs of additional legal fees, accounting and audit fees, directors' and officers' liability insurance premiums and costs related to investor relations.

Financial Income and Finance Expenses

Our finance income and finance expenses in years 2015 and 2014 consist primarily of fair value changes with respect to warrants to purchase Series D-1 and D-2 preferred shares issued to investors and service providers in connection with our D1 investment round, and warrants to purchase Series C-1 preferred shares and warrants to purchase Series C-2 preferred shares issued to Pontifax (investing through three affiliated funds: Pontifax (Cayman) II, L.P., Pontifax (Israel) II L.P., Pontifax (Israel) II- Individual Investors L.P. which we collectively refer to as the "Pontifax Funds"), interest earned on our cash, cash equivalents and short-term investments and changes in provision for royalties primarily to Check –Cap LLC unitholders.

Our finance income and finance expenses in 2016 consist of interest earned on our cash, cash equivalents and short-term investments and changes in provision for royalties primarily to Check–Cap LLC unitholders.

Foreign currency transactions are translated into U.S. dollars using the exchange rates prevailing at the dates of the transactions or valuation where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the statement of operations to "finance expenses"/"finance income."

Taxes on Income

The standard corporate tax rate in Israel for the 2016 tax year is 25%, decreased from 26.5% for the 2015 and 2014 tax year.

We do not generate taxable income in Israel, as we have historically incurred operating losses resulting in carryforward tax losses totaling approximately $30.9 million as of December 31, 2016. We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years. However, a

tax loss that can be utilized in a certain tax year cannot be carried forward to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses.

Under the Law for the Encouragement of Capital Investments, 5719-1959 and other Israeli legislation, we may be entitled to certain additional tax benefits, including reduced tax rates, accelerated depreciation and amortization rates for tax purposes on certain assets, deduction of public offering expenses in three equal annual installments and amortization of other intangible property rights for tax purposes. See Item 10E "Additional Information — Taxation— Israeli Tax Considerations and Government Programs" for additional information concerning these tax benefits.

Results of Operations

For convenience purposes, the numbers set forth in the management's discussion and analysis below are, where applicable, rounded up and presented in millions, whereas the numbers in the tables below are presented in thousands. As result, the percentages set forth in the year-over-year comparisons below are based on numbers that have (where applicable) been rounded up to millions, which may slightly differ than the percentages that would result from the corresponding numbers set forth in the table that are presented in thousands.

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

	Year Ended December 31,	
	2016	2015
	(US$ in thousands, except per share data)	
Research and development expenses, net	$ 5,491	$ 5,837
General and administrative expenses	3,571	6,626
Operating loss	9,062	12,463
Finance income, net	244	173
Loss before income tax	8,818	12,290
Taxes on income	8	-
Net loss	$ 8,826	$ 12,290

Research and Development Expenses, net. Our research and development expenses, net for the year ended December 31, 2016 were $5.49 million, as compared with $5.84 million for the year ended December 31, 2015, a decrease of $0.35 million or 6.0%. The decrease in research and development, net expenses between 2016 and 2015 was primarily due to: a $770,000 increase in grants from NATI (formerly known as the OCS) in 2016; a $556,000 decrease in share-based compensation, primarily due to the absence in 2016 of a $448,000 share-based compensation expense that we recorded in 2015 associated with the one-time grant of options to certain members of our management; and a $368,000 decrease in fees to subcontractors and consultants in 2016 as we increased the number of research, development and clinical employees in 2016. The decrease in research and development expenses, net between 2016 and 2015 was partially offset by a $1.1 million increase in salaries and related expenses as a result of the recruitment of research, development and clinical employees during the course of 2015,

the related expenses for whom were fully accounted for in 2016 and a $229,000 increase in other research and development expenses relating to our clinical trials.

	2016	2015	Change
	(US$ in thousands)		
Salaries and related expenses	$4,683	$3,585	$1,098
Share-based compensation	234	790	(556)
Materials	596	608	(12)
Subcontractors and consultants	320	688	(368)
Depreciation	121	85	36
Cost for registration of patents	150	153	(3)
Other research and development expenses	511	282	229
	6,615	6,191	424
Less participation of NATI (formerly known as the OCS) and the BIRD Foundation	(1,124)	(354)	(770)
Total research and development expenses, net	$5,491	$5,837	$(346)

General and Administrative Expenses. Our general and administrative expenses for the year ended December 31, 2016 were $3.6 million, as compared to $6.6 million for the year ended December 31, 2015, a decrease of $3.0 million, or 46.6%. The decrease in general and administrative expenses is primarily due to the following:

- The absence in 2016 of a $2.0 million share-based compensation expense that we recorded in 2015 relating to the one-time grant of options to certain of our management and warrants to Pontifax entities (for additional information see Item 7B “Major Shareholders and Related Party Transactions—Related Party Transactions—Pontifax Warrants”).

- A $419,000 decrease in salaries and related expenses, due to the absence in 2016 of a $140,000 one-time severance payment to our former chief executive officer that we recorded in 2015 and a $109,000 decrease in provision for bonuses to certain members of our management in 2016.

- A $715,000 decrease in professional services and other general and administrative expenses, primarily relating to a $248,000 decrease in recruiting expenses as in 2015 we recruited a new chief executive officer and a large number of research, development and clinical employees, a $155,000 decrease in legal fees due to our recruitment of an in-house counsel, as well as reduced rates or services of certain other professional service providers.

	2016	2015	Change
	(US$ in thousands)		
Salaries and related expenses	$1,411	$1,830	$(419)
Share-based compensation	975	2,934	(1,959)
Professional services	354	609	(255)
Office rent and maintenance	144	108	36
Depreciation	9	7	2
Other general and administrative expenses	678	1,138	(460)
Total general and administrative expenses	$3,571	$6,626	$(3,055)

Operating Loss. As a result of a $0.5 million decrease in research and development expenses, net for the year ended December 31, 2016 compared to the year ended December 31, 2015, and a $3.0 million decrease in general and administrative expenses in the same period, our operating loss for the year ended December 31, 2016 was $9.1 million, as compared with $12.5 million for the year ended December 31, 2015, a decrease of $3.4 million, or 27.2%.

Finance Income, net. Our finance income, net for the year ended December 31, 2016 was $244,000, as compared to $173,000 for the year ended December 31, 2015, an increase of $71,000. The change in our finance income, net is primarily due to the following:

- The absence in 2016 of $174,000 of finance income that we recorded in 2015 relating to changes in fair value of the warrants to purchase Series D-1 and D-2 preferred shares issued to investors and service providers in connection with our Series D-1 investment round and the warrants to purchase Series C-1 and C-2 preferred shares issued to Pontifax.

- For the year ended December 31, 2016, we recorded $139,000 of interest income on short-term deposits and $56,000 of finance income as a result of exchange rate differences, as compared to $61,000 and $18,000, respectively, for the year ended December 31, 2015.

- For the year ended December 31, 2016, we recorded finance income of $56,000 as a result of changes in provision for royalties, as compared to a finance expense of $33,000 in the year ended December 31, 2015.

- for the year ended December 31, 2016, we had bank fees of $7,000 and interest expenses and fess relating to a loan of $40,000, as compared to bank fees of $7,000 in the year ended December 31, 2015.

Loss before income tax. Our loss before income tax for the year ended December 31, 2016 was $8.82 million, as compared to $12.29 million for the year ended December 31, 2015, a decrease of $3.65 million.

Net Loss. Our net loss for the year ended December 31, 2016 was $8.83 million, as compared to $12.29 million for the year ended December 31, 2015, a decrease of $3.46 million.

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

	Year Ended December 31,	
	2015	2014
	(US$ in thousands, except per share data)	
Research and development expenses, net	$ 5,837	$ 2,832
General and administrative expenses	6,626	1,703
Operating loss	12,463	4,535
Finance income, net	173	3,925
Loss before income tax	12,290	610
Taxes on income	-	-
Net loss	$ 12,290	$ 610

Research and Development Expenses, net. Our research and development expenses, net for the year ended December 31, 2015 were $5.8 million, as compared with $2.8 million for the year ended December 31, 2014, an increase of $3.0 million or 107%. The increase in research and development expenses, net between 2015 and 2014 was primarily due to the progress in the development of our C-Scan system, including increased expenditures due to clinical trial costs associated with the recruitment of 28 employees and independent contractors to the research and development team.

	2015	2014	Change
	(US$ in thousands)		
Salaries and related expenses	$3,585	$2,425	$1,160
Share-based compensation	790	104	686
Materials	608	385	223
Subcontractors and consultants	688	294	394
Depreciation	85	72	13
	153	72	81

Cost for registration of patents			
Other research and development expenses	282	123	159
	6,191	3,475	2,716
Less participation of NATI (formerly known as the OCS) and the BIRD Foundation	(354)	(643)	289
Total research and development expenses, net	$5,837	$2,832	$3,005

General and Administrative Expenses. Our general and administrative expenses for the year ended December 31, 2015 were $6.6 million, as compared to $1.7 million for the year ended December 31, 2014, an increase of $4.9 million, or 288%. The increase in general and administrative expenses is primarily due to the following:

- a $2.7 million increase in share-based compensation, of which $2.0 million relates to the grant of options to purchase 581,542 ordinary shares from October 14, 2015 to our management and warrants to purchase 221,539 ordinary shares to Pontifax in consideration of their commitment to provide us, for no additional consideration, business development services and a representative designated by Pontifax to serve as the chairman of our board of directors (for additional information see Item 7B “Major Shareholders and Related Party Transactions—Related Party Transactions—Pontifax Warrants”).

- a $2.2 million increase in salaries and related expenses, professional services and other general administrative expenses incurred in connection with our initial public offering and concurrent private placement and other public company costs.

	2015	2014	Change
	(US$ in thousands)		
Salaries and related expenses	$1,830	$952	$878
Share-based compensation	2,934	208	2,726
Professional services	609	114	495
Office rent and maintenance	108	105	3
Depreciation	7	7	-
Other general and administrative expenses	1,138	317	821
Total general and administrative expenses	$6,626	$1,703	$4,923

Operating Loss. As a result of a $3.0 million increase in research and development expenses, net for the year ended December 31, 2015 compared to the year ended December 31, 2014, and a $4.9 million increase in general and administrative expenses in the same period, our operating loss for the year ended December 31, 2015 was $12.5 million, as compared with $4.5 million for the year ended December 31, 2014, an increase of $8.0 million, or 178%.

Finance Income, net. Our finance income, net for the year ended December 31, 2015 was $173,000, as compared to $3.9 million for the year ended December 31, 2014, a decrease of $3.8 million. The change in our finance income, net is primarily due to the following:

- For the year ended December 31, 2014, we recorded finance income of $3.5 million compared to finance income of $174,000 for the year ended December 31, 2015. This finance income is a result of changes in fair value of the warrants to purchase Series D-1 and D-2 preferred shares issued to investors and service providers in connection with our Series D-1 investment round and the warrants to purchase Series C-1 and C-2 preferred shares issued to Pontifax.

- For the year ended December 31, 2014, we recorded finance income of $415,000 as a

result of changes in provision for royalties, as compared to a finance expense of $33,000 for the year ended December 31, 2015.

Loss before income tax. Our loss before income tax for the year ended December 31, 2015 was $12.3 million, as compared to $610,000 for the year ended December 31, 2014, an increase of $11.7 million.

Net Loss. Our net loss for the year ended December 31, 2015 was $12.3 million, as compared to $610,000 for the year ended December 31, 2014, an increase of $11.7 million.

B. Liquidity and Capital Resources

Sources of Liquidity

To date, we have funded our operations primarily with the approximately $24.5 million raised through equity financings consummated prior to our initial public offering, $13.5 million through our initial public offering (including the over-allotment exercise), $12.0 million through the private placement consummated concurrently with our initial public offering, $6.0 million though our registered direct offering (including through the exercise of pre-funded warrants issued in the offering), $5.1 million through grants that we received from NATI (formerly known as the OCS) and the BIRD Foundation and $1.0 million drawn down under a credit line.

On July 13, 2014, we entered into a Cooperation and Project Funding Agreement with the BIRD Foundation and Synergy, pursuant to which the BIRD Foundation has agreed to award a grant to Synergy and us in the maximum amount of the lesser of (i) $900,000; and (ii) 50% of the actual expenditures for the funding of a project entitled “Collection & Analysis of Gastrointestinal Images for Diagnostic Adenomatic Polyps and Colorectal Cancer.” The development work was to be performed over a 24 month period by Synergy (or a subcontractor on its behalf) and us. As of

December 31, 2016, we had received funding from the BIRD Foundation in the aggregate amount of approximately $127,000. We shall not be receiving additional funding from the BIRD Foundation for the project, which is no longer active; however, we are considering applying to the BIRD Foundation for funding for related projects. Based on the aggregate expenses that we incurred for the project, we are required to refund to the BIRD Foundation an amount of approximately $12,000. Our research and development expenses, net is presented net of the grant amount received from the BIRD Foundation. As of December 31, 2016, we had not paid any royalties to the BIRD Foundation and had a contingent obligation to the BIRD foundation in the amount of $127,000.

We are required to repay the total sum granted to us and Synergy by the BIRD Foundation, linked to the U.S. Consumer Price Index from date of receipt of each payment, up to 100%, 113%, 125%, 138% and 150% of the linked sum granted by the BIRD Foundation if repaid within one year, two years, three years, four years and five or more years, respectively, of the original project completion date in accordance with the project proposal. Repayments are made at the rate of 5% of gross revenues derived from the product funded by the project. Under the terms of the agreement, if any portion of the product funded by the project is sold outright to a third party prior to full repayment of the grant to the BIRD Foundation, one-half of the sale proceeds will be applied to the repayment of the grant. If the funded product is licensed to a third party, 30% of all payments received under the respective license agreement must be paid to the BIRD Foundation in repayment of the grant.

On August 20, 2014, we entered into a certain credit line agreement, pursuant to which we obtained a credit line in an aggregate principal amount of $12 million from certain lenders and existing shareholders, or the Lenders. The credit line amount was deposited in an escrow account at the closing, which was consummated on October 14, 2014.

We issued to each Lender at closing a warrant, collectively referred to as the Credit Line Warrants, to purchase a number of our ordinary shares constituting 2% of our share capital on a fully diluted basis (assuming conversion of all of our then outstanding convertible securities into ordinary shares at a 1:1 conversion rate) as of the closing for each $1 million (or portion thereof) extended by such Lender. We issued Credit Line Warrants to purchase in the aggregate 2,658,463 of our ordinary shares. The Credit Line Warrants are exercisable for a period of ten years at an exercise price of NIS 0.20 per share, and may be exercised on a net issuance basis. As of December 31, 2016, Credit Line Warrants to purchase an aggregate 2,082,325 ordinary

shares had been exercised and Credit Line Warrants to purchase an aggregate 33,368 warrants expired as a result of the exercise of certain Credit Line Warrants on a net issuance basis.

Under the terms of the credit line agreement, we directed that the full credit line amount be invested in the private placement that was consummated simultaneously with our initial public offering that was consummated on February 24, 2015. We issued to the Lenders a total of 2,000,000 units, each consisting of one ordinary share and one half of a Series A Warrant to purchase one ordinary share, together with 3,000,000 Long Term Incentive Warrants for aggregate gross proceeds of $12,000,000.

On January 4, 2015, we entered into a credit line agreement with Bank Leumi le-Israel B.M., or Bank Leumi, pursuant to which we were entitled to obtain a credit line in the principal amount of up to $1,000,000, or the Bank Leumi Credit Facility. The Bank Leumi Credit Facility was required to be repaid in full by us no later than April 1, 2015 and Bank Leumi's consent was required for early repayment. The drawn portion of the Bank Leumi Credit Facility bore interest at an annual rate of LIBOR plus 5.25% on the basis of a 365-day year, until paid in full. We drew the entire $1,000,000 Bank Leumi Credit Facility. We paid Bank Leumi a facility fee of $20,000 in connection with the facility. To secure the repayment of the Bank Leumi Credit Facility, we granted Bank Leumi (i) a first ranking fixed charge over our goodwill; and (ii) a first ranking floating charge over all of the assets and rights of any type whatsoever, which we had or may acquire in the future, subject to the rights of NATI (formerly known as the OCS) and the BIRD Foundation and the rights under existing and future liens in favor of the First Intentional Bank of Israel Ltd. securing debt or indentures of up to an aggregate amount of $100,000. On March 16, 2015, we repaid all amounts outstanding under the Bank Leumi Credit Facility with the proceeds of our initial public offering and concurrent private

placement.

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On February 24, 2015, we consummated an initial public offering in the United States of 2,000,000 units, each consisting of one ordinary share and one half of a Series A Warrant to purchase one ordinary share. The price per unit sold in the initial public offering was $6.00. Each unit in the initial public offering was issued with one and one half Long Term Incentive Warrants. We granted the underwriters in the initial public offering a 45-day over-allotment option to purchase up to 300,000 additional units (together with an accompanying 450,000 Long Term Incentive Warrants) from us to cover over-allotments. On March 6, 2015, the option to purchase additional 100,000 units was partially exercised. On March 18, 2015, the units were separated into one ordinary share and one-half of a Series A Warrant to purchase one ordinary share and the units ceased to exist. On April 6, 2015, the option to purchase additional 150,000 ordinary shares and 75,000 Series A Warrant was partially exercised. The aggregate offering price of the securities sold in the initial public offering (including the over-allotment option) was approximately $13.5 million. The total expenses of the offering, in cash, including underwriting discounts and commissions, were approximately $2.9 million. Issuance expenses include certain warrants with value of $196,000 issued in connection with the initial public offering. The net proceeds we received from the initial public offering (including the over-allotment option) was approximately $10.8 million, (net of issuance cost of approximately $1.2 million, including certain warrants with value of $125 issued in connection with the private placement). In January 2015, we issued a total of 2,452,376 Long Term Incentive Warrants to purchasers of securities in our initial public offering who completed the required registration process by August 23, 2015.

Immediately prior to the consummation of our initial public offering, certain members of our management exercised options to purchase 307,467 ordinary shares granted to them under the 2006 Unit Option Plan.

On August 11, 2016, we consummated a registered direct offering of 643,614 ordinary shares at a price of $1.90 per share and pre-funded warrants to purchase 2,514,281 ordinary shares at a purchase price of $1.85 per pre-funded warrant. The pre-funded warrants had an exercise price of $0.05 per share, subject to certain adjustments and an expiration date of August 11, 2023, unless otherwise extended in accordance with the terms of the pre-funded warrants. We received gross proceeds from the registered direct offering of approximately $5.9 million (including proceeds from the exercise of 575,000 pre-funded warrants at the closing of the offering). As of December 31, 2016, additional pre-funded warrants to purchase an aggregate 1,649,281 ordinary shares had been exercised, for additional proceeds of $82,500. As of January 23, 2017, all of the remaining pre-funded warrants to purchase an aggregate 290,000 ordinary shares had been exercised, for additional proceeds of $14,500.

For the years ended December 31, 2016, 2015 and 2014, we received $1.5 million, $11,000 and $558,000, respectively, in grants from NATI (formerly known as the OCS) for the financing of a portion of our research and development expenditure.

Our management has plans of increasing our research and development costs in 2017 to reach market in a timely manner. Such plans will increase the burn rate and our management expects that with such increased costs, our existing cash resources and the net proceeds from our initial public offering and concurrent private placement and our registered direct offering will be sufficient to fund our projected operating requirements at least until December 31, 2017. Nevertheless, we will require significant additional financing in the future to fund our operations if and when we progress with our clinical trials in Europe and the United States as well as other potential territories. Management plans include additional fund raising in the next year, which management believe is probable. If adequate additional financing on acceptable terms is not available to us on a

timely basis during 2017, we have the flexibility of downsizing our operations such that our existing cash will be sufficient to fund our cash requirements until June 30, 2018. We have used the best evidence, currently available, in making these estimates, and actual results may differ from or forecasts.

Historical Cash Flows

The following table summarizes our statement of cash flows for the years ended December 31, 2016, 2015 and 2014.

	Year Ended December 31,		
	2016	2015	2014
	(US$ in thousands)		
Net cash used in operating activities	$(7,923)	$(8,628)	$(3,855)
Net cash provided by (used in) investing activities	$4,691	$(5,070)	$