

Edgar Filing: InspireMD, Inc. - Form FWP

InspireMD, Inc.
Form FWP
June 07, 2016

NYSE MKT: NSPR June 2016 Issuer Free Writing Prospectus Filed Pursuant to Rule 433 of the Securities Act of 1933, as amended Registration Statement No. 333 - 210760

Forward Looking Statements This presentation contains "forward - looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward - looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward - looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10 - K and its Quarterly Reports on Form 10 - Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward - looking statements as a result of new information, future events or otherwise. 2

Free Writing Prospectus 3 This presentation highlights basic information about InspireMD, Inc. and the offering. InspireMD, Inc. has filed a registration statement on Form S - 1 (Registration No. 333 - 210760) (including a prospectus) with the U.S. Securities and Exchange Commission (the “SEC”) for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in that registration statement (including, among other things, risk factors described therein) and other documents the issuer has filed with the SEC for more complete information about InspireMD, Inc. and this offering. The preliminary prospectus dated April 14, 2016, and subsequent amendments are available at the SEC website. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov. Alternatively, InspireMD, Inc. or any underwriter or any dealer participating in the offering will arrange to send you the prospectus if you request it by contacting Dawson James Securities, Inc., Attention: Prospectus Department, 1 North Federal Highway, 5th Floor, Boca Raton, FL 33432, mmaclaren@dawsonjames.com or toll free at 866.928.0928.

InspireMD Pioneering fully integrated embolic prevention systems and other advanced medical technology for vascular procedures NYSE MKT: NSPR Stock Price (5/31/16): \$0.465 52 Week Range: \$0.32 - \$4.20 Average Volume: 89K Shares Outstanding (5/31/16): 10.7 M Market Capitalization (5/31/16): \$4.98 M Analyst Coverage: H.C. Wainwright: Yi Chen Dawson James: Sherry Grisewood Empire Asset Management: Cathy Reese Total Cash (3/31/16): \$2.0 M US Headquarters: Boston, MA International Headquarters: Tel Aviv, Israel # of Employees (5/31/2016): 33 4

Investment Highlights • 2016 focus on revenue growth driven by a broader EU launch of CGuard • Strategic distribution partnership with Penumbra (NYSE:PEN) • Significant growth in Italy over the last 3 quarters serving as a leading indicator • Positive clinical trial results using CGuard in a broad patient population, including high risk patients • Advancing into the growing neurovascular and peripheral vascular markets • 2017E CE Mark Submission for NV Guard™ flow diverter for treatment of cerebral vascular aneurysms enabling EU commercialization post approval • A broad portfolio of assets supported by aggressive pursuit of intellectual property protection • Well positioned for strategic collaboration on multiple MicroNet™ product applications • Continued financial discipline in line with development and growth initiatives Focused on commercial execution of CGuard™ EPS and development of pipeline products 5

The Problem Embolization can lead to catastrophic health events 6

Embolization following Carotid Artery Stenting “Plaque protrusion through stent struts occurs in up to 65.5% of conventional carotid stents in relation to plaque morphology/symptomatic status and stent type, providing a mechanism for post carotid artery stenting (CAS) cerebral embolization , either directly or via additional thrombus formation.*” 2/3 of CAS neurovascular events (stroke, TIA) are POST - procedural.** * Musialek, et.al. Eurointerventions 2016;12 published online ahead of print May 2016 ** Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007 7

Pre - Procedure Post - Procedure Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159 - 64 A. Pre - intervention showing 90% occlusion of the carotid artery and an MRI showing an old white matter infarction (obstruction). B. Post - intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro - infarcts (obstructions) post - procedure due to liberation of embolic particles. The Consequences Range from neurological deficit to stroke to death 8

MicroNet™ • Provides revascularization benefit • MicroNet acts as “safety net” by offering greater vessel area coverage to prevent large debris flow through the scaffold • Made of a single fiber from a biocompatible polymer, widely used in other medical implants Proprietary technology for preventing distal embolization and other vascular disease challenges Ultrathin PET* mesh provides meaningful clinical benefit to conventional devices *PET – polyethylene terephthalate 9

Large Addressable Market Expanding the MicroNet™ Platform MGuard™* x \$1.7B AMI Market x CE Mark Cleared x Coronary AMI, SVG CGuard™ x \$500M Market x CE Mark Cleared x FDA IDE draft protocol synopsis x Carotid NVGuard x \$125M Flow Diversion Market x \$550M Aneurysm Market x 2017E CE Mark Planned Submission for Flow Diverter x Neurovascular PVGuard x \$1.7B Market x 2018E CE Mark Planned Submission x Peripheral . *

MGuard is a bare metal stent scaffold 10

CGuard™ Embolic Prevention System(EPS) Combines stent and embolic protection in a single device *Source : JMP Securities, 2014 and Cowen 2014. Carotid Solution: Mesh Covered Technology • CE marked • Self - expanding nitinol stent • Global market valued at \$500M* • Positive CARENET data released 9/14, 1/15 and 5/16 documenting the safety and patency of the CGuard EPS • Positive all - comer data from PARADIGM trials presented 5/15 and 5/16 documenting the safety and benefits of the CGuard EPS • Ongoing launch in Europe, Latin America, South America, & other regions An emerging market opportunity 11

CARENET Clinical Trial • 30 Patient Safety and Efficacy clinical trial • Zero major adverse cardiac or cerebral events (MACCE) at 30 days (Comparative data 5.72%*) • 50% fewer new ischemic lesions with lesion volume being 10x times smaller compared to historical non - mesh carotid artery stenting data • All new ischemic lesions full resolved at 30 days except one • 3.6 % MACCE rate at 6 months (Comparative data 8.09 %**) • Zero strokes or stroke related deaths at 12 months PARADIGM 101 Clinical Trial 101 patient trial evaluating CGuard EPS in unselected, consecutive carotid patients (all - comers) • 99.1% device success • 0 % MACCE (Death/stroke/MI) @ 48 hr • 0% MACCE @ 30 day as determined by independent neurological and angiographic evaluation “ CGuard can safely be used on more than 90% of all - comer patients that have carotid artery stenosis. ” P. Musialek, MD * Trials included in analysis: ARChR pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVeRIC 1+2, MAVeRIC International, PRIAMUS, SAPPHIRE, SECURITY, PROFI, ICSS ** Values extrapolated from event curves Positive CGuard™ Clinical Experience 12

“The most important theme during [EuroPCR 2016] was carotid artery stenting....[The double layered mesh stents] will resolve the main problem of carotid artery stents which was late embolic events.” A. Cremonesi Carotid Market Opportunity • Current standard of care: Surgery • Carotid Endarterectomy (CEA) • The risk of post - procedural cerebral events has been related to [conventional] carotid stents. 1 • Higher risks of stroke at 10 years appear to be attributable to the peri - procedural differences in risk. 2 • Mesh - covered carotid stents may lower the rates of peri - procedural stroke. 2 • CGuard™ clinical studies have demonstrated superior safety • CARENET • PARADIGM • PARADIGM 101 • Immediate EU commercial opportunity (non - US) • EU pursued via new strategic partner Penumbra • Europe, Latin America and other regions are covered by experienced distributors • U.S. development and clinical plan to follow “Game Changing” Minimally Invasive Solution 13 1 Musialek , EuroIntervention 2016;12 online publish ahead of print May 2016 2 Brott , T. Long - Term Results of Stenting versus Endarterectomy for Carotid - Artery Stenosis, New England Journal of Medicine, March 17, 2016

Strategic Distribution Partnership • Distribution agreement with Penumbra • 18 European markets with opportunity to expand • Comprehensive neurovascular product portfolio • CGuard is a synergistic product offering • Growing direct sales force throughout Europe • Establishing a direct sales force focused on peripheral vascular • Successful IPO in September 2015 Broad European commercialization support from a growing neurovascular leader 14

CGuard Distribution (EU) 15 Penumbra (Direct) 18 Countries InspireMD or Distributor E E

CGuard™ Country Case Study • CGuard covered by 2 distributors • Initial success drove 29 Italian carotid interventionalists to initiate the IRON - Guard* registry last year - 20 40 60 80 100 120 140 160 Q1 15 Q2 Q3 Q4 Q1 16 Italy CGuard Revenue Note: Revenue in \$000's Italy – A leading indicator of CGuard Growth 16 * Setacci, et. al., J Cardiovasc Surg. 2015 May 21

Commercial • CE Mark Cleared • 12 - month MASTER I, II MicroNet™ Platform Technology MGuard™ Coronary EPS
NVGuard™ Neurovascular* RGuard™ Renal * CGuard™ Carotid PVGuard™ Peripheral * MGuard™ Drug Eluting * *
Planning & Development Phase Commercial • CE Mark Cleared • CARENET Trial • PARADIGM all - comer trials •
FDA IDE draft protocol synopsis • Penumbra Strategic Partnership 2018E development towards CE Mark Planned
Submission Strategic partner opportunity Exploring Market Opportunities: • Flow Diverter • Intra - Cranial Stent 2017E
CE Mark Planned Submission for Flow Diverter Exploring Market Opportunity Robust Pipeline Expanding
Indications with MicroNet™ 17

Neurovascular Market Opportunity Innovation leads growth * 2013 MRG Neuro Report, 2010 Ev3 Revenue Data **
2014 projection based on 2013 actuals 2014 Competitive Landscape: Relatively Fewer Players Product Company
Approval Pipeline Medtronic/Covidien CE Mark 2014 FDA 2011 Surpass Stryker CE Mark 2010 Silk Balt Extrusion
CE Mark 2008 Flow Diversion For Unruptured Brain Aneurysms Next Generation Technology • Aneurysm Therapy
(all types): \$ 550M* • Flow diverters are estimated to be 25 % of the aneurysm market • Neurovascular products:
estimated 15% CAGR from 2010 - 2016 18 **

Neurovascular Aneurysms Objective • Seal the aneurysm and prevent rupture Current device therapies • Coils to pack the aneurysm • Flow diverters • Highly flexible, dense metal “tube” • Placed in main artery to seal off aneurysm and cause aneurysm thrombosis • Precise delivery required to avoid blocking other vessels Flow Diversion
<http://www.nature.com/nrcardio/journal/v11/n2/full/nrcardio.2013.196.html> 19

InspireMD Flow Diverter Advantage • Low profile, flexible, open cell scaffold = Easy to delivery • Low metal ratio = Potential for reduced anti - thrombosis medication • Re - accessible through MicroNet™ = Allows for further treatment, if needed which is impossible with current flow diverters • Can be placed in side branches and bifurcations = Will not block blood flow into major side vessels, which is impossible with current technology • Published success with MicroNet in coronary and carotid aneurysms 20

Intellectual Property Portfolio Continue to strengthen and broaden patent protection globally. Progress over the last year imparts important rights on existing products and technologies and will enable future pipeline products. 21
PATENT RIGHTS Issued Allowed Pending US 4 0 11 Rest of World (ROW) 16 0 13

EXECUTIVE TEAM BOARD OF DIRECTORS Dr. James Barry, President and CEO • Boston Scientific • Howmedica Division of Pfizer Craig Shore, CFO • Pfizer • General Electric David Blossom, VP Global Marketing & Strategy • Boston Scientific • Covidien Dr. Sol Barer, Chairman • Former Chairman and CEO, Celgene Isaac Blech , Vice Chairman • Private financier in the life science industries Dr. James Barry, President, CEO and Director • SVP Corporate Technology Development at Boston Scientific • Howmedica Division of Pfizer Michael Berman • Pres. Boston Scientific/Scimed • Founder, Velocimed • Director Lutonix Paul Stuka • Founder, Osiris • Fidelity Management and Research Dr. Campbell Rogers • CMO, Heartflow • CSO, Cordis/JNJ • Associate Professor, Harvard School of Medicine Leadership Significant Track Records of Success 22

Use of Proceeds • Commercial Execution of CGuard™ and MGuard™ EPS • Development of NVGuard™ Flow Diverter through CE submission • Working Capital • General Corporate Purposes 23

Investment Highlights • 2016 focus on revenue growth driven by a broader EU launch of CGuard • Strategic distribution partnership with Penumbra (NYSE:PEN) • Significant growth in Italy over the last 3 quarters serving as a leading indicator • Positive clinical trial results using CGuard in a broad patient population, including high risk patients • Advancing into the growing neurovascular and peripheral vascular markets • 2017E CE Mark Submission for NV Guard™ flow diverter for treatment of cerebral vascular aneurysms enabling EU commercialization post approval • A broad portfolio of assets supported by aggressive pursuit of intellectual property protection • Well positioned for strategic collaboration on multiple MicroNet™ product applications • Continued financial discipline in line with development and growth initiatives Focused on commercial execution of CGuard™ EPS and development of pipeline products 24

James Barry, Ph.D., President and CEO 888.776 . 6804 jimb@inspiremd.com Craig Shore, CFO 888.776 . 6804 craigs@inspiremd.com