InspireMD, Inc.
Form S-1/A
December 01, 2011

As filed with the Securities and Exchange Commission on December 1, 2011

SEC File No. 333-174948

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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AMENDMENT NO. 4
TO
FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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InspireMD, Inc.
(Exact name of registrant as specified in its charter)

Delaware	3841	26-2123838
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

3 Menorat Hamaor St.
Tel Aviv, Israel 67448
972-3-691-7691
(Address, including zip code, and telephone number,
including area code, of registrant's principal executive offices)

Ofir Paz
Chief Executive Officer
InspireMD, Inc.
3 Menorat Hamaor St.
Tel Aviv, Israel 67448
972-3-691-7691
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Rick A. Werner, Esq.

Haynes and Boone, LLP
30 Rockefeller Plaza, 26th Floor
New York, New York 10112
Tel. (212) 659-7300
Fax (212) 884-8234

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.
(Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 1, 2011

PRELIMINARY PROSPECTUS

InspireMD, Inc.

414,942 Shares of Common Stock Underlying Warrants

This prospectus relates to the resale of up to 414,942 shares of our common stock to be offered by the selling stockholders upon the exercise of outstanding common stock purchase warrants by the selling stockholders.

The selling stockholders may sell shares of common stock from time to time in the principal market on which our common stock is traded at the prevailing market price or in privately negotiated transactions. See “Plan of Distribution” which begins on page 60.

We will not receive any of the proceeds from the sale of common stock by the selling stockholders. However, we will generate proceeds in the event of a cash exercise of the warrants by the selling stockholders. We intend to use those proceeds, if any, for general corporate purposes. We will pay the expenses of registering these shares.

All expenses of registration incurred in connection with this offering are being borne by us, but all selling and other expenses incurred by the selling stockholders will be borne by the selling stockholders.

Our common stock is quoted on the regulated quotation service of the OTC Bulletin Board under the symbol “NSPR.OB”. On November 30, 2011, the last reported sale price of our common stock as reported on the OTC Bulletin Board was $2.25 per share.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Investing in our common stock is highly speculative and involves a high degree of risk. You should carefully consider the risks and uncertainties in the section entitled “Risk Factors” beginning on page 4 of this prospectus before making a decision to purchase our stock.

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. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2011

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You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

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PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our historical financial statements and related notes included elsewhere in this prospectus or any accompanying prospectus supplement before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our" and "us" for periods prior to the closing of our share exchange transactions on March 31, 2011 refer to InspireMD Ltd., a private company incorporated under the laws of the State of Israel that is now our wholly-owned subsidiary, and its subsidiary, and references to "we," "our" and "us" for periods subsequent to the closing of the share exchange transactions refer to InspireMD, Inc., a publicly traded Delaware corporation, and its direct and indirect subsidiaries, including InspireMD Ltd.

Overview

We are an innovative medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™. MGuard™ provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent (see photograph below of an MGuard™ Stent). Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). According to the TYPHOON STEMI trial (New England Journal of Medicine, 2006) and the SOS SVG Trial (Journal of the American College of Cardiology, 2009), of patients with acute myocardial infarction and saphenous vein graft coronary interventions, 7.5% to 44% experience major adverse cardiac events, including cardiac death, heart attack, and restenting of the artery. When performing stenting procedures in patients with acute coronary symptoms, interventional cardiologists face a difficult dilemma in choosing between bare-metal stents, which have a high rate of restenosis (formation of new blockages), and drug-eluting (drug-coated) stents, which have a high rate of late thrombosis (formation of clots months or years after implantation), require administration of anti-platelet drugs for at least one year post procedure, are more costly than bare-metal stents and have additional side effects. We believe that MGuard™ is a simple, seamless and complete solution for these patients. For the year ended December 31, 2010, our total revenue was approximately $4.9 million and our net loss was approximately $3.4 million. For the nine months ended September 30, 2011, our total revenue was $4.7 million and our net loss was approximately $6.4 million.

MGuardTM Sleeve – Microscopic View

We intend to use our MGuard™ technology in a broad range of coronary related situations in which complex lesions are required and make it an industry standard for treatment of acute coronary syndromes. We believe that patients will benefit from a cost-effective alternative with a greater clinical efficacy and safety profile than other stent technologies. We believe that with our MGuard™ technology, we are well positioned to emerge as a key player in the global stent market.

We also intend to apply our technology to develop additional products used for other vascular procedures, specifically carotid (the arteries that supply blood to the brain) and peripheral (other arteries) procedures.

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In October 2007, our first generation product, the MGuard™ Coronary, received CE Mark approval for treatment of coronary arterial disease in the European Union. CE Mark is a mandatory conformance mark on many products marketed in the European Economic Area and certifies that a product has met European Union consumer safety, health or environmental requirements. We began shipping our product to customers in Europe in January 2008 and have since expanded our global distribution network to Canada, Southeast Asia, India and Latin America.

Our initial MGuard™ products incorporated a stainless steel stent. We replaced this stainless steel platform with a more advanced cobalt-chromium based platform, which we refer to as MGuard Prime™. We believe the new platform will be superior because cobalt-chromium stents are generally known in the industry to provide better deliverability and possibly even a reduction in major adverse cardiac events. In particular, according to Jabara, et. al. ("A Third Generation Ultra-thin Strut Cobalt Chromium Stent: Histopathological Evaluation in Porcine Coronary Arteries," EuroIntervention, November 2009), due to its greater density, cobalt-chromium enables the construction of stents that have both thinner struts and similar radial strength as stainless steel, with its thicker struts. In turn, Jabara, et. al. found that the reduced thickness of the struts provides more flexibility and lower crossing profiles, thereby reducing the inflammatory response and neointimal thickening, potentially lowering restenosis and target vessel revascularization rates.

MGuard Prime™ received CE Mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. We believe we can use and leverage the MGuard™ clinical trial results to market MGuard Prime™. However, we face a number of challenges to the further growth of MGuard™. For example, we face competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. In addition, none of our products are currently approved by the U.S. Food and Drug Administration. Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard™ stent will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Furthermore, our rights to our intellectual property with respect to our products could be challenged. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MGuard™ stent based on one or more of these patents. Additionally, there is a strong preference to use drug-eluting stents in some countries. Over the last decade, there has been an increasing tendency to use drug-eluting stents in percutaneous coronary intervention (PCI), commonly known as angioplasty (a therapeutic procedure to treat narrowed coronary arteries of the heart found in patients with heart disease), with a usage rate of drug-eluting stents in PCI approaching 70-80% in some countries, even though drug-eluting stents do not address thrombus management in acute myocardial infarction. Also, the use of other bare-metal stents is preferred over the use of MGuard™ products in certain circumstances, such as when placing the stent at the entrance to large side branches, known as jailing large side branches. Unless otherwise indicated, in this prospectus, references to MGuard™ are to both our initial product, MGuard™, and MGuard Prime™, as applicable.

Recent Events

On October 31, 2011, our stockholders authorized our board of directors to amend our amended and restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio of one-for-two to one-for-four, at any time prior to our 2012 annual stockholders' meeting, the exact ratio of the reverse stock split

to be determined by the board. As of the date of this prospectus, we have not effected the reverse stock split and, as such, the information with respect to our common stock in this prospectus and the accompanying financial statements and related notes does not give effect to any reverse stock split.

On October 4, 2011, InspireMD Ltd., our wholly-owned subsidiary, entered into a clinical trial services agreement with Harvard Clinical Research Institute, Inc., pursuant to which Harvard Clinical Research Institute, Inc. will conduct a study entitled "MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction" on our behalf. We will pay Harvard Clinical Research Institute, Inc. an estimated fee of approximately $10 million for conducting the study, subject to adjustment dependent upon changes in the scope and nature of the study, as well as other costs to be determined by the parties.

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On March 31, 2011, we completed a series of share exchange transactions pursuant to which we issued the shareholders of InspireMD Ltd. 50,666,663 shares of common stock in exchange for all of InspireMD Ltd.'s issued and outstanding ordinary shares, resulting in the former shareholders of InspireMD Ltd. holding a controlling interest in us and InspireMD Ltd. becoming our wholly-owned subsidiary.

Immediately following the share exchange transactions, we transferred all of our pre-share exchange operating assets and liabilities to our wholly-owned subsidiary, Saguaro Holdings, Inc., a Delaware corporation, and transferred all of Saguaro Holdings, Inc.'s outstanding capital stock to Lynn Briggs, our then-majority stockholder and our former president, chief executive officer, chief financial officer, secretary-treasurer and sole director, in exchange for the cancellation of 7,500,000 shares of our common stock held by Ms. Briggs.

After the share exchange transactions and the divestiture of our pre-share exchange operating assets and liabilities, we succeeded to the business of InspireMD Ltd. as our sole line of business, and all of our then-current officers and directors resigned and were replaced by some of the officers and directors of InspireMD Ltd.

Contemporaneously with the foregoing transactions, we completed a private placement pursuant to which we sold 6,454,002 shares of common stock and five-year warrants to purchase up to 3,226,999 shares of common stock at an exercise price of $1.80 per share for aggregate cash proceeds of $9,013,404 and the cancellation of $667,596 of indebtedness held by investors. In addition, on April 18, 2011 and April 21, 2011, we completed private placements pursuant to which we sold an aggregate of 983,334 shares of common stock and five-year warrants to purchase up to 491,667 shares of common stock at an exercise price of $1.80 per share for aggregate cash proceeds of $1,475,000.

Before the share exchange transactions, our corporate name was Saguaro Resources, Inc., and our trading symbol was SAGU.OB. On March 28, 2011, we changed our corporate name to InspireMD, Inc. and on April 11, 2011 our trading symbol was changed to NSPR.OB.

The Offering

Common stock offered by the selling stockholders:	414,942 shares of our common stock to be offered by the selling stockholders upon the exercise of outstanding common stock purchase warrants.
Common stock outstanding prior to the offering:	68,178,947
Common stock outstanding after this offering:	68,593,889 (1)
Use of proceeds:	We will not receive any proceeds from the sale of the common stock offered by the selling stockholders. However, we will generate proceeds in the event of a cash exercise of the warrants by the selling stockholders. We intend to use those proceeds, if any, for general corporate purposes.
Offering Price:	All or part of the shares of common stock offered hereby may be sold from time to time in amounts and on terms to be determined by the selling stockholders at the time of sale.

OTC Bulletin Board symbol:	NSPR.OB
Risk factors:	You should carefully consider the information set forth in this prospectus and, in particular, the specific factors set forth in the “Risk Factors” section beginning on page 5 of this prospectus before deciding whether or not to invest in shares of our common stock.

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(1) The number of shares of common stock outstanding after the offering is based upon 68,178,947 shares outstanding as of November 30, 2011 and assumes the exercise of all warrants with respect to those shares being registered for resale pursuant to the registration statement of which this prospectus forms a part.

The number of shares of common stock outstanding after this offering excludes:

- 7,723,583 shares of common stock issuable upon the exercise of currently outstanding warrants with exercise prices ranging from $1.23 to $1.80 per share and having a weighted average exercise price of $1.63 per share;
- 12,298,587 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.0 to $2.60 and having a weighted average exercise price of $1.09 per share; and
- 6,684,047 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan.

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Risk Factors

Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should carefully consider the risks described below and the financial and other information included in this prospectus. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. In such case, the trading price and market value of our common stock could decline and you may lose part or all of your investment in our common stock. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Risks Related to Our Business

We expect to derive our revenue from sales of our MGuardTM stent products and other products we may develop. If we fail to generate revenue from this source, our results of operations and the value of our business would be materially and adversely affected.

We expect our revenue to be generated from sales of our MGuard™ stent products and other products we may develop. Future sales of these products, if any, will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. If we fail to generate such revenues, our results of operations and the value of our business and securities could be materially and adversely affected.

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue.

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our pending patents may not provide us with commercially meaningful protection for our products or afford a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not be issued from any pending or future patent applications owned by or licensed to us, and moreover, patents that may be issued to us in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

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The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, patent applications in the U.S. are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the U.S. The laws of some foreign jurisdictions do not protect intellectual property rights to the same degree as in the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

We may initiate litigation to enforce our patent rights on any patents issued on pending patent applications, which may prompt adversaries in such litigation to challenge the validity, scope or enforceability of our patents. If a court decides that such patents are not valid, not enforceable or of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patents are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

We have a history of net losses and may experience future losses

To date, we have experienced net losses. A substantial portion of the expenses associated with our manufacturing facilities are fixed in nature (i.e., depreciation) and will reduce our operating margin until such time, if ever, as we are able to increase utilization of our capacity through increased sales of our products. The clinical trials necessary to support our anticipated growth will be expensive and lengthy. In addition, our strategic plan will require a significant investment in clinical trials, product development and sales and marketing programs, which may not result in the accelerated revenue growth that we anticipate. As a result, there can be no assurance that we will ever generate substantial revenues or sustain profitability.

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We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our MGuard™ stent at our facilities in Tel Aviv, Israel, and we have contracted with QualiMed Innovative Medizinprodukte GmbH, a German manufacturer, to assist in production. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard™ stent until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our MGuard™ stent for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

We currently have limited resources, facilities and experience to commercially manufacture our product candidates. In order to produce our MGuard™ stent in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or "scale up," the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity, and developing commercial-scale manufacturing facilities will require the investment of substantial funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If unable to do so, we may not be able to produce our MGuard™ stent in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all. If we develop and obtain regulatory approval for our MGuard™ stent and are unable to manufacture a sufficient supply of our MGuard™ stent, our revenues, business and financial prospects would be adversely affected. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline. Also, our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

Additionally, any damage to or destruction of our Tel Aviv facilities or its equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce MGuard™ stents.

Finally, the production of our MGuard™ stent must occur in a highly controlled, clean environment to minimize particles and other yield and quality-limiting contaminants. In spite of stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are unable to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and results of operations.

Clinical trials necessary to support a pre-market approval application will be lengthy and expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such delay or failure of clinical trials could prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business.

Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard™ stent will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Clinical trials supporting a pre-market approval applications for the Cypher stent developed by Johnson & Johnson and the Taxus Express2 stent developed by Boston Scientific Corporation, which were approved by the U.S. Food and Drug Administration and are currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively, and a 12-month follow up period. In some trials, a greater number of patients and a longer follow up period may be required. The U.S. Food and Drug Administration may require us to submit data on a greater number of patients or for a longer follow-up period than those for pre-market approval applications for the

Cypher stent and the Taxus Express2 stent. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

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In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our products under development may be delayed by many factors, including governmental or regulatory delays and changes in regulatory requirements, policy and guidelines or our inability or the inability of any potential licensee to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials.

Physicians may not widely adopt the MGuard™ stent unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of the MGuard™ stent provides a safe and effective alternative to other existing treatments for coronary artery disease.

We believe that physicians will not widely adopt the MGuard™ stent unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our MGuard™ stent provides a safe and effective alternative to other existing treatments for coronary artery disease, including coronary artery bypass grafting balloon angioplasty, bare-metal stents and other drug-eluting stents, provided by Johnson & Johnson, Boston Scientific Corporation, Medtronic Inc., Abbott Laboratories and others.

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that the MGuard™ stents are an attractive alternative to other procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other drug-eluting stents or bare-metal stents that have received regulatory approval and that are available on the market, our ability to successfully market the MGuard™ stent will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our MGuard™ stent will vary. Clinical trials conducted with the MGuard™ stent have involved procedures performed by physicians who are technically proficient and are high-volume stent users. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our MGuard™ stent will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

In addition, currently, physicians consider drug-eluting stents to be the industry standard for treatment of coronary artery disease. While we believe that the MGuard™ stent is a safe and effective alternative, it is not a drug-eluting stent, which may further hinder its support and adoption by physicians.

Our products are based on a new technology, and we have only limited experience in regulatory affairs, which may affect our ability or the time required to navigate complex regulatory requirements and obtain necessary regulatory approvals, if such approvals are received at all. Regulatory delays or denials may increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Because our products are new and long-term success measures have not been completely validated, regulatory agencies, including the U.S. Food and Drug Administration, may take a significant amount of time in evaluating product approval applications. For example, there are currently several methods of measuring restenosis and we do not know which of these metrics, or combination of these metrics, will be considered appropriate by the U.S. Food and Drug Administration for evaluating the clinical efficacy of stents. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. Any change in the accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality

assurance personnel are currently composed of only 5 employees. As a result, we may experience a long regulatory process in connection with obtaining regulatory approvals for our products.

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In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the U.S., Europe and Asia, which can be cny adjustments, and to recommend annual compensation for the coming year. Palatin s chief financial officer and human resources manager gather and report on information about compensation levels in comparable companies. We review the performance of each executive officer and the financial condition of the Company. We then consider the following major components of executive compensation:

Base salary. The employment agreement with each executive sets an initial base salary, which is competitive in our industry, given the executive s experience and qualifications, at the time we enter into the agreement. The committee annually reviews each executive officer s base salary. Among the factors taken into consideration are (1) individual and corporate performance, (2) levels of responsibility, (3) prior experience, (4) breadth of knowledge of the industry, and (5) competitive pay practices. If salaries at comparable companies appear to have increased, we recommend similar increases, but only if each executive s historical performance warrants an increase and if the increase is prudent in view of Palatin s financial condition.

Annual bonus. In addition to the competitive base salary, we intend to reward executives each year for the achievement of specific goals, which may be financial, operational or technological. We consider objectively measurable goals, such as obtaining new investment capital, negotiating valuable contracts, or meeting regulatory requirements, and more subjective goals, such as quality of management performance and consistency of effort. Palatin s objectives consist of operating, strategic and financial goals that the board considers to be critical to Palatin s overall goal of building stockholder value. Our recommendations for cash bonuses also take into account Palatin s liquidity and capital resources at the time. Until Palatin s operations generate substantial income, we may recommend bonuses which consist partly or mainly of stock options. Stock options granted as part of bonus compensation will usually be immediately exercisable, or will vest over a shorter time than other incentive options.

Long-term incentives. At present, Palatin s only long-term incentive programs are its 1996 stock option plan and 2005 stock plan. Palatin does not have a defined benefit pension plan, and contributions to executives accounts under Palatin s 401(K) plan are limited by federal tax regulations. Through option grants, executives receive significant equity incentives to build long-term stockholder value. The exercise price of options granted under the plan is at least 100% of fair market value of the common stock on the date of grant. Employees receive value from these grants only if the common stock appreciates over the long-term. We determine the size of option grants based on competitive practices at leading companies in the biotechnology industry and Palatin s philosophy of significantly linking executive compensation with stockholder interests.

Fiscal year 2005 compensation. During the fiscal year ended June 30, 2005, under employment agreements with Dr. Spana, Mr. Wills and Dr. Sharma, we provided for annual base salaries of $340,000 per year for Dr. Spana, $275,000 for Mr. Wills and $196,000 for Dr. Sharma. The base salaries for these executive officers, as provided in their employment agreements, reflect comparable salary figures for the industry, necessary to engage and retain individuals with their skills. In the fiscal year ended June 30, 2005, we approved stock option grants for these executive officers, subject to shareholder approval of additional shares under the 1996 Stock Option Plan. Such additional shares were not approved by the shareholders and the related option grants were cancelled. We granted cash bonuses to these executive officers in fiscal 2005 based on the attainment of important corporate objectives, including regulatory approval of one of our products and the completion of a collaborative development agreement for another of our products. Dr. Hallam entered into an employment agreement with us commencing May 9, 2005, which provided for base salary at the rate of $275,000 per year.

The base salary, bonus and grants of stock options for our chief executive officer, Carl Spana, Ph.D., were determined in accordance with the criteria described above under Determining executive compensation. Dr. Spana s

compensation reflects the board s subjective assessment of (1) his performance, (2) his skills in relation to other chief executive officers in Palatin s industry, and (3) the board s assessment of Palatin s performance.

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Considering these factors, the committee set Dr. Spana s base annual salary at $320,000 when we entered into our employment agreement with him effective October 1, 2003 and $340,000 for the fiscal year ended June 30, 2005.

Certain Tax Considerations. Section 162(m) of the Internal Revenue Code limits the Company to a deduction for federal income tax purposes of not more than $1 million of compensation paid to certain executive officers in a taxable year. Compensation above $1 million may be deducted if it is performance-based compensation within the meaning of the Code.

The committee believes that at the present time it is unlikely that the compensation paid to any executive officer in a taxable year will exceed $1 million. Therefore, the board has not established a policy for determining which forms of incentive compensation awarded to executive officers will be designed to qualify as performance based compensation.

SUBMITTED BY THE COMPENSATION COMMITTEE
Robert I. Taber, Ph.D. Chairman
Robert K. deVeer, Jr.
Zola P. Horovitz, Ph.D.
Errol De Souza, Ph.D.

STOCK PERFORMANCE GRAPH

The following graph compares the yearly change in the cumulative total shareholder return on our common stock with the cumulative total return on the Nasdaq Composite Index and the Nasdaq Biotechnology Index for the last five fiscal years, ending June 30, 2005. The graph assumes the investment of $100 in each stock or index on June 30, 2000, and the reinvestment of any dividends (we have never paid a dividend).

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STOCK OWNERSHIP INFORMATION

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

The rules of the SEC require us to disclose late filings of reports of stock ownership and changes in stock ownership by our directors and officers. To the best of our knowledge, all of the filings for our directors and officers were made on a timely basis in the fiscal year ended June 30, 2005 except for one report by Dr. Molinoff, relating to a grant of stock options, which was filed late.

BENEFICIAL OWNERSHIP OF MANAGEMENT AND OTHERS

The tables below show the beneficial stock ownership and voting power, as of October 14, 2005, of:

each director, each of the named officers, and all current directors and officers as a group; and

all persons who, to our knowledge, beneficially own more than five percent of the common stock or Series A preferred stock.

Beneficial ownership here means direct or indirect voting or investment power over outstanding stock and stock which a person has the right to acquire now or within 60 days after October 14, 2005. Please see the footnotes for more detailed explanations of the holdings. Except as otherwise noted, to our knowledge, the persons named in the tables beneficially own and have sole voting and investment power over all shares listed.

The common stock has one vote per share and the Series A preferred stock has approximately 38.46 votes per share. Voting power is calculated on the basis of the aggregate of common stock and Series A preferred stock outstanding as of October 14, 2005. On October 14, 2005, 58,770,737 shares of common stock and 11,347 shares of Series A preferred stock were outstanding.

The address for all members of our management is c/o Palatin Technologies, Inc., 4C Cedar Brook Drive, Cranbury, NJ 08512. Addresses of other beneficial owners are in the footnotes to the table of beneficial owners.

MANAGEMENT:

Class	Name of Beneficial Owner	Shares	Percent of Class	Percent of Voting Power
Common	Carl Spana, Ph.D.	939,385(1)	1.6%	*
Common	Stephen T. Wills	694,000(2)	1.2%	*
Common	Trevor C. Hallam	62,500(3)	*	*
Common	Shubh D. Sharma, Ph.D.	203,280(4)	*	*
Common	John K.A. Prendergast, Ph.D.	440,006(5)	*	*

Common	Perry B. Molinoff, M.D.	292,916(6)	*	*
Common	Robert K. deVeer, Jr.	223,773(7)	*	*
Common	Zola P. Horovitz, Ph.D.	118,333(8)	*	*
Common	Robert I. Taber, Ph.D.	113,333(9)	*	*
Common	Errol DeSouza, Ph.D.	64,583(10)	*	*
Common	J. Stanley Hull	11,061(11)	*	*

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Class	Name of Beneficial Owner	Shares	Percent of Class	Percent of Voting Power
Common	All current directors and executive officers as a group (eleven persons):	3,163,170(12)	5.1%	*

*Less than one percent.

(1) Includes 901,712 shares which Dr. Spana has the right to acquire under options.
(2) Includes 669,500 shares which Mr. Wills has the right to acquire under options.
(3) Includes 62,500 shares which Dr. Hallam has the right to acquire under options.
(4) Includes 203,265 shares which Dr. Sharma has the right to acquire under options.
(5) Includes 422,333 shares which Dr. Prendergast has the right to acquire under options.
(6) Includes 282,916 shares which Dr. Molinoff has the right to acquire under options.
(7) Includes 222,773 shares which Mr. deVeer has the right to acquire under options.
(8) Includes 113,333 shares which Dr. Horovitz has the right to acquire under options.
(9) Includes 108,333 shares which Dr. Taber has the right to acquire under options.
(10) Includes 64,583 shares which Dr. De Souza has the right to acquire under options.
(11) Includes 11,061 shares which Mr. Hull has the right to acquire under options.
(12) Includes 3,062,359 shares which directors and officers have the right to acquire under options.

5% OR GREATER BENEFICIAL OWNERS:

Class	Name of Beneficial Owner	Shares	Percent of Class	Percent of Voting Power
Common	King Pharmaceuticals, Inc. (1)	6,630,580(2)	11.1	9.6%

Common	ProQuest [3]	6,161,972[4]	10.3%	8.3%
Common	Lurie Investments [5]	4,285,984[6]	7.2%	6.0%
Series A Preferred	J.F. Shea Co., Inc. [7]	5,000	44.1%	*

*Less than one percent.

(1) Address is 501 Fifth Street, Bristol, TN 37620.
(2) Includes 955,119 shares which King has the right to acquire under warrants.
(3) Includes the ownership of ProQuest Investments, L.P., ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P. and ProQuest Companion Fund, L.P. ProQuest Associates LLC is the general partner of ProQuest Investments, L.P. and ProQuest Companion Fund, L.P. ProQuest Associates II LLC is the general partner of ProQuest Investments II, L.P. and ProQuest Investments II Advisors Fund, L.P. Address is 600 Alexander Park, Suite 204, Princeton, NJ 08540.
(4) Includes 1,232,395 shares which the ProQuest entities have the right to acquire under warrants.
(5) Includes the ownership of Lurie Investment Fund, LLC, ALFATECH, LLC, and WASK Investments, LLC. Mark Slezak is the investment manager for all three entities. Address is c/o Lurie Investments, 2 N. Riverside Plaza, Suite 1500, Chicago, IL 60606.
(6) Includes 766,197 shares which Lurie Investment Fund, LLC, ALFATECH, LLC, and WASK Investments, LLC have the right to acquire under warrants
(7) Address is 655 Brea Canyon Road, Walnut, CA 91789.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

John K.A. Prendergast, Ph.D. In July 2003, we entered into an employment agreement with Dr. Prendergast under which he serves as chairman of the board. During the fiscal year ended June 30, 2005, he received a salary of $50,000 per year. In addition, he may participate in all health benefit programs that we establish, to the extent that his position, tenure, salary, age, health and other qualifications make him eligible to participate.

Perry B. Molinoff, M.D. In November 2003, we entered into a consulting agreement with Dr. Molinoff under which we paid him $5,000 per month for consulting services. The consulting agreement expired in November 2004.

OTHER ITEMS OF BUSINESS

Other than the items of business discussed in this proxy statement, we are not aware of any matters that will come before the meeting. If other items of business properly come before the meeting, the proxy holders will vote shares in accordance with their judgment.

STOCKHOLDER PROPOSALS FOR NEXT ANNUAL MEETING

Stockholders may submit proposals on matters appropriate for stockholder action at annual meetings in accordance with regulations adopted by the SEC. To be considered for inclusion in the proxy statement and form of proxy relating to the next annual meeting of stockholders, such proposals must be received at our executive offices, 4C Cedar Brook Drive, Cranbury, NJ 08512, not later than July 1, 2006. Proposals should be directed to the attention of the Secretary.

For any proposal that is not submitted for inclusion in next year s proxy statement (as described in the preceding paragraph) but is instead sought to be presented directly at next year s annual meeting, SEC rules permit proxies to be voted at the discretion of the management if (a) we receive notice of the proposal before the close of business on September 17, 2006 and we advise stockholders in next year s proxy statement about the nature of the matter and how management intends to vote on such matter, or (b) we did not receive notice of the proposal prior to September 17, 2006.

ANNUAL REPORT ON FORM 10-K

Our annual report on Form 10-K for the fiscal year ended June 30, 2005, including the financial statements and schedules but excluding exhibits, is being sent with this proxy statement without charge to each person whose proxy is being solicited.

INFORMATION INCORPORATED BY REFERENCE

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act of 1933 or the Securities Exchange Act of 1934 that might incorporate this proxy statement in whole or in part, the audit committee report, the compensation committee report and the stock performance graph which follows the compensation committee report will not be deemed to be incorporated by reference into any such filing.

Your cooperation in giving this matter your immediate attention and returning your proxy card is greatly appreciated.

By order of the board of directors,
STEPHEN T. WILLS, *Secretary*
October 28, 2005

[proxy card front]

PALATIN TECHNOLOGIES, INC.

4C CEDAR BROOK DRIVE
CRANBURY, NEW JERSEY 08512

ANNUAL MEETING OF STOCKHOLDERS DECEMBER 2, 2005

THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS

The undersigned appoints Carl Spana, Ph.D. and Stephen T. Wills (each with full power to act without the other) as proxy holders with full power of substitution, to vote all shares of common stock and Series A Convertible Preferred Stock of Palatin Technologies, Inc., a Delaware corporation, held of record by the undersigned as of October 14, 2005 at Palatin s annual meeting of stockholders to be held Friday, December 2, 2005 and at any postponement or adjournment of the meeting.

(Continued and to be signed on reverse side)

[proxy card reverse]

ANNUAL MEETING OF STOCKHOLDERS OF

PALATIN TECHNOLOGIES, INC.

December 2, 2005

Please date, sign and mail
your proxy card in the
envelope provided as soon
as possible.

Please detach along perforated line and mail in the envelope provided.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE ELECTION OF DIRECTORS AND FOR PROPOSAL 2.
PLEASE SIGN, DATE AND RETURN PROMPTLY IN THE ENCLOSED ENVELOPE. PLEASE MARK YOUR VOTE IN BLUE OR BLACK INK AS SHOWN HERE x

1. Election of Directors:		2. To ratify the appointment of KPMG LLP as Palatin's independent auditors for the fiscal year ending June 30, 2006.	FOR	AGAINST	ABSTAIN
			o	o	o
	NOMINEES				
o FOR ALL NOMINEES	o Carl Spana, Ph.D. o John K.A. Prendergast, Ph.D. o Perry B. Molinoff, M.D. o Robert K. deVeer, Jr.	3. In their discretion, the proxy holders are authorized to vote upon such other matters as may properly come before the meeting or any postponement or adjournment of the meeting.	FOR	AGAINST	ABSTAIN
			o	o	o

o WITHHOLD AUTHORITY FOR ALL NOMINEES

o Zola P. Horovitz, Ph.D.
o Robert I. Taber, Ph.D.
o Errol De Souza, Ph.D.
o J. Stanley Hull

The proxy holders will vote the shares of the undersigned stockholder as instructed above. If no choice is specified by the stockholder, the proxy holders will vote the shares FOR proposals no. 1, 2 and 3 and on any other matter coming before the meeting in the discretion of the proxy holders.

o FOR ALL EXCEPT (See instructions below)

The undersigned revokes any proxy previously given to vote or act with respect to such shares and ratifies and confirms all actions which the proxy holders or their substitutes may lawfully do in accordance with the instructions on this proxy card.

Please complete, sign, date and return this proxy card in the enclosed envelope. No postage is required if mailed in the United States.

(**INSTRUCTION**: To withhold authority to vote for any individual nominee(s), mark "**FOR ALL EXCEPT**" and fill in the circle next to each nominee you wish to withhold, as shown here: n

To change the address on your account, please check the box at right and indicate your new address in the address space above. Please note that changes to the registered name(s) on the account may not be submitted via this method. o

Signature of stockholder	Date:	Signature of stockholder	Date:

NOTE: Please sign exactly as your name or names appear on this Proxy. When shares are held

jointly, each holder should sign. When signing as executor, administrator, attorney, trustee or guardian, please give full title as such. If the signer is a corporation, please sign full corporate name by duly authorized officer, giving full title as such. If signer is a partnership, please sign in partnership name by authorized person.