SAMPLE OPERATING COMPANY PPM EXCERPT

OPERATING COMPANY PPM EXCERPT

CAPITAL FUND LAW GROUP

INTRODUCTION

The Following is a concise model excerpt of a private placement memorandum (PPM) for an operating company (a single-entity issuer, rather than an investment fund). The PPM is based on a fictitious early stage New York medical device company raising series A financing for FDA approval and initial manufacturing.

Although the document is focused on a narrow industry, the excerpt illustrates the level of specificity that an operating company PPM should have, particular in its risk factors. Many issuers make the mistake of relying on template-driven boilerplate language that fails to identify risks and contingencies specific to the company's business and regulatory climate.

CAPITAL FUND LAW GROUP

Name: _____[1]

Copy No.: _____[2]

XYZ Medical, LLC

A NEW YORK LIMITED LIABILITY COMPANY

CONFIDENTIAL OFFERING MEMORANDUM[3]

(AN ILLUSTRATIVE EXCERPT)

January 1, 2015 [4]

Targeting up to 8,000,000 of

Class A Units ($1.00 per offered unit)

Offering Available Exclusively to Accredited Investors

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1 Issuers must carefully track the circulation of the PPM and the other offering documents to demonstrate that no advertising or general solicitation was used in the offering (when not relying on Rule 506(c). Additionally, tracking circulation of offering documents is essential to satisfy New York's pre-offer Regulation D filing requirement and to satisfy potential SEC or state audits. Beyond the regulatory requirements, as a practical matter it is important to know which version of an offering document was given to which investor, as modifications are common.

Each PPM should bear the name of the intended offeree and a unique identifying number. The fund manager should maintain a spreadsheet showing the name and number of each PPM distributed, together with the date of offer, the version of the document, and a description of any written information provided to the investor.

2 As noted above, each memorandum should be numbered, preferably non-sequentially.

3 This document is an illustrative excerpt of a private placement memorandum for a fictitious, New York-based medical device manufacturer raising series A financing for FDA approval and initial manufacturing.

4 Generally the date of a PPM does not reflect the date that the PPM was given to an investor, but the date on which the most recent version of the PPM was finalized. When material changes occur that affect the fund or its management, such changes should be reflected in an amended PPM and the date should be modified accordingly.

IMPORTANT GENERAL CONSIDERATIONS

This Private Placement Memorandum (this "*Memorandum*") relates to the private offering by XYZ Medical, LLC, a New York limited liability company ("*we*," "*us*," "*our*," or the "*Company*"), of up to $8,000,000 of its Class A Units (the "*Class A Units*") at a price per Class A Unit of $1.00 for a total offering price of $8,000,000, which will constitute equity ownership of thirty-five percent (35.00%) of the Company. The Class A Units are being offered on a "best efforts" basis by our Company.

These securities are speculative, and an investment in them involves a high degree of risk. See "*Risk Factors*" in this Memorandum beginning on page 10 for a discussion of some of the risks that you should consider before making an investment decision. No public market exists with respect to any of our securities, and none is expected to develop in the foreseeable future. You must be prepared to bear the economic risk of any investment for an indefinite period of time and be able to withstand a total loss of your investment.

The securities described in this Memorandum have not been registered with or approved by the U.S. Securities and Exchange Commission (the "*Commission*"), nor has the Commission or any applicable state or other jurisdiction's securities commission or other regulatory authority passed upon the accuracy or adequacy of this Memorandum or endorsed the merits of this offering (this "*Offering*"). Any representation to the contrary is unlawful. None of the securities may be resold, transferred, or otherwise disposed of unless the transaction effecting such disposition is registered under the U.S. Securities Act of 1933, as amended (the "*Securities Act*"), or an exemption therefrom is available and our Company receives an opinion of counsel acceptable to it that such registration is not required pursuant to such exemption. Each investor ("*Investor*") will sign an agreement that will contain representations, warranties, and covenants consistent with the foregoing.[5]

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5 This required disclosure informs investors that the notice filing of a Regulation D offering does not imply that the SEC or any state has sanctioned the offering. This seeks to clarify that the filing of a Form D notice filing does not involve government approval, as in the case of a public offering. New York requires a submittal of the offering in connection with the Form D notice filing prior to making an offering in the state but does not approve or disapprove the offering. Additionally, when a broker-dealer is used as a placement agent, the offering documents must be reviewed by FINRA.

We reserve the right to modify, amend, and/or withdraw all or any portion of this Offering, to accept subscriptions for part of the securities offered hereby and continue the Offering, to approve or disapprove each Investor, and to accept or reject any subscription in whole or in part in our sole discretion.

CONFIDENTIALITY NOTICE

This Memorandum and the materials accompanying this Memorandum contain confidential, proprietary, and nonpublic information, including without limitation, business plans, financial information, and data (collectively, the "*Information*") regarding our Company. Each recipient hereof agrees by accepting this Memorandum that the Information is of a confidential nature and that such recipient will treat the Information in a strictly confidential manner and that such recipient will not, directly or indirectly, disclose or permit such recipient's affiliates to disclose any Information to any other person or entity, or reproduce the Information, in whole or in part, without the Company's prior written consent. The recipient of this Memorandum further agrees to use the Information solely for the purpose of analyzing the desirability of a purchase of Class A Units of our Company and for no other purpose whatsoever. The recipient hereof agrees not to use the Information in any way that is harmful to or competitive with us or our affiliates. The recipient of this Memorandum agrees to return it and the related documentation if the recipient does not commit to purchase Class A Units of our Company in this Offering.

THESE ARE SPECULATIVE SECURITIES WHICH INVOLVE A HIGH DEGREE OF RISK. ONLY THOSE INVESTORS WHO CAN BEAR THE LOSS OF THEIR ENTIRE INVESTMENT SHOULD INVEST IN THESE CLASS A UNITS.

THIS OFFERING IS NOT UNDERWRITTEN. THE OFFERING PRICE HAS BEEN ARBITRARILY SET BY THE MANAGEMENT OF THE COMPANY. THERE CAN BE NO ASSURANCE THAT ANY OF THE SECURITIES WILL BE SOLD.

THE SECURITIES DESCRIBED HEREIN HAVE NOT BEEN REGISTERED PURSUANT TO THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), NOR UNDER THE SECURITIES ACTS OF NEW YORK OR OTHER STATES. THIS OFFERING IS MADE UNDER RULE 506 OF REGULATION D OF THE SECURITIES ACT AND AS ENACTED BY THE SECURITIES AND EXCHANGE COMMISSION UNDER THE SECURITIES ACT, AS WELL AS OTHER EXEMPTIONS FROM REGISTRATION REQUIREMENTS, INCLUDING SECTION 4(a)(2) OF THE SECURITIES ACT.

These materials are for the personal use of the Offeree whose name appears above and are not to be transferred or electronically forwarded to any other person.

IMPORTANT SECURITIES LAW NOTICES

THIS OFFERING IS BEING MADE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION FOR AN OFFER AND SALE OF CLASS A UNITS WHICH DOES NOT INVOLVE A PUBLIC OFFERING. EACH PURCHASER OF CLASS A UNITS OF OUR COMPANY OFFERED HEREBY, IN MAKING A PURCHASE, WILL BE DEEMED TO HAVE MADE CERTAIN ACKNOWLEDGMENTS, REPRESENTATIONS, AND AGREEMENTS AS SET FORTH HEREIN.

THE PURCHASE OF CLASS A UNITS OF OUR COMPANY OFFERED HEREBY INVOLVES A HIGH DEGREE OF RISK AND SHOULD BE CONSIDERED ONLY BY PERSONS WHO ARE ABLE TO SUSTAIN A TOTAL LOSS OF THEIR PURCHASE. PROSPECTIVE INVESTORS SHOULD CAREFULLY CONSIDER THE "RISK FACTORS" CONTAINED HEREIN.

WE HAVE THE UNCONDITIONAL RIGHT TO ACCEPT OR REJECT ANY PURCHASE, IN WHOLE OR IN PART, FOR ANY REASON OR WITHOUT A SPECIFIC REASON, IN OUR SOLE AND ABSOLUTE DISCRETION (EVEN AFTER RECEIPT AND CLEARANCE OF SUCH INVESTOR'S FUNDS).

NO PERSON HAS BEEN AUTHORIZED TO PROVIDE ANY INFORMATION WITH RESPECT TO OUR CLASS A UNITS, OUR COMPANY, OR OUR AFFILIATES EXCEPT FOR THE INFORMATION CONTAINED HEREIN. RECIPIENTS SHOULD NOT RELY ON ANY MATERIALS OTHER THAN AS SET FORTH HEREIN.[6] THE INFORMATION CONTAINS DESCRIPTIONS AND OTHER MATTERS AS OF THE DATE OF THIS MEMORANDUM. NEITHER WE NOR ANY OTHER PERSON OR ENTITY IS UNDER ANY OBLIGATION TO UPDATE OR OTHERWISE REVISE THE INFORMATION FOLLOWING ITS DISTRIBUTION, AND RECIPIENTS SHOULD NOT EXPECT ANY SUCH UPDATE OR REVISION. RECIPIENTS ARE URGED TO CONDUCT AN INDEPENDENT INVESTIGATION AND EVALUATION OF OUR COMPANY BEFORE CHOOSING TO PURCHASE CLASS A UNITS OF THE COMPANY.

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6 While this clause attempts to mitigate statements conflicting with the PPM by telling the investors they may not rely upon them, the effectiveness of such language in a court proceeding is uncertain. Any statement made by a representative of a hedge fund to a prospective investor concerning the offering, whether verbal or written, has the potential to be construed as a representation, warranty, or material misstatement.

Issuers need to be just as careful when crafting statements in marketing material, presentations and email as they would be when making disclosures in the PPM. Experienced legal counsel should review all marketing material prior to circulation. Marketing material should bear legends instructing investors to make investment decisions based on the PPM.

THE INFORMATION CONTAINED HEREIN HAS BEEN PROVIDED BY US AND OTHER SOURCES IDENTIFIED HEREIN, BUT THERE CAN BE NO ASSURANCE AS TO THE ACCURACY OR COMPLETENESS OF SUCH INFORMATION. EACH PROSPECTIVE INVESTOR OF CLASS A UNITS OF OUR COMPANY MUST COMPLY WITH ALL APPLICABLE LAWS AND REGULATIONS IN FORCE IN ANY JURISDICTION IN CONNECTION WITH THE SUBSEQUENT OFFER OR SALE OF CLASS A UNITS PURCHASED PURSUANT TO THIS MEMORANDUM. IN MAKING A PURCHASE DECISION, PROSPECTIVE INVESTORS MUST RELY ON THEIR OWN EXAMINATION OF US AND THE TERMS OF THIS OFFERING, INCLUDING THE MERITS OF THE PURCHASE AND THE RISKS INVOLVED. THE CONTENTS OF THIS MEMORANDUM ARE NOT TO BE CONSTRUED AS LEGAL, BUSINESS, OR TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT AN ATTORNEY, BUSINESS ADVISOR, AND/OR TAX ADVISOR, AS APPLICABLE, AS TO LEGAL, BUSINESS, OR TAX ADVICE.

THIS MEMORANDUM CONTAINS SUMMARIES BELIEVED TO BE ACCURATE IN ALL MATERIAL RESPECTS AS TO THE TERMS OF CERTAIN DOCUMENTS DESCRIBED HEREIN, BUT REFERENCE IS HEREBY MADE TO THE ACTUAL DOCUMENTS (COPIES OF WHICH WILL BE MADE AVAILABLE TO PROSPECTIVE INVESTORS UPON REASONABLE REQUEST) FOR COMPLETE INFORMATION WITH RESPECT THERETO, AND ALL SUCH SUMMARIES ARE QUALIFIED IN THEIR ENTIRETY BY SUCH REFERENCE.

THIS OFFERING CAN BE WITHDRAWN AT ANY TIME BEFORE CLOSING AND IS SPECIFICALLY MADE SUBJECT TO THE TERMS DESCRIBED IN THIS MEMORANDUM.

THE CLASS A UNITS OF THE COMPANY OFFERED HEREBY WILL BE SOLD SUBJECT TO THE SUBSCRIPTION AGREEMENT AND OTHER PURCHASE DOCUMENTATION BEING DELIVERED WITH THIS MEMORANDUM, WHICH CONTAIN CERTAIN REPRESENTATIONS, WARRANTIES, TERMS, AND CONDITIONS. EACH INVESTOR SHOULD CAREFULLY REVIEW THE PROVISIONS OF SUCH DOCUMENTATION BEFORE PURCHASING.

THE DELIVERY OF THIS MEMORANDUM TO A POTENTIAL INVESTOR SHALL NOT UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS NOT BEEN ANY CHANGE IN OUR AFFAIRS SINCE THE DATE HEREOF. WE WILL MAKE AVAILABLE TO ANY PROSPECTIVE QUALIFIED INVESTOR THE OPPORTUNITY TO ASK QUESTIONS OF AND RECEIVE ANSWERS FROM US CONCERNING THE TERMS AND CONDITIONS OF THE OFFERING AND THE BUSINESS AND OPERATIONS OF OUR COMPANY.

NOTE ON FORWARD-LOOKING STATEMENTS

This Memorandum contains forward-looking statements concerning our plans, intentions, strategies, expectations and predictions concerning our future activities and results of operations and other future events or conditions. For this purpose, any statements contained in this Memorandum that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements generally can be identified by the use of forward-looking terminology such as "believe," "may," "will," "could," "intend," "estimate," "might," or "continue" or the negative or other variations of these words or comparable terminology.

A variety of factors could cause actual results or activities or actual events or conditions to differ materially from those estimated or projected in the forward-looking statements. Some of these factors may be beyond our control. The plans, strategies, and intentions of management may change based upon increased experience with our business model, as well as in response to competition, general economic trends, or perceived opportunities, risks, or other developments. Important factors that could cause actual results to differ materially from our expectations are disclosed under the caption "*Risk Factors*," below.[7]

Projections concerning our future results of operations and expansion plans are based on a number of assumptions and estimates made by management. To the extent that actual events differ materially from these assumptions and estimates, actual results will differ from those projected. See "*Risk Factors*," below.

[End of section excerpt. This section has been significantly shortened for use in this sample.]

7 A key concept of a securities offering document is to include multiple references to important information or key risks. When a discussed topic can be found in greater detail elsewhere in the PPM, a cross-reference to the specific section should be included.

THE OFFERING

The following statements related to the Class A Units offered hereby are summaries, do not purport to be complete, and are subject to and qualified in their entirety by reference to all of the provisions contained elsewhere in this Memorandum or to the other documents referenced in this Memorandum.[8]

Issuer:	XYZ Medical, LLC is a New York limited liability company, which is treated as a partnership for tax purposes.
Amount of Financing and Related Matters:	Targeting up to 8,000,000 of Class A Units which will be approximately thirty-five percent (35.00%) of the equity in the Company. The Company anticipates that multiple closings will occur beginning on or after the date of this Memorandum and ceasing upon raising $8,000,000 or at the discretion of the Company, whichever is earlier. The Company may, in its sole discretion, determine when to cause such multiple closings for the Class A Units to occur (each of such dates, as applicable, a "*Closing Date*").
Type of Security:	Class A Units.
Managers:	Our Company will be managed by a Board of Managers elected by our current members ("*Managers*"), and discussed in "*Our Management*" section of the Memorandum. The Managers may be changed from time to time according to the provisions of our Operating Agreement.

8 The summary of terms provides highlights of the key components of the offering, the equity structure, and key investment terms. Each of these items would be dealt with in detail in the body of a typical PPM. For purposes of this excerpt, we have necessarily shortened the summary of terms to include only a few key provisions. Notably, we have not included information summarizing the fictitious investment company's management, business and technology.

Capitalization:	See "*Capitalization and Indebtedness*," below.
Investors; Minimum Investment:	Investors must be "accredited investors" as that term is defined in Rule 501 of Regulation D of the Securities Act. The minimum investment shall be equal to $100,000 provided that the Company may, in its sole discretion, accept commitments of lesser amounts for Class A Units.
Operating Agreement:	As a condition of purchasing Class A Units, the Company and each of its members (including Investors of the Class A Units) will sign a counterpart to the Company's Operating Agreement (our "*Operating Agreement*") that, among other things, will (i) set forth the profit and loss allocations and distributions to all members, (ii) prohibit transfers of Class A Units or withdrawals by holders of Class A Units and (iii) describe the economic rights of each class of members, unless certain requirements are met. See "***EXHIBIT A*** – Operating Agreement." [9]
Subscriptions:	Class A Units can be subscribed for by completing a Subscription Agreement and executing a counterpart signature page to our Operating Agreement. Once a Subscription Agreement is submitted to and accepted by us, such Investor will be bound by the terms

9 It is vital that the PPM properly reflect the underlying governing documents (in this case, the operating agreement). In performing offering document reviews from prior drafters, we often discover significant discrepancies between the summarized terms of the PPM and the actual terms of the governing documents. One reason for this is that many view the PPM as the primary offering document, to which an operating agreement may be quickly conformed.

It is important to understand the distinction between the functions of the PPM versus that of the governing documents and subscription agreement. The PPM is not a binding contractual document, but a disclosure of the terms and risks of investment in the company and a summary of the binding terms in the governing documents and subscription agreement.

of such Subscription Agreement and our Operating Agreement effective as of the next applicable closing date. Our Manager and any of their respective affiliates may purchase Class A Units in this Offering.

Fiscal Year:

Our fiscal year will end on December 31st of each year.

Additional Capital Commitments or Contributions:

No Investor shall be required to make, or shall be subject to assessment for, any additional capital contributions to our Company. *See "Anti-Dilution Rights" below*.

Allocations and Distributions of Profits and Losses:

Allocations and Distributions from Operations. In general, Investors will be entitled to receive allocations and distributions of profits and losses in our Company as follows, and in the following order:

(i) First, to Class A Unit holders in proportion to their membership interest in the company;

(ii) Then, to common unit holders in proportion to their membership interest in the Company.

Distributions will be made based on the amount of "net available cash flow" as such amount is determined by our Managers from time to time. Allocations and distributions are more particularly described in our Operating Agreement attached as ***EXHIBIT A***.

Minimum Tax Distributions. Notwithstanding the foregoing, our Operating Agreement provides for tax distributions to our members on not less than an annual basis; *provided, however,* there is no guarantee that our Company will have sufficient net available cash flow to make such distributions. Any such tax distribution shall be considered an advance against

	the next distribution(s) payable to the applicable holder of membership interest units and shall reduce such distribution(s) on a dollar-for-dollar basis.
Liquidation:	Liquidation. In the event we are sold, merged, acquired, liquidated, dissolved or wound up, the holders of Class A Units will be entitled to a distribution of assets remaining after the payment of all expenses and costs to our creditors, to all holders of Class A Units, in accordance with the holders of Units' positive capital account balances. In this regard, the capital account balances of all holders of Class A Units shall be determined after taking into consideration the allocation of all profits and losses, including profits and losses accrued or incurred during winding up, in accordance with the requirements of our articles of organization, Operating Agreement and the New York Limited Liability Company Law. This distribution of Company assets will be made prior to any liquidating distribution to the holders of Common Units.
Transfer Restrictions; No Withdrawal Rights:	Transfer of our Class A Units is restricted by the terms of our Operating Agreement, and generally may not be effected except for: (i) lifetime or testamentary transfers by a member of all or any portion of his or her Class A Units to or for the benefit of his or her family or descendants (or a trust or other entity for the benefit of same); and (ii) transfers following compliance with the right of first refusal procedures set forth in our Operating Agreement in favor of the Company and the other members. Members are not permitted to withdraw from our Company without the approval of our Managers, which may be granted or denied in the sole discretion of our Managers.

	The Class A Units are "restricted securities" and, therefore, may be transferred only pursuant to registration or qualification under federal and state securities laws or under an exemption from such registration or qualification requirements.
No Participation in Management or Voting Rights:	Our Company is managed by our Managers; thus, holders of Class A Units will have no right to participate in the management of the Company. Our Class A Units are voting membership interest units. Investors will receive voting rights equal to their equity interest in the Company. However, because the Class A Units being offered comprise only 35% of the total equity of the Company, Investors will not be able to change, control, or participate in the management of the Company or affairs of the business.
No Registration Rights:	We will not grant any registration rights to any purchasers of the Class A Units in this Offering.
No Anti-Dilution Rights:	Holders of our Class A Units will not be entitled to any preference to purchase additional Class A or other membership interest units in the Company in the event of additional equity securities offerings.
Use of Proceeds:	After deducting offering expenses, we intend to use the proceeds of this Offering to acquire additional technologies, pay salaries of officers, executives, and employees and conduct clinical trials, expand research and development capabilities and for general working capital purposes. See "*Use of Proceeds*" below.

[End of section excert; this section has been significantly shortened for use in this sample.]

RISK FACTORS[10]

The purchase of the Class A Units entails certain risks that Investors should consider before making a decision to purchase the Class A Units. There can be no assurance that any rate of return or other investment objectives will be realized or that there will be any return of capital. Prospective Investors should consider the following factors among others in making their investment decision. [11]

Risks Related to Our Business

Our Company has limited operating history and was recently formed.

The Company is newly formed, and therefore, has limited operating history. There is no assurance that the Company will operate profitability or that your investment in whole or in part will be returned. The Company is subject to all the risks inherent in the establishment of a new business venture. The likelihood of success of the Company must be considered in light of the problems, expenses, difficulties, complications, uncertainties and delays frequently encountered with the formation of any new business. XYZ Medical, LLC, was established in 2015 and has been focused on raising capital and developing its medical device products to market. Because the company is new, with limited operating history, there is no assurance that XYZ Medical, LLC, will realize earnings from operations or net profits in the future.

Our products have yet to be commercialized.

Because of the novelty of the Company's medical device technology, there is no way to predict all of the risks associated with this unique venture. The Company may not generate sufficient sales proceeds to pay all of its research, development, marketing, manufacturing and operating expenses, taxes, and debt service requirements. There is no assurance that we will generate any cash flow.

Our products may not achieve broad market acceptance or be commercially successful.

We expect that sales of our devices will account for the vast majority of our revenues for at least

10 The risk factor section is one of the most valuable components of a private placement memorandum for liability mitigation. Risk factors should be one of the first sections in a private placement memorandum. This section is usually quite voluminous, often spanning dozens of pages, and covering many subcategories, with disclosures ranging from broad and generic risks to highly. In this illustrative excerpt, we have provided two of the many risk factor categories (which have been shortened considerably for this excerpt).

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the next several years. The products we intend to develop may not gain broad market acceptance unless we are able to convince physicians, hospitals and patients of their benefits. Moreover, even if physicians and hospitals understand the benefits of any of our products, they still may elect not to use our products for a variety of reasons.

We have limited internal manufacturing resources, and if we are unable to provide an adequate supply of our products, our growth could be limited and our business could be harmed.

Final assembly of many of our product components is expected to occur at our manufacturing facility. If our facility experiences a disruption or if we are unable to make our lease payments, we would have no other means of assembling those components until we are able to restore the manufacturing capability at our current facility or develop the same capability at an alternative facility.

In connection with the commercialization of our products, we expect that we will need to increase, or "scale up," the production process of our components over the anticipated initial level of production. While we have taken steps in anticipation of growth, manufacturers often encounter difficulties in scaling up production, such as problems involving yields, quality control and assurance, and shortages of qualified personnel. If the scaled-up production process is not efficient or produces a product that does not meet quality and other standards, we may be unable to meet market demand and our revenues, business and financial prospects would be adversely affected.

Our reliance on single-source suppliers could harm our ability to meet demand for our products in a timely manner or within budget.[12]

Many of the components and component assemblies of our products are anticipated to be provided to us by single-source suppliers. We expect to purchase components and component assemblies through purchase orders, rather than long-term supply agreements and generally will not maintain large volumes of inventory. While we believe alternative suppliers exist and will be identified, the disruption or termination of the supply of components and component assemblies could cause a significant increase in the cost of these components, which could affect our operating results.

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12 When disclosing business risks, issuers are often tempted to add mitigating language explaining why their business has a high probability of avoiding a disclosed risk. Such risk factor clauses are simple to identify: They often begin with "while," "though" or "however." SEC releases have given specific guidance to avoid mitigating language in risk factors. Risk factors should be limited to identification and brief description of material risks.

That is not to say disclosure of mitigating strategies should not be discussed in the PPM, but the language should not appear in the risk factors. The appropriate place to elaborate on risk mitigation strategies is the business and management sections.

Our anticipated dependence on a limited number of third-party suppliers and the challenges we may face in obtaining adequate supplies involve several risks, including limited control over pricing, availability, quality and delivery schedules. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the supplier of a key component or component assembly of our products, we may be required to verify that the new supplier maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new supplier could delay our ability to manufacture our products in a timely manner or within budget.

Our future success depends on our ability to obtain regulatory clearances or approvals for our products. We cannot be certain that we will be able to do so in a timely fashion, or at all.[13]

We do not have the necessary regulatory clearances or approvals to market our devices in the United States or in any foreign market. In the United States, without clearances or approvals from the Food and Drug Administration ("FDA"), we cannot market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, unless an exemption applies. To obtain FDA clearance or approval, we must first receive premarket clearance under Section 510(k) of the federal Food, Drug, and Cosmetic Act.

In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology, safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The 510(k) clearance process generally takes three to twelve months from submission, but can take significantly longer.

The process of obtaining PMA approval is much more costly and uncertain than the 510(k) clearance process. The PMA approval process can be lengthy and expensive and requires an applicant to demonstrate the safety and effectiveness of the devices based, in part, on data obtained in clinical trials. The PMA process generally takes one to three years, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained.

If the third-parties on which we may need to rely to conduct any clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for our products or any additional claims that we may seek for our products.

13 Proper risk factor disclosure is at the heart of a well-drafted PPM. Risk factors should be specific, relevant to the investment strategy and management background, and thorough. Inadequate attention to risk factors (or relying on boilerplate risk factors) can be problematic.

We do not have the independent ability to conduct pre-clinical and clinical trials. To the extent that we will need to conduct such trials, we will need to 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 regulatory clearance or approval for a product candidate or additional claims we may seek for our products on a timely basis, if at all. As such, 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 clinical trials may not support our product candidate claims or any additional claims we may seek for our products and may result in the discovery of adverse side effects.[14]

Even if any clinical trial that we need to undertake is completed as planned, we cannot be certain that its results will support our product candidate claims or any new indications that we may seek for our products or that the FDA or foreign authorities will agree with our conclusions regarding the results of those trials. The clinical trial process may fail to demonstrate that our products or a product candidate is safe and effective for the proposed indicated use, which could cause us to stop seeking additional clearances or approvals for our products, abandon the devices, or delay development of other product candidates. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize a product candidate. 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.

We could become subject to product liability claims that could be expensive, divert management's attention and harm our business.

Our business exposes us to potential product liability risks that are inherent in the development, manufacturing, marketing and sale of medical devices. We may be held liable if our products cause injury or death or are found otherwise unsuitable or defective during usage. Our products incorporate mechanical and electrical parts, complex computer software and other sophisticated components, any of which can have defective or inferior parts or contain defects, errors or failures. Complex computer software is particularly vulnerable to errors and failures, especially when first introduced.

14 Proper risk factor disclosure is at the heart of a well-drafted PPM. Risk factors should be specific, relevant to the investment strategy and management background, and thorough. Inadequate attention to risk factors (or relying on boilerplate risk factors) can be problematic.

The medical device industry has historically been subject to extensive litigation over product liability claims. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Although we intend to maintain product liability insurance, the coverage is subject to deductibles and limitations, and may not be adequate to cover future claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or in adequate amounts. A product liability claim, regardless of its merit or eventual outcome could result in: decreased demand for our products; injury to our reputation;

We may not be able to operate if there are certain changed events.

Unexpected negative events concerning either the intellectual property, product to be developed, or the economy in general could alter investment conditions to the extent that dilution of existing investors is required in order to raise necessary capital. While the officers have the right to loan additional capital to the Company, the officers may not be in a position to do so. In such event, there can be no assurance that the current management team would remain in place or that the Company's business plan would not materially change as a result of a shift in control.

Any adverse change in general economic conditions, significant price increases, or adverse occurrences affecting our industry, could have a material adverse effect on us and the results of our operations.

Our Managers may allocate their time to other businesses thereby causing conflicts of interest in its determination as to how much time to devote to the Company's affairs.

The Managers may be engaged in other business endeavors and are not obligated to contribute any specific number of hours per week to the Company's affairs. If the other business affairs of our Managers require them to devote more substantial amounts of time to such affairs, it could limit their ability to devote time to the affairs of the Company, which could have a negative impact on our ability to operate efficiently.

Risks Related to our Intellectual Property

If we, or the third-parties from whom we license intellectual property, are unable to secure and maintain patent or other intellectual property protection for the intellectual property covering our marketed products or our product candidates, our ability to compete will be harmed.

Our commercial success depends, in part, on obtaining and maintaining patent and other intellectual property protection for the technologies contained in our marketed products and product candidates. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Our patent position is uncertain and complex, in part, because of our dependence on intellectual property that we

license from others. If we, or the third-parties from whom we license intellectual property, fail to obtain adequate patent or other intellectual property protection for intellectual property covering our marketed products or product candidates, or if any protection is reduced or eliminated, others could use the intellectual property covering our marketed products or product candidates, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or have rights to.

United States patents and patent applications may be subject to interference proceedings and United States patents may be subject to reissue and reexamination proceedings in the United States Patent and Trademark Office. Any of these proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, reexamination and opposition proceedings may be costly and time consuming, and we, or the third-parties from whom we license intellectual property, may be unsuccessful in such proceedings. Thus, any patents that we license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may not result in patents being issued or may have claims that do not cover our products or product candidates. Even if any of our pending or future patent applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. In addition, many countries limit the enforceability of patents against third-parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical devices and procedures.

We may face claims that we are violating the intellectual property rights of others.

Although we are not aware of any potential violations of others' intellectual property rights, we may face claims, including from direct competitors, other companies, scientists or research universities, asserting that our technology or the commercial use of such technology infringes or otherwise violates the intellectual property rights of others.

We cannot be certain that our technologies and processes do not violate the intellectual property rights of others. If we are successful in developing technologies that allow us to earn revenues and our market profile grows we could become increasingly subject to such claims.

We may also face infringement claims from the employees, consultants, agents and outside organizations we have engaged to develop our technology. While we have sought to protect ourselves against such claims through contractual means, we cannot provide any assurance that such contractual provisions are adequate, and any of these parties might claim full or partial ownership of the intellectual property in the technology that they were engaged to develop.

If we were found to be infringing or otherwise violating the intellectual property rights of others, we could face significant costs to implement work-around methods, and we cannot provide any assurance that any such work-around would be available or technically equivalent to our potential technology. In such cases, we might need to license a third-party's intellectual property, although any required license might not be available on acceptable terms, or at all. If we are unable to work around such infringement or obtain a license on acceptable terms, we might face substantial monetary judgments against us or an injunction against continuing to use or license such technology, which might cause us to cease operations.

In addition, even if we are not infringing or otherwise violating the intellectual property rights of others, we could nonetheless incur substantial costs in defending ourselves in suits brought against us for alleged infringement. Also, if we are to enter into a license agreement in the future and it provides that we will defend and indemnify our customer licensees for claims against them relating to any alleged infringement of the intellectual property rights of third-parties in connection with such customer licensees' use of such technologies, we may incur substantial costs defending and indemnifying any customer licensees to the extent they are subject to these types of claims. Such suits, even if without merit, would likely require our management team to dedicate substantial time to addressing the issues presented. Any party bringing claims might have greater resources than we do, which could potentially lead to us settling claims against which we might otherwise prevail on the merits.

Any claims brought against us or any customer licensees alleging that we have violated the intellectual property of others could have negative consequences for our financial condition, results of operations and business, each of which could be materially adversely affected as a result.

Protecting and enforcing our intellectual property rights could consume monetary funds needed for other company objectives.

Protecting and enforcing our intellectual property rights and combating unlicensed copying and use of our intellectual property can be difficult and expensive. Litigation filed by or against the Company and excessive legal costs could result in insufficient cash available to continue our business objective. Similarly, reductions in the legal protection for our intellectual property rights could adversely affect revenue.

[End of illustrative excerpt; this section has been significantly shortened for use in this sample.]