CEL SCI CORP
Form 424B5
February 17, 2017

PROSPECTUS SUPPLEMENT	Filed pursuant to Rule 424(b)(5)
(To Prospectus dated October 30, 2015)	Registration No. 333-205444

CEL-SCI CORPORATION
Up to 10,000,000 Shares of Common Stock

We are offering an aggregate of 10,000,000 shares of common stock, $0.01 par value per share, directly to the investors in this offering at a price of $0.10 per share. In a concurrent private placement, we are also selling to investors a warrant (Series GG) to purchase one share of common stock for each share of common stock purchased for cash in this offering. The warrants will be exercisable beginning on the six-month anniversary of the date of issuance, at an exercise price of $0.12 per share and will expire on the five and a half year anniversary of the initial issuance date. The warrants and the common stock issuable upon the exercise of the warrants are not being registered under the Securities Act of 1933, as amended, or the Securities Act, pursuant to the registration statement of which this prospectus supplement and the accompanying base prospectus form a part and are not being offered pursuant to this prospectus supplement and the accompanying base prospectus. The warrants and the common stock issuable upon the exercise of the warrants are being offered pursuant to an exemption from the registration requirement of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Rule 506(c) of Regulation D.

Our common stock is currently traded on the NYSE MKT under the symbol “CVM.” On February 16, 2017, the closing price of our common stock on the NYSE MKT was $0.12 per share. The aggregate market value of our outstanding voting common stock held by non-affiliates, based upon a closing sale price of our common stock on February 16, 2017 ($0.12) was $20,458,000. During the 12 calendar month period that ends on, and includes, the date of this prospectus supplement, we have offered $1.0 million of securities pursuant to General Instruction I.B.6. of Form S-3. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of the aggregate market value of the voting and non-voting common equity in any 12 month period so long as our public float remains below $75 million.

An investment in our common stock involves a high degree of risk. See “Risk Factors” beginning on page S-15 of this Prospectus Supplement, the Risk Factors in the accompanying Prospectus and the risks set forth under the caption “Item 1A. Risk Factors” included in our most recent Annual Report on Form 10-K and 10 K/A, which is incorporated by reference herein, for a discussion of information that should be considered in connection with an investment in our securities.

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

We have retained H.C. Wainwright & Co., LLC to act as exclusive placement agent in connection with this offering to use its “reasonable best efforts” to solicit offers to purchase our common shares. The placement agent is not purchasing or selling any of our common shares offered pursuant to this prospectus supplement or the accompanying prospectus. See “Plan of Distribution” beginning on page S-58 of this prospectus supplement for more information regarding these arrangements.

	Offering Price	Placement Agent’s Fees	Proceeds, Before
Per Share	$0.10	$0.007	$0.093

Total (1)	$1,000,000	$70,000(2)	$930,000(3)

(1)
Assumes the sale of the maximum amount of securities being offered. Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us.

(2)
In addition, we have agreed to reimburse the placement agent for certain expenses and to issue to the placement agent warrants to purchase 500,000 shares of our common stock, at an exercise price of $0.125 per share. See “Plan of Distribution” beginning on page S-58 for a complete description of commissions, compensation and fees payable to the placement agent.

(3)
The amount of the offering proceeds to us presented in this table does not give effect to any exercise of the warrants (Series GG) being issued in the concurrent private placement.

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We anticipate delivery of the shares will be made on or about February 23, 2017, subject to customary closing conditions.

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Exclusive Placement Agent
Rodman& Renshaw
a unit of H.C. Wainwright & Co.

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Prospectus Supplement

PROSPECTUS

You should rely only on the information contained in this prospectus supplement and the accompanying prospectus, any document incorporated or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we may prepare in connection with this offering. Neither we nor the placement agent has authorized anyone to provide you with any additional or different information. If anyone provides you with any additional or different information, you should not rely on it. Neither this prospectus supplement nor the accompanying prospectus, nor any such free writing prospectus, is an offer to sell or a solicitation of an offer to buy any securities other than the securities to which it relates, or an offer to sell or the solicitation of an offer to buy securities in any jurisdiction where, or to any person to whom, it is unlawful to make an offer or solicitation. You should not assume that the information contained in this prospectus supplement, the accompanying prospectus, any document incorporated or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus, or any free writing prospectus that we may prepare in connection with this offering is correct on any date after their respective dates. Our business, financial condition, liquidity, results of operations and prospects may have changed since those respective dates.

ABOUT THIS PROSPECTUS SUPPLEMENT

This document forms part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration process. This document is in two parts. The first part consists of this prospectus supplement, including the documents incorporated by reference herein, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference therein, provides more general information. We urge you to carefully read this prospectus supplement and the accompanying prospectus, and the documents incorporated herein and therein, before buying any of the securities being offered by this prospectus supplement and the accompanying prospectus. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement that we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference therein. In addition, any statement in a filing we make with the SEC that adds to, updates or changes information contained in an earlier filing we made with the SEC shall be deemed to modify and supersede such information in the earlier filing.

This prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein and therein, may include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

In this prospectus supplement, unless otherwise specified or the context requires otherwise, we use the terms “CEL-SCI,” the “Company,” “we,” “us” and “our” to refer to CEL-SCI Corporation. Our fiscal year ends on September 30.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. To fully understand this offering and its consequences to you, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the information referred to under the heading "Risk Factors" in this prospectus supplement and the accompanying prospectus, the financial statements and other information incorporated by reference in this prospectus supplement and the accompanying prospectus when making an investment decision.

Our Company

We are dedicated to research and development directed at improving the treatment of cancer and other diseases by using the immune system, the body's natural defense system. We are currently focused on the development of the following product candidates and technologies:

1)
Multikine® (Leukocyte Interleukin, Injection), or Multikine, an investigational immunotherapy under development for the potential treatment of certain head and neck cancers, and anal warts or cervical dysplasia in human immunodeficiency virus, or HIV, and human papillomavirus, or HPV co-infected patients;

2)
L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology, or LEAPS, with two investigational therapies, LEAPS-H1N1-DC, a product candidate under development for the potential treatment of pandemic influenza in hospitalized patients, and CEL-2000 and CEL-4000, vaccine product candidates under development for the potential treatment of rheumatoid arthritis.

The following chart depicts our product candidates, their indications and their current stage of development:

MULTIKINE

Our lead investigational therapy, Multikine, is currently being developed as a potential therapeutic agent directed at using the immune system to produce an anti-tumor immune response. Data from Phase 1 and Phase 2 clinical trials suggest that Multikine simulates the activities of a healthy person's immune system, enabling it to use the body's own anti-tumor immune response. Multikine is the trademark we have registered for this investigational therapy, and this proprietary name is subject to review by the U.S. Food and Drug Administration, or FDA, in connection with our future anticipated regulatory submission for approval. Multikine has not been licensed or approved for sale, barter or exchange by the FDA or any other regulatory agency, such as the European Medicine Agency, or EMA. Neither has its safety or efficacy been established for any use.

Multikine is an immunotherapy product candidate comprised of a patented defined mixture of 14 human natural cytokines and is manufactured in a proprietary manner in our manufacturing facility. We spent over 10 years and more than $80 million developing and validating the manufacturing process for Multikine. The pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors, which contain elements of the body's natural mix of defenses against cancer.

Multikine is designed to be used in a different way than immune therapy is normally used. It is designed to be administered locally to treat local tumors before any other therapy has been administered. For example, in the Phase 3 clinical trial, Multikine is injected locally at the site of the tumor and near the adjacent draining lymph nodes as a first line of treatment before surgery, radiation and/or chemotherapy because that is when the immune system is thought to be strongest. The goal is to help the intact immune system recognize and kill the micro metastases that usually cause recurrence of the cancer. In short, we believe that local administration and administration before weakening of the immune system by chemotherapy and radiation will result in better anti-tumor response than if Multikine were administered as a second- or later-line therapy. In clinical studies of Multikine, administration of the investigational therapy to head and neck cancer patients has demonstrated the potential for less or no appreciable toxicity.

Source: Adapted from Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005

The first indication CEL-SCI is pursuing for its investigational drug product candidate Multikine is an indication for the neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN (hereafter also referred to as advanced primary head and neck cancer). As detailed below, the Phase 3 Clinical trial of the Multikine investigational drug as neoadjuvant therapy in SCCHN is currently on Partial Clinical Hold by the US FDA. SCCHN is a type of head and neck cancer, and CEL-SCI believes that, in the aggregate, there is a large, unmet medical need among head and neck cancer patients. CEL-SCI believes the last FDA approval of a therapy indicated for the treatment of advanced primary head and neck cancer was over 50 years ago. In the aggregate, head and neck cancer represents about 6% of the world's cancer cases, with approximately over 650,000 patients diagnosed worldwide each year, and nearly 60,000 patients diagnosed annually in the United States. Multikine investigational immunotherapy was granted Orphan Drug designation for neoadjuvant therapy in patients with SCCHN by the FDA in the United States.

Status of Phase 3 Clinical Trial

Following submissions to regulatory authorities in 24 countries around the world, including the FDA in the United States, in a global Phase 3 clinical trial of the investigational Multikine therapy as a potential neoadjuvant therapy in patients with SCCHN was initially commenced in late 2010. This clinical trial is currently on Partial Clinical Hold.

This trial is currently primarily under the management of two clinical research organizations, or CROs: ICON Inc. (who acquired Aptiv Solutions, Inc., one of the two CROs), or ICON, and Ergomed Clinical Research Limited, or Ergomed. Ergomed is responsible for new patient enrollment and the clinical study management of the various study sites, although enrollment of new patients has been on hold since we received verbal notice of FDA's Partial Clinical Hold on September 26, 2016. The following chart refects the number of patients enrolled per month from the point at which the study management was transferred to the new CROs and the enrollment since then and until the FDA put the study on partial clinical hold.

The Phase 3 study was designed with the objective that, if the study endpoint, which is an improvement in overall survival of the subjects treated with the Multikine treatment regimen plus the current standard of care (SOC) as compared to subjects treated with the current SOC only, is satisfied, the study results are expected to be used to support applications that we plan to submit to regulatory agencies in order to seek commercial marketing approvals for Multikine in major markets around the world. This assessment can only be made when a certain number of deaths have occurred in these two main comparator groups of the study.

The primary endpoint for the original protocol for this Phase 3 head and neck cancer study required that a 10% increase in overall survival be obtained in the Multikine group which also is administered CIZ (CIZ = low dose (non-chemotherapeutic) of cyclophosphamide, indomethacin and Zinc-multivitamins) all of which are thought to enhance Multikine activity), plus Standard of Care (Surgery + Radiotherapy or Chemoradiotherapy) arm of the study over the Control comparator (Standard of Care alone) arm. As the study originally was designed, the final determination of whether this endpoint had been successfully reached could only be determined when 298 events (deaths) had occurred in the combined comparator arms of the study. Under the original study design, the plan was to enroll 880 patients in order to be able to have 784 evaluable patients for the per-protocol analysis.

In August 2016, we announced that the currently available data from the Phase 3 clinical study reflected that the accumulation of deaths in the study was lower than that which was anticipated based on reported literature at the Phase 3 study's inception. If the number of deaths continued to be accumulated at the current rate, it had been determined that it would take longer than originally planned to complete the study. To minimize this eventuality, we decided it would be necessary to enroll up to 1,273 patients to have 1,146 evaluable patients. There were also other changes in the protocol, such as the required number of deaths (392) and a required overall survival of 6.5% in favor of the Multikine comparator arm. With this increased patient enrollment, we expected a corresponding increase in the number of deaths, and, if this plan were implemented, the study could be completed in a more timely manner. As required by law and in order to be able to implement the plan, we submitted an amendment to the existing Phase 3 protocol for our head and neck cancer study to multiple regulatory agencies in the countries abroad where the Phase 3 study is being conducted as well as to the FDA to allow for this expansion in patient enrollment.

On September 26, 2016, we received verbal notice from FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. At such time, enrollment in the Phase 3 study was 926 patients. Pursuant to this communication from FDA, patients currently receiving study treatments can continue to receive treatment, and patients already enrolled in the study will continue to be followed.

On October 21, 2016, we received a partial clinical hold letter from FDA and, on November 21, 2016, we submitted a response to FDA's partial clinical hold letter.

In its partial clinical hold letter, FDA identified the following specific deficiencies: a) FDA stated that there is an unreasonable and significant risk of illness or injury to human subjects and cited among other things the absence of prompt reports by us to the FDA of IDMC recommendations to close the study entirely (made in spring of 2014) or at least to close it to accrual of new patients (made in spring of 2016); b) FDA stated that the investigator brochure is misleading, erroneous, and materially incomplete; and c) FDA stated that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, FDA also identified the information needed to resolve these deficiencies. In addition, FDA's partial clinical hold letter included two requests relating to quality information regarding our investigational final drug product, which were noted by FDA as non-hold issues. We believe that our response submitted to FDA on November 18, 2016, addressed each of the deficiencies identified by FDA including detailing our belief that, under the applicable FDA guidance, there was no obligation to report the cited IDMC recommendations to the FDA at the time they were issued, and it also requested a face-to-face meeting with FDA, and outlined our commitment to diligently work with FDA in an effort to have the partial clinical hold for the study lifted.

On December 8, 2016, FDA advised us that the Agency was denying our request for a meeting at that time because FDA's review of our November 18, 2016 response was ongoing. We also were advised that we would be receiving a letter addressing its November 18, 2016 response by December 18, 2016.

On December 16, 2016, FDA issued an Incomplete Response To Hold letter to us indicating that based on the Agency's preliminary review of our November 18, 2016 submission, FDA has determined that it is not a complete response to all of the issues listed in FDA's clinical hold letter. FDA identified the following specific deficiencies: a) FDA stated that we did not provide the information identified as necessary to address FDA's statement that patients enrolled in the study are exposed to unreasonable and significant risk of illness or injury to human subjects; b) FDA stated that we did not provide the information identified as necessary to address FDA's statement that continued enrollment of patients in the study exposes the patients to unreasonable risks and the FDA furthermore stated that the study is unlikely to demonstrate that the addition of our investigational drug Multikine to the standard of care is superior to standard of care and thus should be terminated for futility; (c) FDA stated that we did not provide the information identified as necessary to address FDA's statement that the investigator brochure is misleading, erroneous, and materially incomplete; (d) FDA stated that we did not provide the information identified as necessary to address FDA's statement that the proposed revised clinical protocol is inadequate in design to meet its stated objectives and FDA furthermore stated that this deficiency cannot be addressed by further revisions to the protocol. In its incomplete response to hold letter, FDA also identified the steps we must take to address these deficiencies. In addition, FDA's incomplete response to hold letter noted with respect to FDA's two requests relating to quality information regarding our investigational final drug product, which we had been instructed by FDA to submit separately from the response to the partial clinical hold, which again were noted by FDA as non-hold issues, that our November 18, 2016, submission had not included the information addressing these two requests.

In early January 2017, in preparation for the request for a Type A meeting with FDA and resolution of the partial clinical hold issues, we prepared a comprehensive submission to FDA detailing our belief, accompanied by what we believe to be appropriate supporting data, records, and information reflecting that we have taken the steps necessary to address the specific deficiencies identified by FDA, including: a) demonstrating that patients enrolled in the study are not exposed to unreasonable and significant risk of illness or injury; b) demonstrating that continued enrollment of patients in the study does not expose the patients to unreasonable risks and that the study should not be terminated for futility; (c) demonstrating that a supplemented investigator brochure is not misleading, erroneous, or materially incomplete; (d) demonstrating that the proposed revised clinical protocol is adequate in design to meet its stated objectives and that this deficiency can be addressed by the proposed revisions to the protocol.

On February 8, 2017, we met with FDA. At this meeting, there was a discussion of steps that would be required to lift the partial clinical hold. We have immediately begun working on those steps which, subject to the FDA's review of our submission upon their completion, may or may not result in the lifting of the partial clinical hold. We expect to receive formal letter from the FDA following our meeting in the next few weeks.

Subject to the partial clinical hold, we estimate that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by our partners, would be approximately $13.5 million. Should FDA lift the partial clinical hold and allow the amended protocol submitted to them to proceed, which requires an enrollment of up to 1,273 subjects, the remaining cost of the Phase 3 clinical trial will be higher than currently estimated. This is in addition to the approximately $36.0 million that CEL-SCI already had spent on the trial as of December 31, 2016. This number may be affected by the rate of any future patient enrollment, rate of death accumulation in the study, foreign currency exchange rates, and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated. If FDA will only lift the partial clinical hold with termination of the current study and initiation of a new clinical trial, any such new trial can only be initiated if permitted by FDA and as appropriate other regulatory authorities around the world after the requisite submissions are made to them, and the additional duration and costs of the Phase 3 clinical program would likely exceed those already incurred in connection with the Phase 3 clinical trial. If there is a need to conduct an additional Phase 3 pivotal study, any such requirement would have significant and severe material consequences for us and could impact our ability to continue as a going concern.

We will not be able to enroll any additional patients in the Phase 3 study unless FDA lifts the partial clinical hold. In addition, in the spring of 2016, the IDMC recommended to us that new patient enrollment should stop in the Phase 3 study, but patients already on study should continue to be treated and followed. Although we had expected to work through the concerns raised by the IDMC while we worked through the partial clinical hold with FDA, the IDMC informed us on December 13, 2016, that because the study is on partial clinical hold imposed by FDA, the IDMC has no formal recommendation regarding continuation of the trial at this time. Another IDMC meeting was held on February 6, 2017. Due to the fact that the study is still on partial clinical hold imposed by the FDA, the IDMC had no formal recommendation regarding continuation of the trial at this time. If the partial clinical hold is not lifted by FDA or if it is determined by FDA that the study has been compromised, the study may be terminated, or if the partial clinical hold is lifted by FDA but the IDMC continues to recommend that enrollment not be allowed to continue, the study may be terminated by us.

If the partial clinical hold is not lifted, the Phase 3 study will not be able to be completed to its prespecified endpoints in a timely manner, if at all, and, if the Phase 3 study cannot be completed to its prespecified endpoints, the study would not be able to be used as the pivotal study supporting a marketing application in the United States, and at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted, if it is not lifted in a timely fashion, the nature and duration of the partial clinical hold could irreparably harm the data from the Phase 3 study such that it may no longer be able to be used as the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted in a timely fashion, it remains possible that the regulatory authorities could determine that the Phase 3 study is not sufficient to be used as a single pivotal study supporting a marketing application in the United States.

Throughout the course of the Phase 3 study, an Independent Data Monitoring Committee, or IDMC, has met periodically to review safety data from the Phase 3 study, and the IDMC is expected to continue doing so throughout the remainder of the Phase 3 study. At various points in the study at which the IDMC has completed review of the safety data and has issued recommendations, it has recommended that the Phase 3 study may continue, although on two occasions the IDMC has issued recommendations that would have closed the study entirely (spring of 2014) or at least closed it to accrual of new patients (spring of 2016). On one occasion, in the spring of 2014, the IDMC made a recommendation that the study be closed for safety and efficacy reasons. However, following review of additional information submitted by us, the IDMC recommended that the study may continue. In the spring of 2016, with close to 800 patients enrolled, the IDMC made a recommendation that enrollment in the Phase 3 study should stop, but that patients already enrolled in the study should continue treatment and follow-up. CEL-SCI responded to this letter and indicated it would address the remaining three requests (generally relating to study design considerations) that were not part of the IDMC recommendation in a follow-up correspondence.

However, before CEL-SCI could provide our follow-up response to the remaining three requests, the IDMC sent another letter (a) indicating that our initial letter responding to the IDMC recommendation was unresponsive and (b) also indicating that the IDMC was deeply concerned about patient safety in the trial based on its review of cumulative data. The IDMC's initial letter in the spring of 2016 did not mention that the IDMC was concerned about safety. Instead, the initial letter in the spring of 2016 noted that the study should be closed to further accrual, and that patients who had been randomized may continue treatment and should be followed. The statement that patients who had been randomized may continue treatment suggested to us that safety was not an issue. Because no safety concern had been raised by the IDMC since the spring of 2014, when, after further communications with CEL-SCI, the IDMC issued its recommendation that the study should proceed, CEL-SCI believed based on the entirety of the course of correspondence with the IDMC that acute safety was not an issue underlying the IDMC's recommendation to halt accrual in the spring of 2016. As noted above, all other correspondence to CEL-SCI from the IDMC from study initiation through September 2015, with the exception of the recommendation in spring 2014, stated that the IDMC recommends “the study may continue". CEL-SCI responded to the IDMC’s recommendation in spring of 2016 with a

statistical analysis showing that more patients were needed in order to complete the study in a reasonable amount of follow-up time, since the observed death rate in the study was lower than that which was predicted from the literature at the onset of the study. Subsequently a protocol amendment was prepared based on the analysis provided to the IDMC and submitted to FDA in July 2016, and a copy was then sent to the IDMC in response to its request for a copy ofthe submission. To date, CEL-SCI has not received a response from the IDMC regarding this protocol amendment. However, two months after the amendment was submitted to FDA, FDA placed the protocol on partial clinical hold. CEL-SCI expects to work through the concerns raised by the IDMC while CEL-SCI works through the partial hold with FDA. Ultimately, the decision as to whether CEL-SCI's drug product candidate is safe and effective can only be made by FDA and/or by other regulatory authorities based upon an assessment of all of the data from an entire drug development program submitted as part of an application for marketing approval. As detailed elsewhere in this document, whether the partial clinical hold is lifted or not, the current Phase 3 clinical study for CEL-SCI's investigational drug may or may not be able to be used as the pivotal study supporting a marketing application in the United States, and, if not, at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States.

Follow-Up Analysis of Overall Survival in Phase 2 Patients

Prior to starting the Phase 3 study, we had tested Multikine in over 200 patients. The following is a summary of results from our last Phase 2 study conducted with Multikine. This study employed the same treatment protocol as is being followed in our Phase 3 study:

Reported potential for improved survival: In a follow-up analysis of the Phase 2 clinical study population, which used the same dosage and treatment regimen as is being used in the Phase 3 study, head and neck cancer patients with locally advanced primary disease who received CEL-SCI's investigational therapy Multikine as first-line investigational therapy, followed by surgery and radiotherapy, were reported by the clinical investigators to have had a 63.2% overall survival, or OS, rate at a median of 3.33 years from surgery. This percentage of OS was arrived at as follows: of the 21 subjects enrolled in the Phase 2 study, the consent for the survival follow-up portion of the study was received from 19 subjects. OS was calculated using the entire treatment population that consented to the follow-up portion of the study (19 subjects), including two subjects who, as later determined by three pathologists blinded to the study, did not have oral squamous cell carcinoma, or OSCC. These two subjects were thus not evaluable per the protocol and were not included in the pathology portion of the study for purposes of calculating complete response rate, as described below, but were included in the OS calculation. The overall survival rate of subjects receiving the investigational therapy in this study was compared to the overall survival rate that was calculated based upon a review of 55 clinical trials conducted in the same cancer population (with a total of 7,294 patients studied), and reported in the peer reviewed scientific literature between 1987 and 2007. Review of this literature showed an approximate survival rate of 47.5% at 3.5 years from treatment. Therefore, the results of CEL-SCI's final Phase 2 study were considered to be potentially favorable in terms of overall survival, recognizing the limitations of this early-phase study. It should be noted that an earlier investigational therapy Multikine study appears to lend support to the overall survival findings described above - Feinmesser et al Arch Otolaryngol. Surg. 2003. However, no definitive conclusions can be drawn from these data about the potential efficacy or safety profile of this investigational therapy. Moreover, further research is required, and these results must be confirmed in the Phase 3 clinical trial of this investigational therapy that is currently in progress. Subject to completion of that Phase 3 clinical trial and the FDA's review and acceptance of our entire data set on this investigational therapy, we believe that these early-stage clinical trial results indicate the potential for our Multikine product candidate to become a treatment for advanced primary head and neck cancer, if approved.

Reported average of 50% reduction in tumor cells in Phase 2 trials (based on 19 patients evaluable by pathology, having OSCC): The clinical investigators who administered the three-week Multikine treatment regimen used in the Phase 2 study reported that, as was determined in a controlled pathology study, Multikine administration appeared to have caused, on average, the disappearance of about half of the cancer cells present at surgery (as determined by histopathology assessing the area of Stroma/Tumor (Mean+/- Standard Error of the Mean of the number of cells counted per filed)) even before the start of standard therapy, which normally includes surgery, radiation and chemotherapy (Timar et al JCO 2005).

Reported 10.5% complete response in the final Phase 2 trial (based on 19 patients evaluable by pathology, having OSCC): The clinical investigators who administered the three-week Multikine investigational treatment regimen used in the Phase 2 study reported that, as was determined in a controlled pathology study, the tumor apparently was no longer present (as determined by histopathology) in approximately 10.5% of evaluable patients with OSCC (Timar et al JCO 2005). In the original study, 21 subjects received Multikine, two of which were later excluded, as subsequent analysis by three pathologists blinded to the study revealed that these two patients did not have OSCC. Two subjects in this study had a complete response, leaving a reported complete response rate of two out of 19 assessable subjects with OSCC (or 10.5%) (Timar et al, JCO 2005).

Adverse events reported in clinical trials: In clinical trials conducted to date with the Multikine investigational therapy, adverse events which have been reported by the clinical investigators as possibly or probably related to Multikine administration included pain at the injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation.

Subsequently, an analysis on the 21 subjects originally treated with Multikine in the study to evaluate overall survival was conducted, as described above. In connection with the follow-up portion of the study for overall survival, we also conducted an unreported post-hoc analysis of complete response rate in the study population, which included subjects who provided consent for the follow-up and who also had OSCC. Two of the 21 subjects did not re-consent for follow-up, and two of the remaining 19 subjects were excluded from the post-hoc complete response rate analysis as they had previously been determined by pathology analysis to not have OSCC. The two complete responders with OSCC both consented to the follow-up study. Therefore, the post-hoc analysis of complete response was based on a calculation of the two complete responders out of 17 evaluable subjects who consented to the follow-up analysis and who also had OSCC (or 11.8%).

Furthermore, we reported an overall response rate of 42.1% based on the number of evaluable patients who experienced a favorable response to the treatment, including those who experienced minor, major and complete responses. Out of the 19 evaluable patients, two experienced a complete response, two experienced a major response, and four experienced a minor response to treatment. Thus, we calculated the number of patients experiencing a favorable response as eight patients out of 19 (or 42.1%) (Timar et al, JCO 2005).

The clinical significance of these and other data, to date, from the multiple Multikine clinical trials, is not yet known. These preliminary clinical data do suggest the potential to demonstrate a possible improvement in the clinical outcome for patients treated with Multikine.

Peri-Anal Warts and Cervical Dysplasia in HIV/HPV Co-Infected Patients

HPV is a very common sexually transmitted disease in the United States and other parts of the world. It can lead to cancer of the cervix, penis, anus, esophagus and head and neck. Our focus in HPV, however, is not on developing an antiviral for the potential treatment or prevention of HPV in the general population. Instead, our focus is on developing an immunotherapy product candidate designed to be administered to patients who are immune-suppressed by other diseases, such as HIV, and who are therefore less able or unable to control HPV and its resultant or co-morbid diseases. Such patients have limited treatment options available to them.

One condition that is commonly associated with both HIV and HPV is the occurrence of anal intraepithelial dysplasia, or AIN, and anal and genital warts. The incidence of AIN in HIV-infected people is estimated to be about 25%. The incidence of anal HPV infection in HIV-infected men who have sex with men, or MSM, is estimated to be as high as 95%. In the aggregate, the United States and Europe have about 875,000 HIV-infected patients with AIN (assuming AIN prevalence of approximately 25% of the aggregate HIV-infected population). Persistent HPV infection in the anal region is thought to be responsible for up to 80% of anal cancers, and men and women who are HIV positive have a 30-fold increase in their risk of anal cancer. Persistent HPV infection can also be a precursor to cervical cancer, as well as certain head and neck cancers.

In October 2013, CEL-SCI signed a cooperative research and development agreement, or CRADA, with the U.S. Naval Medical Center, San Diego, or the USNMC. Pursuant to this agreement, the USNMC was to conduct a Phase 1 study, approved by the Human Subjects Institutional Review Board, of our investigational immunotherapy, Multikine, in HIV/HPV co-infected men and women with peri-anal warts. The purpose of this study was to evaluate the safety and clinical impact of Multikine as a potential treatment of peri-anal warts and assess its effect on AIN in HIV/HPV co-infected men and women.

In July 2015, CEL-SCI added a clinical site at the University of California, San Francisco, or UCSF, and Key Opinion Leader, or KOL, to the ongoing Phase 1 study. In August 2016, the U.S. Navy discontinued this Phase 1 study because of difficulties in enrolling patients. UCSF is continuing with the study.

In October 2013, we entered into a co-development and profit sharing agreement with Ergomed for development of Multikine as a potential treatment of HIV/HPV co-infected men and women with peri-anal warts. This agreement is supporting the development of Multikine with UCSF.

The treatment regimen for this Phase 1 study of up to 15 HIV/HPV co-infected patient volunteers with peri-anal warts, being conducted by doctors at UCSF, is identical to the regimen that was used in an earlier Institutional Review Board-approved Multikine Phase 1 study in HIV/HPV co-infected patients, which was conducted at the University of Maryland. In that study, the Multikine investigational therapy was administered to HIV/HPV co-infected women with cervical dysplasia, resulting in visual and histological evidence of clearance of lesions in three out of the eight subjects.

Furthermore, in this earlier Phase 1 study, the number of HPV viral sub-types in three volunteer subjects tested were reduced post-treatment with Multikine, as opposed to pre-treatment, as determined by in situ polymerase chain reaction performed on tissue biopsy collected before and after Multikine treatment. As reported by the investigators in the earlier study, the study volunteers, except one subject volunteer, all appeared to tolerate the treatment with no reported serious adverse events.

MANUFACTURING FACILITY

Before starting the Phase 3 clinical trial, CEL-SCI needed to build a dedicated manufacturing facility to produce Multikine. This facility has been completed and validated, and has produced multiple clinical lots for the Phase 3 clinical trial. The facility has also passed review by a European Union Qualified Person on several occasions.

CEL-SCI’s lease on the manufacturing facility expires on October 31, 2028. CEL-SCI completed validation of its new manufacturing facility in January 2010. The state-of-the-art facility is being used to manufacture Multikine for CEL-SCI’s Phase 3 clinical trial. In addition to using this facility to manufacture Multikine, CEL-SCI, only if the facility is not being used for Multikine, may offer the use of the facility as a service to pharmaceutical companies and others, particularly those that need to “fill and finish” their drugs in a cold environment (4 degrees Celsius, or approximately 39 degrees Fahrenheit). Fill and finish is the process of filling injectable drugs in a sterile manner and is a key part of the manufacturing process for many medicines. However, priority will always be given to Multikine as management considers the Multikine supply to the clinical studies and preparation for a final marketing approval to be more important than offering fill and finish services.

LEAPS

Our patented T-cell Modulation Process, referred to as LEAPS (Ligand Epitope Antigen Presentation System), uses "heteroconjugates" to direct the body to choose a specific immune response. LEAPS is designed to stimulate the human immune system to more effectively fight bacterial, viral and parasitic infections as well as autoimmune, allergies, transplantation rejection and cancer, when it cannot do so on its own. Administered like a vaccine, LEAPS combines T-cell binding ligands with small, disease-associated peptide antigens, and may provide a new method to treat and prevent certain diseases.

The ability to generate a specific immune response is important because many diseases are often not combated effectively due to the body's selection of the "inappropriate" immune response. The capability to specifically reprogram an immune response may offer a more effective approach than existing vaccines and drugs in attacking an underlying disease.

On July 15, 2014 CEL-SCI announced that it has been awarded a Phase 1 Small Business Innovation Research (SBIR) grant in the amount of $225,000 from the National Institute of Arthritis Muscoskeletal and Skin Diseases, which is part of the National Institutes of Health. The grant is funding the further development of CEL-SCI's LEAPS technology as a potential treatment for rheumatoid arthritis, an autoimmune disease of the joints. The work is being conducted at Rush University Medical Center in Chicago, Illinois in the laboratories of Tibor Glant, MD, Ph.D., The Jorge O. Galante Professor of Orthopedic Surgery; Katalin Mikecz, MD, Ph.D. Professor of Orthopedic Surgery & Biochemistry; and Allison Finnegan, Ph.D. Professor of Medicine.

With the support of the SBIR grant, CEL-SCI is developing two new drug candidates, CEL-2000 and CEL-4000, as potential rheumatoid arthritis therapeutic vaccines. The data from animal studies using the CEL-2000 treatment vaccine demonstrated that it could be used as an effective treatment against rheumatoid arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments currently on the market for arthritic conditions associated with the Th17 signature cytokine TNF- . The data for CEL-4000 indicates it could be effective against rheumatoid arthritis cases where a Th1 signature cytokine (IFN-c) is dominant. CEL-2000 and CEL-4000 have the potential to be a more disease-specific therapy, significantly less expensive, act at an earlier step in the disease process than current therapies and may be useful in patients not responding to existing rheumatoid arthritis therapies. CEL-SCI believes this represents a large unmet medical need in the rheumatoid arthritis market.

On November 14, 2016, CEL-SCI announced new preclinical data that demonstrate its investigational new drug candidate CEL-4000 has the potential for use as a therapeutic vaccine to treat rheumatoid arthritis. This efficacy study was supported in part by the SBIR Phase I Grant and was conducted in collaboration with Drs. Katalin Mikecz and Tibor Glant, and their research team at Rush University Medical Center in Chicago, IL.

In March 2015, CEL-SCI and its collaborators published a review article on vaccine therapies for rheumatoid arthritis based in part on work supported by the SBIR grant. The article is entitled "Rheumatoid arthritis vaccine therapies: perspectives and lessons from therapeutic Ligand Epitope Antigen Presentation System vaccines for models of rheumatoid arthritis" and was published in Expert Rev. Vaccines 1 - 18 and can be found at http://www.ncbi.nlm.nih.gov/ pubmed/25787143.

In August 2012, Dr. Zimmerman, CEL-SCI's Senior Vice President of Research, Cellular Immunology, gave a Keynote presentation at the OMICS 2nd International Conference on Vaccines and Vaccinations in Chicago. This presentation showed how the LEAPS peptides administered altered only select cytokines specific for each disease model, thereby improving the status of the test animals and even preventing death and morbidity. These results support the growing body of evidence that provides for its mode of action by a common format in these unrelated conditions by regulation of Th1 (e.g., IL12 and IFN-c) and their action on reducing TNF- and other inflammatory cytokines as well regulation of antibodies to these disease associated antigens. This was also illustrated by a schematic model showing how these pathways interact and result in the overall effect of protection and regulation of cytokines in a beneficial manner.

In February 2010, CEL-SCI announced that its CEL-2000 vaccine demonstrated that it was able to block the progression of rheumatoid arthritis in a mouse model, where a Th17 signature cytokine (TNF-) is dominant. The results were published in the scientific peer-reviewed Journal of International Immunopharmacology (online edition) in an article titled "CEL-2000: A Therapeutic Vaccine for Rheumatoid Arthritis Arrests Disease Development and Alters Serum Cytokine / Chemokine Patterns in the Bovine Collagen Type II Induced Arthritis in the DBA Mouse Model" Int Immunopharmacol. 2010 Apr; 10(4):412-21 http://www. ncbi.nlm.nih.gov/pubmed/20074669.

Using the LEAPS technology, CEL-SCI has created a potential peptide treatment for H1N1 (swine flu) hospitalized patients. This LEAPS flu treatment is designed to focus on the conserved, non-changing epitopes of the different strains of Type A Influenza viruses (H1N1, H5N1, H3N1, etc.), including "swine", "avian or bird", and "Spanish Influenza", in order to minimize the chance of viral "escape by mutations" from immune recognition. Therefore one should think of this treatment not really as an H1N1 treatment, but as a potential pandemic flu treatment. CEL-SCI's LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models.

In September 2009, the U.S. FDA advised CEL-SCI that it could proceed with its first clinical trial to evaluate the effect of LEAPS-H1N1 treatment on the white blood cells of hospitalized H1N1 patients. This followed an expedited initial review of CEL-SCI's regulatory submission for this study proposal.

In November 2009, CEL-SCI announced that The Johns Hopkins University School of Medicine had given clearance for CEL-SCI's first clinical study to proceed using LEAPS-H1N1. Soon after the start of the study, the number of hospitalized H1N1 patients dramatically declined and the study was unable to complete the enrollment of patients.

Additional work on this treatment for the pandemic flu is being pursued in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, USA. In May 2011 NIAID scientists presented data at the Keystone Conference on "Pathogenesis of Influenza: Virus-Host Interactions" in Hong Kong, China, showing the positive results of efficacy studies in mice of LEAPS H1N1 activated dendritic cells (DCs) to treat the H1N1 virus. Scientists at the NIAID found that H1N1-infected mice treated with LEAPS-H1N1 DCs showed a survival advantage over mice treated with control DCs. The work was performed in collaboration with scientists led by Kanta Subbarao, M.D., Chief of the Emerging Respiratory Diseases Section in NIAID's Division of Intramural Research, part of the National Institutes of Health, USA.

In July 2013, CEL-SCI announced the publication of the results of influenza studies by researchers from the NIAID in the Journal of Clinical Investigation (www.jci.org/articles/view/67550). The studies described in the publication show that when CEL-SCI's investigational J-LEAPS Influenza Virus treatments were used "in vitro" to activate DCs, these activated DCs, when injected into influenza infected mice, arrested the progression of lethal influenza virus infection in these mice. The work was performed in the laboratory of Dr. Subbarao.

Even though the various LEAPS drug candidates have not yet been given to humans, they have been tested in vitro with human cells. They have induced similar cytokine responses that were seen in these animal models, which may indicate that the LEAPS technology might translate to humans. The LEAPS candidates have demonstrated protection against lethal herpes simplex virus (HSV1) and H1N1 influenza infection, as a prophylactic or therapeutic agent in animals. They have also shown some level of efficacy in animals in two autoimmune conditions, curtailing and sometimes preventing disease progression in arthritis and myocarditis animal models. CEL-SCI's belief is that the LEAPS technology may be a significant alternative to the vaccines currently available on the market for these diseases.

None of the LEAPS investigational products have been approved for sale, barter or exchange by the FDA or any other regulatory agency for any use to treat disease in animals or humans. The safety or efficacy of these products has not been established for any use. Lastly, no definitive conclusions can be drawn from the early-phase, preclinical-trials data involving these investigational products. Before obtaining marketing approval from the FDA in the United States, and by comparable agencies in most foreign countries, these product candidates must undergo rigorous preclinical and clinical testing which is costly and time consuming and subject to unanticipated delays. There can be no assurance that these approvals will be granted.

Corporate Information

We were formed as a Colorado corporation in 1983. Our principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, Virginia 22182. Our telephone number is 703-506-9460 and our web site is www.cel-sci.com. The information contained in, and that which can be accessed through, our website is not incorporated into and does not form a part of this prospectus supplement.

The Offering	
Issuer	CEL-SCI Corporation
Securities offered by us	10,000,000 shares of common stock.
Purchase price	$0.10
Common stock outstanding immediately prior to this offering.(1)	190,965,450 shares.
Common stock to be outstanding immediately after this offering.(1)	200,965,450 shares.
Concurrent Private Placement	In a concurrent private placement, we are selling to the purchasers of shares of our common stock in this offering warrants to purchase 100% of the number of shares of our common stock purchased by such investors in this offering, or up to 10,000,000 warrants. We will receive gross proceeds from the concurrent private placement transaction solely to the extent such warrants are exercised for cash. The warrants will be exercisable on the six month anniversary of the issuance date at an exercise price of $0.12 per share and will expire 5 and a half years from the date of issuance. The warrants and the shares of our common stock issuable upon the exercise of the warrants are not being offered pursuant to this prospectus supplement and the accompanying prospectus and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. See “Private Placement Transaction and Warrants” on page S-57 of this prospectus supplement.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $830,000 after deducting estimated placement agent’s fees and estimated offering expenses payable by us. We intend to use the net proceeds from this offering primarily for the Phase 3 clinical study and general corporate purposes. See “Use of Proceeds.”
Dividend policy	We have not declared or paid any cash or other dividends on our common stock and do not expect to declare or pay any cash or other dividends in the foreseeable future.
Risk factors	Investing in our securities involves a high degree of risk, and the purchasers of our securities may lose all or part of their investment. Before deciding to invest in our securities, please carefully read “Risk Factors” beginning on page S-15 of this Prospectus Supplement, the Risk Factors in the accompanying Prospectus and the risks set forth under the caption “Item 1A. Risk Factors” included in our most recent Annual Report on Form 10-K and 10 K/A, which is incorporated by reference herein.

NYSE MKT trading symbol CVM

(1) This number is based on 190,965,450 shares outstanding as of February 17, 2017, which excludes, as of such date (i) 170,195,764 shares that may be issued upon the exercise of outstanding warrants, with a weighted average exercise price of $0.52 per share and (ii) 8,212,250 shares that may be issued upon the exercise of outstanding options, with a weighted average exercise price of $2.35 per share; and (iii) 10,000,000 shares of common underlying the warrants (Series GG) to be issued in the concurrent private placement, at an exercise price of $0.12 per share; and (iv) 500,000 shares of common stock issuable upon exercise of the placement agent warrants.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following risks, the risks described in our Annual Report on Form 10-K and 10 K/A for the year ended September 30, 2016, as well as the other information and data set forth in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein before making an investment decision with respect to our common stock and warrants. The risks and uncertainties we described are not the only ones facing us. Additional risks not presently known to us, or that we currently deem immaterial, may also impair our business operations. If any of these risks were to occur, our business, financial condition, result of operations and liquidity would likely suffer. In that event, the trading price of our common stock would decline, and you could lose all or part of your investment. Some statements in this prospectus supplement, including statements in the following risk factors, constitute forward-looking statements. See “Forward-Looking Statements.”

Risks Related to CEL-SCI

Our Phase 3 Study has been placed on partial clinical hold by the FDA

We received a partial clinical hold letter from FDA stating that our Phase 3 study had been placed on clinical hold, precluding us from continuing the study except that patients enrolled prior to September 26, 2016 may continue to receive protocol-specified treatment at the discretion of the treating physician with written confirmation of their consent to remain on study after receiving an updated informed consent document. The FDA's partial clinical hold letter identified the following specific deficiencies: there is an unreasonable and significant risk of illness or injury to human subjects; the investigator brochure is misleading, erroneous, and materially incomplete; and that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, the FDA also identified the information needed to resolve these deficiencies. Although we believe we addressed each of the deficiencies identified by the FDA in our response to FDA, we have also requested a face-to-face meeting with FDA. We met with FDA on February 8, 2017. At this meeting, there was a discussion of steps that would be required to lift the partial clinical hold. We expect to receive a formal letter from the FDA following our meeting in the next few weeks. We have immediately begun working on those steps which, subject to the FDA's review of our submission upon their completion, may or may not result in the lifting of the partial clinical hold. We will not be able to enroll any additional patients in the Phase 3 study unless FDA lifts the clinical hold. In addition, in the spring of 2016, the IDMC recommended to us that new patient enrollment should stop in the Phase 3 study, but patients already on study should continue to be treated and followed. We expect to work through the concerns raised by the IDMC while we work through the partial hold with FDA. However, if the clinical hold is not removed or if it is determined that the study has been compromised or if the IDMC does not allow enrollment to continue, the study may be terminated.

We have incurred significant losses since inception, and we anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have a history of net losses, expect to incur substantial losses and have negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. Since the date of our formation and through December 31, 2016, we incurred net losses of approximately $282 million. We have relied principally upon the proceeds from the public and private sales of our securities to finance our activities to date. To date, we have not commercialized any products or generated any revenue from the sale of products, and we do not expect to generate any product revenue for the foreseeable future. We do not know whether or when we will generate product revenue or become profitable.

We are heavily dependent on the success of Multikine which is under clinical development. We cannot be certain that Multikine will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. On September 26, 2016, FDA placed our Phase 3 clinical trial for Multikine on partial clinical hold. We will not be able to enroll any additional patients in the Phase 3 clinical trial unless FDA removes the clinical hold. In addition, prior to FDA's issuance of the partial clinical hold, we were discussing with our Independent Data Monitoring Committee issues related to enrollment of additional patients in trial. Multikine is our only product candidate in late-stage clinical development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop approved and marketable drug products.

Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur significant operating and capital expenditures as we:

continue to undertake preclinical development and clinical trials for product candidates;

seek regulatory approvals for product candidates; and

implement additional internal systems and infrastructure.

To become and remain profitable, we must succeed in developing and commercializing our product candidates, which must generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering or acquiring additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment.

We will require substantial additional capital to remain in operation. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product candidates' development or commercialization efforts.

As of December 31, 2016, we had cash and cash equivalents of $2.4 million. We believe that we will continue to expend substantial resources for the foreseeable future developing Multikine, LEAPS and any other product candidates or technologies that we may develop or acquire. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

the rate of progress of, results of and cost of completing Phase 3 clinical development of Multikine for the treatment of certain head and neck cancers;

the results of our applications to and meetings with the FDA, the EMA and other regulatory authorities and the consequential effect on our operating costs;

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assuming favorable Phase 3 clinical results, the cost, timing and outcome of our efforts to obtain marketing approval for Multikine in the United States, Europe and in other jurisdictions, including the preparation and filing of regulatory submissions for Multikine with the FDA, the EMA and other regulatory authorities;

the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for Multikine, LEAPS and other product candidates and technologies that we may develop or acquire;

the timing of, and the costs involved in, obtaining regulatory approvals for LEAPS if clinical studies are successful;

the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;

the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

the cost of having our product candidates manufactured for clinical trials and in preparation for commercialization;

our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs, and the outcome of such litigation; and

the extent to which we acquire or in-license other products or technologies.

Based on our current operating plan, and absent any future financings or strategic partnerships, we believe that the net proceeds we receive from this offering and our existing cash and cash equivalents and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements into April 2017. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for Multikine, LEAPS, or any other product candidates or technologies that we develop or acquire, or delay, limit, reduce or terminate our sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. Due to recurring losses from operations and future liquidity needs, there is substantial doubt about our ability to continue as a going concern without additional capital becoming available. The doubt about our ability to continue as a going concern could have an adverse impact on our ability to execute our business plan, result in the reluctance on the part of certain suppliers to do business with us, or adversely affect our ability to raise additional debt or equity capital.

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The costs of our product candidate development and clinical trials are difficult to estimate and will be very high for many years, preventing us from making a profit for the foreseeable future, if ever.

Clinical and other studies necessary to obtain approval of a new drug can be time consuming and costly, especially in the United States, but also in foreign countries. Our estimates of the costs associated with future clinical trials and research may be substantially lower than what we actually experience. It is impossible to predict what we will face in the development of a product candidate, such as Multikine. The purpose of clinical trials is to provide both us and regulatory authorities with safety and efficacy data in humans. It is relatively common to revise a trial or add subjects to a trial in progress. The difficult and often complex steps necessary to obtain regulatory approval, especially that of the FDA, and the EMA, involve significant costs and may require several years to complete. We expect that we will need substantial additional financing over an extended period of time in order to fund the costs of future clinical trials, related research, and general and administrative expenses.

The extent of our clinical trials and research programs are primarily based upon the amount of capital available to us and the extent to which we receive regulatory approvals for clinical trials. We have established estimates of the future costs of the Phase 3 clinical trial for Multikine, but, as explained above, that estimate may not prove correct.

An adverse determination in any current or future lawsuits or arbitration proceedings to which we are a party could have a material adverse effect on us.

We are currently involved in a pending arbitration proceeding, CEL-SCI Corporation v. inVentiv Health Clinical, LLC (f/k/a PharmaNet LLC) and PharmaNet GmbH (f/k/a PharmaNet AG). We initiated the proceedings against inVentiv Health Clinical, LLC, or inVentiv, the former third-party CRO, and are seeking payment for damages related to inVentiv's prior involvement in the Phase 3 clinical trial of Multikine. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, we are seeking at least $50 million in damages in our amended statement of claim.

In an amended statement of claim, we asserted the claims set forth above as well as an additional claim for professional malpractice. The arbitrator subsequently granted inVentiv's motion to dismiss the professional malpractice claim based on the "economic loss doctrine" which, under New Jersey law, is a legal doctrine that, under certain circumstances, prohibits bringing a negligence-based claim alongside a claim for breach of contract. The arbitrator denied the remainder of inVentiv's motion, which had sought to dismiss certain other aspects of the amended statement of claim. In particular, the arbitrator rejected inVentiv's argument that several aspects of the amended statement of claim were beyond the arbitrator's jurisdiction.

In connection with the pending arbitration proceedings, inVentiv has asserted counterclaims against us for (i) breach of contract, seeking at least $2 million in damages for services allegedly performed by inVentiv; (ii) breach of contract, seeking at least $1 million in damages for the alleged use of inVentiv's name in connection with publications and promotions in violation of the parties' contract; (iii) opportunistic breach, restitution and unjust enrichment, seeking at least $20 million in disgorgement of alleged unjust profits allegedly made by us as a result of the purported breaches referenced in subsection (ii); and (iv) defamation, seeking at least $1 million in damages for allegedly defamatory statements made about inVentiv. We believe inVentiv's counterclaims are meritless and intend to vigorously defend against them. However, if such defense is unsuccessful, and inVentiv successfully asserts any of its counterclaims, such an adverse determination could have a material adverse effect on our business, results, financial condition and liquidity.

In October 2015, we signed an arbitration funding agreement with a company established by Lake Whillans Litigation Finance, LLC, a firm specializing in funding litigation expenses. Pursuant to the agreement, an affiliate of Lake Whillans provides us with up to $5 million in funding for litigation expenses to support our arbitration claims against inVentiv. The funding is available to us to fund the expenses of the ongoing arbitration and will only be repaid if we receive proceeds from the arbitration.

The arbitration hearing on the merits began on September 26, 2016.

Additionally, we may also be the target of claims asserting violations of securities fraud and derivative actions, or other litigation or arbitration proceedings in the future. Any future litigation could result in substantial costs and divert management's attention and resources. These lawsuits or arbitration proceedings may result in large judgments or settlements against us, any of which could have a material adverse effect on our business, operating results, financial condition and liquidity.

We have received subpoenas from the Securities and Exchange Commission.

We have received subpoenas from the Securities and Exchange Commission, which is conducting a non-public, private investigation relating to certain of our private and public financings as well as reports, articles and other publications prepared by third parties concerning us, the pending arbitration between us and our former CRO, inVentiv Health, and our Phase 3 clinical trial. This is the first SEC investigation involving us. While we are confident that we have the appropriate policies and procedures in place to ensure compliance with all SEC rules and regulations, we cannot predict when the SEC will conclude its investigation or the outcome of the investigation. We are cooperating fully with the SEC in this matter.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure may create uncertainty regarding compliance matters. New or changed laws, regulations and standards are subject to varying interpretations in many cases. As a result, their application in practice may evolve over time. We are committed to maintaining high standards of corporate governance and public disclosure. Complying with evolving interpretations of new or changing legal requirements may cause us to incur higher costs as we revise current practices, policies and procedures, and may divert management time and attention from potential revenue-generating activities to compliance matters. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may also be harmed. Further, our board members, chief executive officer, and other executive officers could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers which could harm our business.

We have not established a definite plan for the marketing of Multikine, if approved.

We have not established a definitive plan for marketing nor have we established a price structure for any of our product candidates, if approved. However, we intend, if we are in a position to do so, to sell Multikine ourselves in certain markets where it is approved, and or to enter into written marketing agreements with various third parties with established sales forces in such markets. The sales forces in turn would, we believe, focus on selling Multikine to targeted cancer centers, physicians and clinics involved in the treatment of head and neck cancer. We have already licensed future sales of Multikine, if approved, to three companies: Teva Pharmaceuticals in Israel, Turkey, Serbia and Croatia; Orient Europharma in Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia and New Zealand; and Byron BioPharma, LLC in South Africa. We believe that these companies will have the resources to market Multikine appropriately in their respective territories, if approved, but there is no guarantee that they will. There is no assurance that we will be able to find qualified third-party partners to market our product in other areas, on terms that are favorable to us, or at all.

We may encounter problems, delays and additional expenses in developing marketing plans with third parties. In addition, even if Multikine, if approved, is cost-effective and demonstrated to increase overall patient survival, we may experience other limitations involving the proposed sale of Multikine, such as uncertainty of third-party coverage and reimbursement. There is no assurance that we can successfully market Multikine, if approved, or any other product candidates we may develop.

We hope to expand our clinical development capabilities in the future, and any difficulties hiring or retaining key personnel or managing this growth could disrupt our operations.

We are highly dependent on the principal members of our management and development staff. If the Phase 3 Multikine clinical trial is successful, we expect to expand our clinical development and manufacturing capabilities, which will involve hiring additional employees. Future growth will require us to continue to implement and improve our managerial, operational and financial systems and to continue to retain, recruit and train additional qualified personnel, which may impose a strain on our administrative and operational infrastructure. The competition for qualified personnel in the biopharmaceutical field is intense. We are highly dependent on our ability to attract, retain and motivate highly qualified management and specialized personnel required for clinical development. Due to our limited resources, we may not be able to manage effectively the expansion of our operations or recruit and train additional qualified personnel. If we are unable to retain key personnel or manage our future growth effectively, we may not be able to implement our business plan.

If product liability or patient injury lawsuits are brought against us, we may incur substantial liabilities and may be required to limit clinical testing or future commercialization of Multikine or our other product candidates.

We face an inherent risk of product liability as a result of the clinical testing of Multikine and other product candidates, and will face an even greater risk if we commercialize any of our product candidates. For example, we may be sued if our Multikine or LEAPS product candidates, or any other future product candidates, allegedly cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing or, if approved, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

Furthermore, Multikine is made, in part, from components of human blood. There are inherent risks associated with products that involve human blood such as possible contamination with viruses, including hepatitis or HIV. Any possible contamination could cause injuries to patients who receive contaminated Multikine, or could require us to destroy batches of Multikine, thereby subjecting us to possible financial losses, lawsuits and harm to our business.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the clinical testing or commercialization of our product candidates, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for Multikine or our other product candidates, if approved;

injury to our reputation;

withdrawal of existing, or failure to enroll additional, clinical trial participants;

costs to defend any related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients;

product candidate recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

inability to commercialize Multikine or our other product candidates; and

a decline in the price of our common stock.

Although we have product liability insurance for Multikine in the amount of $5.0 million, the successful prosecution of a product liability case against us could have a materially adverse effect upon our business if the amount of any judgment exceeds our insurance coverage. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. We commenced the Phase 3 clinical trial for Multikine in December 2010. Although no claims have been brought to date, participants in our clinical trials could bring civil actions against us for

any unanticipated harmful effects allegedly arising from the use of Multikine or any other product candidate that we may attempt to develop.

Our commercial success depends, in part, upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if we obtain regulatory approval for our product candidates, any resulting product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

the efficacy and safety as demonstrated in clinical trials;

the timing of market introduction of such product candidate as well as competitive products;

the clinical indications for which the drug is approved;

the approval, availability, market acceptance and reimbursement for the companion diagnostic;

acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;

the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that are targeted with such product candidate;

the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;

the cost of treatment in relation to alternative treatments;

the availability of adequate reimbursement and pricing by third-party payors and government authorities;

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors and patients, we will not be able to generate significant revenues, and we may not become or remain profitable.

Our Independent Registered Public Accountants have included in its report on our financial statements a paragraph stating that we may be unable to continue as a going concern.

As a result of our recurring losses from operations, our independent registered public accounting firm, BDO USA, LLP, has issued a report in connection with their audit of our financial statements for the year ended September 30, 2016, that included an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. The doubt about our ability to continue as a going concern could have an adverse impact on our ability to execute our business plan, result in the reluctance on the part of certain suppliers to do business with us, or adversely affect our ability to raise additional debt or equity capital.

Risks Related to Government Approvals

Our product candidates must undergo rigorous preclinical and clinical testing and regulatory approvals, which could be costly and time-consuming and subject us to unanticipated delays or prevent us from marketing any products.

Our product candidates are subject to premarket approval from the FDA in the United States, the EMA in the European Union, and by comparable agencies in most foreign countries before they can be sold. Before obtaining marketing approval, these product candidates must undergo costly and time consuming preclinical and clinical testing which could subject us to unanticipated delays and may prevent us from marketing our product candidates. There can be no assurance that such approvals will be granted on a timely basis, if at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our current and future clinical trials may not be successful.

Although we are involved in Phase 1 and Phase 3 clinical trials for Multikine, we may experience delays in our the clinical trials and we do not know whether the clinical trials need to be redesigned, enroll patients on a timely basis or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

the availability of financial resources needed to commence and complete our planned trials;

obtaining regulatory approval to commence a trial;

suspending enrollment in clinical trials, as in the case of the partial clinical hold issued by FDA related to our Phase 3 clinical trial for Multikine;

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining Institutional Review Board, or IRB, approval at each clinical trial site;

recruiting suitable patients to participate in a trial;

having patients complete a trial or return for post-treatment follow-up;

clinical trial sites deviating from trial protocol or dropping out of a trial;

adding new clinical trial sites; or

manufacturing sufficient quantities of our product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the competence of the CRO running the study, size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

On October 31, 2013, we commenced arbitration proceedings against inVentiv Health Clinical, LLC, or inVentiv, our former clinical research organization (CRO). The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, we are seeking at least $50 million in damages in its amended statement of claim.

In connection with the pending arbitration proceedings, inVentiv has asserted counterclaims against us for (i) breach of contract, seeking at least $2 million in damages for services allegedly performed by inVentiv; (ii) breach of contract, seeking at least $1 million in damages for our alleged use of inVentiv's name in connection with publications and promotions in violation of the parties' contract; (iii) opportunistic breach, restitution and unjust enrichment, seeking at least $20 million in disgorgement of alleged unjust profits allegedly made by us as a result of the purported breaches referenced in subsection (ii); and (iv) defamation, seeking at least $1 million in damages for allegedly defamatory statements made about inVentiv. Should our allegations be found to be true, regulatory authorities may rule the data collected by that our former CRO unusable in support of our marketing applications. Even if our allegations are not found to be true, regulatory authorities may rule the data collected by that former CRO unusable in support of our marketing applications. In either case, we have proposed to enroll approximately 125 additional subjects in our Phase 3 study beyond the study design that was in place prior to FDA's imposition of a partial clinical hold on the study, but those additional subjects can only be enrolled if the partial clinical hold is lifted. The need to enroll those additional patients will cause additional delays in our clinical testing and development program, and there is no guarantee that the partial clinical hold will be lifted, that if the partial clinical hold is lifted the study will be in a position that additional patients can be recruited and enrolled, or that we can successfully enroll the additional patients necessary to complete the study if the clinical hold is lifted. Currently, the Phase 3 study has been placed on partial clinical hold by FDA. In its partial clinical hold letter, FDA identified the following specific deficiencies: a) FDA stated that there is an unreasonable and significant risk of illness or injury to human subjects; b) FDA stated that the investigator brochure is misleading, erroneous, and materially incomplete; and c) FDA stated that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, FDA also identified the information needed to resolve these deficiencies. In our response submitted to FDA on November 18, 2016, we believe we addressed each of the deficiencies identified by FDA, requested a face-to-face meeting with FDA, and detailed its commitment to diligently work with FDA in an effort to have the partial clinical hold for the study lifted. We met with FDA on February 8, 2017. At this meeting, there was a discussion of steps that would be required to lift the partial clinical hold. We have immediately begun working on those steps which, subject to the FDA's review of our submission upon their completion, may or may not result in the lifting of the partial clinical hold. If the partial clinical hold is not ever lifted, the Phase 3 study will not be able to be completed to its prespecified endpoints in a timely manner, if at all, and, if the Phase 3 study cannot be completed to its prespecified endpoints, the study would not be able to be used as the pivotal study supporting a marketing application in the United States, and at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted, if it is not lifted in a timely fashion, the nature and duration of the partial clinical hold could irreparably harm the data from the Phase 3 study such that it may no longer be able to be used as the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted in a timely fashion, it remains possible that the regulatory authorities could determine that the Phase 3 study is not sufficient to be used as a single pivotal study supporting a marketing application in the United States. In either of these latter circumstances, at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. If there is a need to conduct an additional Phase 3 pivotal study, any such requirement would have significant and severe material consequences for us and could impact our ability to continue as a going concern.

We could also encounter significant delays and/or need to terminate a development program for a product candidate if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in addition to existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, one or more of the IRBs for the institutions in which such trials are being conducted, by us upon a final recommendation by the Independent Data Monitoring Committee, or IDMC, with which we agree for such trial, or by FDA or other regulatory authorities, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, as a result of inspection of the clinical trial operations or trial site(s) by FDA or other regulatory authorities, the imposition of a clinical hold or partial clinical hold such as the partial clinical hold currently imposed by FDA on the Phase 3 study of our investigational drug Multikine as detailed elsewhere in this prospectus supplement, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. The occurrence of any one or more of these events would have significant and severe material consequences for us and could impact our ability to continue as an ongoing concern.

If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to a delay or the denial of regulatory approval for our product candidates.

We cannot be certain when or under what conditions we will undertake future clinical trials. A variety of issues may delay our Phase 3 clinical trial for Multikine, such as patients in the Phase 3 clinical trial dying at a slower rate than projected and the existing partial clinical hold, or preclinical and early clinical trials for our other product candidates. For example, early trials, or the plans for later trials, may not satisfy the requirements of regulatory authorities, such as the FDA. We may fail to find subjects willing to enroll in our trials. We manufacture Multikine in our own manufacturing facility, but rely on third-party vendors to manage the trial process and other activities, and these vendors may fail to meet appropriate standards. Accordingly, the clinical trials relating to our product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our product candidates. The data collected from our clinical trials may not be sufficient to support regulatory approval of our various product candidates, including Multikine. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates in the United States, which could prevent us from achieving profitability. Although we had positive results in our Phase 2 trials for Multikine, those results were for a very small sample set, and we will not know how Multikine will perform in a larger set of subjects until we are well into, or complete, our Phase 3 clinical trial.

The development and testing of product candidates and the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, termination of the Phase 3 study, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The requirements governing the conduct of clinical trials, manufacturing and marketing of our product candidates, including Multikine, outside the United States vary from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different trial designs. Foreign regulatory approval processes include all of the risks associated with the FDA approval process. Some of those agencies also must approve prices for products approved for marketing. Approval of a product by the FDA or the EMA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory requirements for product approval in any country during the clinical trial process and regulatory agency review of each submitted new application may cause delays or rejections.

We have only limited experience in filing and pursuing applications necessary to gain regulatory approvals. Our lack of experience may impede our ability to obtain timely approvals from regulatory agencies, if at all. We will not be able to commercialize Multikine and other product candidates until we have obtained regulatory approval. In addition, regulatory authorities may also limit the types of patients to which we or our third-party partners may market Multikine or our other product candidates. Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect our or our third-party partners' ability to successfully market our product candidates.

Even if we obtain regulatory approval for our investigational products, we will be subject to stringent, ongoing government regulation.

If our investigational products receive regulatory approval, either in the United States or internationally, those products will be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, and may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance of the safety and efficacy of the investigational products. We will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

product design, development and manufacture;

product application and use

adverse drug experience;

product advertising and promotion;

product manufacturing, including good manufacturing practices

record keeping requirements;

registration and listing of our establishments and products with the FDA, EMA and other state and national agencies;

product storage and shipping;

drug sampling and distribution requirements;

electronic record and signature requirements; and

labeling changes or modifications.

We and any of our third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as current, Good Manufacturing Practices, or cGMPs, and their foreign equivalents, which are enforced by the FDA, the EMA and other national regulatory bodies through their facilities inspection programs. If our facilities, or the facilities of our contract manufacturers or suppliers, cannot pass a pre-approval plant inspection or fail such inspections in the future, the FDA, EMA or other national regulators will not approve our marketing applications for our product candidates, or may withdraw any prior approval. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our product candidates meet applicable specifications and other requirements.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to, among other things, license suspension or revocation, criminal prosecution, seizure, injunction, fines, be forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval for such products or for other product candidates for which we seek approval. This could materially harm our financial results, reputation and stock price. Additionally, we may not be able to obtain the labeling claims necessary or desirable for product promotion. If we or other parties identify

adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be suspended or withdrawn. We may be required to reformulate our products, conduct additional clinical trials, make changes in product labeling or indications of use, or submit additional marketing applications to support any changes. If we encounter any of the foregoing problems, our business and results of operations will be harmed and the market price of our common stock may decline.

The FDA and other governmental authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We cannot predict the extent of adverse government regulations which might arise from future legislative or administrative action. Without government approval, we will be unable to sell any of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and/or prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw approvals of such product;

regulatory authorities may require additional warnings on the label;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties and meet regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to prepare for, conduct, monitor and manage data for our preclinical and clinical programs. We rely on these parties for all aspects of the execution of our preclinical and clinical trials, and although we diligently oversee and carefully manage our CROs, we directly control only certain aspects of their activities and rely upon them to provide timely, complete, and accurate reports on their conduct of our studies. Although such third parties provide support and represent us for regulatory purposes in the context of our clinical trials, ultimately we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs acting on our behalf, as well as principal investigators and trial sites, are required to comply with Good Clinical Practice, or GCP and other applicable requirements, which are implemented through regulations and guidelines enforced by the FDA, the Competent

Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs or other applicable regulations, the clinical data generated in our clinical trials may be determined to be unreliable and we may therefore need to enroll additional subjects in our clinical trials, or the FDA, EMA or comparable foreign regulatory authorities may require us to perform an additional clinical trial or trials before approving our marketing applications. Moreover, if we or any of our CROs, principal investigators, or trial sites, fail to comply with applicable regulatory and GCP requirements, then we, our CROs, principal investigators, or trial sites may be subject to enforcement actions, such as fines, warning letters, untitled letters, clinical holds, civil or criminal penalties, and/or injunctions. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under GMP regulations. Our failure to comply with these regulations may require us to delay or repeat clinical trials, which would delay the regulatory approval process.

For example, we are currently involved in a dispute with our former CRO relating to the conduct of our Phase 3 study where we allege (i) breach of contract, (ii) fraud in the inducement, and (iii) fraud. In connection with this dispute, we have alleged that our CRO failed to properly select, monitor and supervise the study sites and principal investigators, ensure proper enrollment of subjects, and ensure strict compliance with the Phase 3 trial protocol and GCP and other applicable regulatory requirements. Should our allegations be found to be true regulatory authorities may rule the data collected by that former CRO unusable in support of our marketing applications. This would result in our having to enroll approximately 125 additional subjects in our Phase 3 study beyond our current plans, which could cause additional delays in our clinical testing and development program. Currently the Phase 3 study is on partial clinical hold.

If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully fulfill their regulatory obligations, carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we diligently oversee and carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in our clinical development in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We have obtained orphan drug designation from the FDA for Multikine for neoadjuvant, or primary, therapy in patients with squamous cell carcinoma of the head and neck, but we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full Biologics License Application, or BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even though we have received orphan drug designation for Multikine for the treatment of squamous cell carcinoma of the head and neck, we may not be the first to obtain marketing approval of a product for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication, or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Our current and future relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable healthcare laws and regulations.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors may expose us to broadly applicable healthcare laws, including, without limitation:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal Physician Payments Sunshine Act and its implementing regulations, which imposed annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, all of which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our current and future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also adversely affect our business.

Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers and other third-party payors. We anticipate that government authorities and other third-party payors will continue efforts to contain healthcare costs by limiting the coverage and reimbursement levels for new drugs. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

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Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs that may result in more limited coverage or downward pressure on the price we may otherwise receive for our product candidates. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and established the Center for Medicare and Medicaid Innovation with broad authority to test and implement new payment models under Medicare and Medicaid, which are designed to reduce expenditures while preserving and enhancing quality of care.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers. On April 16, 2015, President Obama signed into law the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA. Among other things, MACRA creates incentives for physicians to participate in alternative payment models under Medicare that emphasize quality and value in place of the traditional, volume-based fee-for-service program. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Foreign governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market Multikine in both the United States and foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to Multikine. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. Coverage and reimbursement decisions in one foreign jurisdiction may impact decisions in other countries. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that demonstrate our product candidate is more effective than current treatments and that compare the cost-effectiveness of Multikine to other available therapies. If reimbursement of Multikine is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Risks Related to Intellectual Property

We may not be able to achieve or maintain a competitive position, and other technological developments may result in our proprietary technologies becoming uneconomical or obsolete.

We are involved in a biomedical field that is undergoing rapid and significant technological change. The pace of change continues to accelerate. The successful development of product candidates from our compounds, compositions and processes, through research financed by us, or as a result of possible third-party licensing arrangements with pharmaceutical or other companies, is not assured. We may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all.

Many companies are working on drugs designed to cure or treat cancer or cure and treat viruses, such as HPV or H1N1. Many of these companies have financial, research and development, and marketing resources which are much greater than ours and are capable of providing significant long-term competition either by establishing in-house research groups or by forming collaborative ventures with other entities. In addition, smaller companies and non-profit institutions are active in research relating to cancer and infectious diseases. The future market share of Multikine or our other product candidates, if approved, will be reduced or eliminated if our competitors develop and obtain approval for products that are safer or more effective than our product candidates. Moreover, the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are often evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether:

we were the first to make the inventions covered by each of our issued patents and pending patent applications;

we were the first to file patent applications for these inventions;

others will independently develop similar or alternative technologies or duplicate any of our technologies;

any of our pending patent applications will result in issued patents;

any of our patents will be valid or enforceable;

any patents issued to us or our collaboration partners will provide us with any competitive advantages, or will be challenged by third parties;

we will be able to develop additional proprietary technologies that are patentable;

the U.S. government will exercise any of its statutory rights to our intellectual property that was developed with government funding; or

our business may infringe the patents or other proprietary rights of others.

Our patents might not protect our technology from competitors, in which case we may not have any advantage over competitors in selling any products that we may develop.

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent position, as well as our ability to maintain adequate intellectual property protection for our technologies, product candidates, and any future products in the United States and other countries. If we do not adequately protect our technology, product candidates and future products, competitors may be able to use or practice them and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Certain aspects of our technologies are covered by U.S. and foreign patents. In addition, we have a number of new patent applications pending. There is no assurance that the applications still pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection any issued patents might afford us. Disputes may arise between us and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time consuming and there can be no assurance that we will be in a position, or will deem it advisable, to carry on such a defense. A suit for patent infringement could result in increasing costs, delaying or halting development, or even forcing us to abandon a product candidate. Other private and public concerns, including universities, may have filed applications for, may have been issued, or may obtain additional patents and other proprietary rights to technology potentially useful or necessary to us. We are not currently aware of any such patents, but the scope and validity of such patents, if any, and the cost and availability of such rights are impossible to predict.

Much of our intellectual property is protected as trade secrets or confidential know-how, not as a patent.

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. Much of our intellectual property pertains to our manufacturing system, certain aspects of which may not be suitable for patent filings and must be protected as trade secrets and/or confidential know-how. This type of information must be protected diligently by us to protect its disclosure to competitors, since legal protections after disclosure may be minimal or non-existent. Accordingly, much of our value of this intellectual property is dependent upon our ability to keep our trade secrets and know-how confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally, and is using, trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, in some cases a regulator considering our application for product candidate approval may require the disclosure of some or all of our proprietary information. In such a case, we must decide whether to disclose the information or forego approval in a particular country. If we are unable to market our product candidates in key countries, our opportunities and value may suffer.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of such trade secrets and/or confidential know-how.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and employees.

Risks related to this Offering

Management will have broad discretion as to the use of the proceeds from this offering.

We currently intend to use the net proceeds from the offering for the Phase 3 clinical study and general corporate purposes. See “Use of Proceeds” on page S-44 of this prospectus supplement. We have not designated the specific amount of net proceeds to us from this offering that will be used for these purposes. Accordingly, our management will have broad discretion as to the allocation of these net proceeds and could use them for purposes other than those contemplated at the time of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

In addition, the net proceeds from this offering will not be sufficient to complete clinical trials and other studies required for the approval of any product candidate, including the Phase 3 clinical trial of Multikine, by the FDA or any other regulatory authority, and we will need significant additional funds in order to complete the Phase 3 Multikine study.

Because there is no minimum required for the offering to close, investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus.

We have not specified a minimum offering amount nor have or will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.

You will experience immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering.

Since the assumed public offering price of the securities offered pursuant to this prospectus supplement and the accompanying prospectus is higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. After giving effect to the sale of 10,000,000 shares of common stock and warrants in this offering, and after deducting estimated placement agent’s fees and estimated offering expenses payable by us, if you purchase securities in this offering, you will suffer immediate and substantial dilution of approximately $0.08 per share in the net tangible book value of the common stock you acquire based on our net tangible book value as of December 31, 2016.

In the event that any Series GG warrants are exercised, you will experience additional dilution to the extent that the exercise price of those warrants is higher than the net tangible book value of our common stock at the time of exercise.

Furthermore, in the past, we issued options and warrants to acquire shares of our common stock at prices below the public offering price shown on the cover page of this prospectus. To the extent these outstanding options and warrants are ultimately exercised, investors purchasing common stock in this offering may sustain further dilution.

You may experience future dilution as a result of future equity offerings or other equity issuances.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. If we sell common stock, convertible securities or other equity securities, your investment in our common stock will be diluted. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Our outstanding options and warrants may adversely affect the trading price of our common stock.

As of February 17, 2017, there were outstanding warrants and options which allow the holders to purchase 170,195,764 shares that may be issued upon the exercise of outstanding warrants, with a weighted average exercise price of $0.52 per share, and 8,812,250 shares that may be issued upon the exercise of outstanding options, with a weighted average exercise price of $2.35 per share. The outstanding options and warrants could adversely affect our ability to obtain future financing or engage in certain mergers or other transactions, since the holders of options and warrants can be expected to exercise them at a time when we may be able to obtain additional capital through a new offering of securities on terms more favorable to us than the terms of the outstanding options and warrants. For the life of the options and warrants, the holders have the opportunity to profit from a rise in the market price of our common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding options and warrants will also dilute the ownership interests of our existing stockholders.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Taking into account our public offerings and other transactions, we may have triggered an “ownership change” limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could result in increased tax liability to us.

Since we do not intend to pay dividends on our common stock, any potential return to investors will result only from any increases in the price of our common stock.

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no common stock dividends have been declared or paid by us and we have no intention of paying any common stock dividends in the foreseeable future. Additionally, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to our investors will therefore be limited to appreciation in the price of our common stock, which may never occur. If our stock price does not increase, our investors are unlikely to receive any return on their investments in our common stock.

The price of our common stock has been volatile and is likely to continue to be volatile, which could result in substantial losses for our shareholders.

Our stock price has been, and is likely to continue to be, volatile. As a result of this volatility, you may not be able to sell your shares at or above its current market price. The market price for our common stock may be influenced by many factors, including:

actual or anticipated fluctuations in our financial condition and operating results;

actual or anticipated changes in our growth rate relative to our competitors;

competition from existing products or new products or product candidates that may emerge;

development of new technologies that may address our markets and may make our technology less attractive;

changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;

announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

developments or disputes concerning patent applications, issued patents or other proprietary rights;

the recruitment or departure of key personnel;

failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

variations in our financial results or those of companies that are perceived to be similar to us;

changes to coverage and reimbursement levels by commercial third-party payors and government payors, including Medicare, and any announcements relating to reimbursement levels;

general economic, industry and market conditions; and

the other factors described in this “Risk Factors” section.

We have been advised that we are not in compliance with certain continued listing standards of the NYSE MKT.

On December 9, 2016, we received a letter from the NYSE MKT, our current listing exchange, which advised us that, based upon our Quarterly Report for the quarter ended June 30, 2016, we were noncompliant with certain continued listing standards of the NYSE MKT. We can maintain our listing by submitting a plan of compliance by January 9, 2017. This plan must advise of actions we have taken or will take to regain compliance with the continued listing standards by June 11, 2018. We submitted such a plan on January 9, 2017. If the plan is not acceptable, or we do not make sufficient progress under the plan to reestablish compliance by June 11, 2018, the staff of the exchange may initiate proceedings to delist our securities from the NYSE MKT. We may appeal a delisting determination in accordance with the rules of the exchange.

In addition, the NYSE MKT will not normally remove the securities of an issuer which is otherwise below the stockholders’ equity criteria noted above if the issuer has a market capitalization of at least $50 million.

The letter from the NYSE MKT has no immediate effect on the listing of our securities on the exchange.

Under our amended bylaws, stockholders that initiate certain proceedings may be obligated to reimburse us and our officers and directors for all fees, costs and expenses incurred in connection with such proceedings if the claim proves unsuccessful.

On February 18, 2015, we adopted new bylaws which include a fee-shifting provision in Article X for stockholder claims. Article X provides that in the event any stockholder initiates or asserts a claim against us, or any of our officers or directors, including any derivative claim or claim purportedly filed on our behalf, and the stockholder does not obtain a judgment on the merits that substantially achieves, in substance and amount, the full remedy sought, then the stockholder will be obligated to reimburse us and any of our officers or directors named in the action, for all fees, costs and expenses of every kind and description that we or our officers or directors may incur in connection with the claim. In adopting Article X, it is our intent that:

all actions, including federal securities law claims, would be subject to Article X;

the phrase “a judgment on the merits” means the determination by a court of competent jurisdiction on the matters submitted to the court;

the phrase “substantially achieves, in both substance and amount” means the plaintiffs in the action would be awarded at least 90% of the relief sought;

only persons who were stockholders at the time an action was brought would be subject to Article X; and

only the directors or officers named in the action would be allowed to recover.

The fee-shifting provision contained in Article X of our bylaws is not limited to specific types of actions, but is rather potentially applicable to the fullest extent permitted by law. Fee-shifting bylaws are relatively new and untested. The case law and potential legislative action on fee-shifting bylaws are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such bylaws. For example, it is unclear whether our ability to invoke our fee-shifting bylaw in connection with claims under the federal securities laws, including any claims related to this offering, would be pre-empted by federal law. Similarly, it is unclear how courts might apply the standard that a claiming stockholder must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of our fee-shifting bylaw in connection with such claims, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting bylaw in any particular dispute, including any claims related to this offering. In addition, given the unsettled state of the law related to fee-shifting bylaws, such as ours, we may incur significant additional costs associated with resolving disputes with respect to such bylaw, which could adversely affect our business and financial condition.

If a stockholder that brings any such claim, suit, action or proceeding is unable to obtain the required judgment, the attorneys' fees and other litigation expenses that might be shifted to a claiming stockholder are potentially significant. This fee-shifting bylaw, therefore, may dissuade or discourage stockholders (and their attorneys) from initiating lawsuits or claims against us or our directors and officers. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our stockholders or otherwise discourage plaintiffs' attorneys from representing our stockholders at all. As a result, this bylaw may limit the ability of stockholders to affect our management and direction, particularly through litigation or the threat of litigation.

The provision of our amended bylaws requiring exclusive venue in the U.S. District Court for Delaware for certain types of lawsuits may have the effect of discouraging lawsuits against us and our directors and officers.

Article X of our amended bylaws provides that stockholder claims brought against us, or our officers or directors, including any derivative claim or claim purportedly filed on our behalf, must be brought in the U.S. District Court for the district of Delaware and that with respect to any such claim, the laws of Delaware will apply.

The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum the stockholder finds favorable for disputes with us or our directors or officers, and may have the effect of discouraging lawsuits with respect to claims that may benefit us or our stockholders.

FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents that are incorporated or deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus, contain or incorporate by reference "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can generally identify these forward-looking statements by forward-looking words such as "anticipates," "believes," "expects," "intends," "future," "could," "estimates," "plans," "would," "should," "potential," "continues" and simil expressions (as well as other words or expressions referencing future events, conditions or circumstances). These forward-looking statements involve risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements, including, but not limited to:

the progress and timing of, and the amount of expenses associated with, our research, development and commercialization activities for our product candidates, including Multikine;

the expected progress, rate, timing and success of patient enrollment in our Phase 3 clinical trial of Multikine that is currently subject to a partial clinical hold by FDA;

our expectations regarding the timing, costs and outcome of any pending or future litigation matters, lawsuits or arbitration proceedings, including but not limited to the pending arbitration proceeding we initiated against our former clinical research organization, or CRO;

the success of our clinical studies for our product candidates;

our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;

our expectations regarding federal, state and foreign regulatory requirements;

the therapeutic benefits and effectiveness of our product candidates;

the safety profile and related adverse events of our product candidates;

our ability to manufacture sufficient amounts of Multikine or our other product candidates for use in our clinical studies or, if approved, for commercialization activities following such regulatory approvals;

our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates;

our expectations as to future financial performance, expense levels and liquidity sources;

our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;

anticipated trends and challenges in our potential markets;

our ability to attract, retain and motivate key personnel;

our ability to continue as a going concern; and

our liquidity.

All forward-looking statements contained herein are expressly qualified in their entirety by this cautionary statement, the risk factors set forth under the heading “Risk Factors” and elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated or deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus. The forward-looking statements contained in this prospectus supplement, the accompanying prospectus and any document incorporated or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus, speak only as of their respective dates. Except to the extent required by applicable laws and regulations, we undertake no obligation to update these forward-looking statements to reflect new information, events or circumstances after the date of this prospectus supplement or to reflect the occurrence of unanticipated events. In light of these risks and uncertainties, the forward-looking events and circumstances described in this prospectus supplement, the accompanying prospectus and the documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus may not occur and actual results could differ materially from those anticipated or implied in such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $830,000 after deducting estimated placement agent's fees and estimated offering expenses payable by us. Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us.

We intend to use the net proceeds from the offering for the Phase 3 clinical study and general corporate purposes. We have not yet determined the amount of net proceeds to be used specifically for these purposes. The net proceeds from this offering will not be sufficient to complete clinical trials and other studies required for the approval of any product candidate, including the Phase 3 clinical trial of Multikine, by the FDA or any other regulatory authority, and we will need significant additional funds in order to complete the Phase 3 Multikine study.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management with regard to the use of the net proceeds. Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing instruments.

PRICE RANGE OF COMMON STOCK

Our common stock is publicly traded on the NYSE MKT under the symbol "CVM". The following table sets forth, for the periods indicated, the high and low intraday sale prices of our common stock as reported by the NYSE MKT.

	HIGH	LOW
FY 2017		
First Quarter (through December 31, 2016)	$0.31	$0.06
FY 2016		
Fourth Quarter (through September 30, 2016)	$0.54	$0.24
Third Quarter (through June 30, 2016)	$0.60	$0.44
Second Quarter (through March 31, 2016)	$0.66	$0.36
First Quarter (through December 31, 2015)	$0.75	$0.36
FY 2015		
Fourth Quarter (through September 30, 2015)	$0.80	$0.48
Third Quarter (through June 30, 2015)	$1.09	$0.59
Second Quarter (through March 31, 2015)	$1.23	$0.59
First Quarter (through December 31, 2014)	$0.91	$0.54

On February 16, 2017, the last reported sale price of our common stock on the NYSE MKT was $0.12 per share. As of February 17, 2017, there were 190,965,450 shares of our common stock outstanding held by approximately 1,000 holders of record.

DILUTION

If you invest in our common stock in this offering, your interest will be immediately diluted to the extent of the difference between the public offering price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of December 31, 2016, we had a net tangible book value of $0.02 per share of common stock. Our net tangible book value represents total tangible assets less total liabilities, all divided by the number of shares of common stock outstanding on December 31, 2016.

The calculations below do not give any effect to the shares of common stock issuable upon the exercise of the warrants sold in this offering or to the proceeds from any exercise of the warrants.

After giving effect to the sale of shares of common stock in this offering, and after deducting the placement agent's fees estimated offering expenses, our as adjusted net tangible book value at December 31, 2016 would have been approximately $4.2 million, or $0.02 per share. This represents no immediate increase in as adjusted net tangible book value per share to existing stockholders and an immediate dilution of $0.08 per share to new investors. The following table illustrates this per share dilution:

Public offering price per share	$0.10
Net tangible book value per share as of December 31, 2016	$0.02
Increase in net tangible book value per share attributable to this offering	--
As adjusted net tangible book value per share after this offering	$0.02
Dilution per share to new investors participating in this offering	$0.08

This number is based on 190,931,286 shares of our common stock outstanding as of December 31, 2016, which excludes(i) 170,195,764 shares that may be issued upon the exercise of outstanding warrants, with a weighted average exercise price of $0.52 per share; (ii) 8,212,250 shares that may be issued upon the exercise of outstanding options, with a weighted average exercise price of $2.35 per share; (iii) 10,000,000 shares of common underlying the warrants (Series GG) to be issued in the concurrent private placement, at an exercise price of $0.12 per share; and (iv) 500,000 shares of common stock issuable upon exercise of the placement agent warrants, at an exercise price of $0.125 per share.

CAPITALIZATION

The following table sets forth (i) our actual cash and cash equivalents and consolidated capitalization as of December 31, 2016, and (ii) our cash and cash equivalents and consolidated capitalization as of December 31, 2016, adjusted to give effect to this offering. No adjustments have been made to reflect normal operations by us or other developments with our business after December 31, 2016. As a result, the as adjusted information provided below is not indicative of our actual cash and cash equivalents position or consolidated capitalization as of any date. You should read this table in conjunction with "Use of Proceeds" in this prospectus supplement and the consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Quarterly Report on Form 10-Q for the quarter ended December 31, 2016, which is incorporated by reference in this prospectus supplement.

	As of December 31, 2016	
	Actual	As Adjusted
Cash and cash equivalents	$2,386,673	$3,216,673
Capital lease	25,227	25,227
Total debt	25,227	25,227
Stockholders' equity:		
Preferred stock, par value $0.01; 200,000 shares authorized; -0- shares issued and outstanding, actual and as adjusted	--	--
Common stock, par value $0.01; 600,000,000 shares authorized; 190,931,286 shares issued and outstanding, actual(1); 200,931,286 shares issued and outstanding, as adjusted(1)	1,909,313	2,009,313
Additional paid-in capital(2)	284,655,153	284,553,992
Accumulated deficit	(282,131,175)	(282,131,175)
Total stockholders' equity	4,433,291	4,432,130
Total capitalization	-	$4,457,357

(1) Excludes shares that may be issued upon the exercise of outstanding warrants or options as shown in the following table:

Security	Shares Issuable Upon Exercise/Conversion	Exercise/ConversionPrice	Expiration Date
Series P warrants	590,001	$4.50	March 6, 2017
Series S warrants(a)	25,928,010	$1.25	October 11, 2018
Series U warrants	445,514	$1.75	October 17, 2017
Series V warrants	20,253,164	$0.79	May 28, 2020
Series W warrants	17,223,248	$0.67	October 28, 2020
Series X warrants	3,000,000	$0.37	January 13, 2021
Series Y warrants	650,000	$0.48	February 15, 2021
Series Z warrants	6,600,000	$0.55	November 23, 2021
Series ZZ warrants	500,000	$0.55	May 18, 2021
Series AA warrants	5,000,000	$0.55	February 22, 2022
Series BB warrants	400,000	$0.55	August 22, 2021
Series CC warrants	17,012,000	$0.20	December 8, 2021

Series DD warrants	34,024,000	$0.18	June 8, 2017
Series EE warrants	34,024,000	$0.18	September 8, 2017
Series FF warrants	1,701,200	$0.16	December 1, 2021
Related party warrants	2,844,627	$0.53	August 18, 2017
Incentive stock options	1,648,966	$2.97(c)	September 13, 2017–August 5, 2024
Non-qualified stock options(b)	6,563,284	$2.19(c)	March 5, 2017– July 31, 2026

a)
Series S warrants are publicly traded on the NYSE MKT under the symbol “CVM WS.”
b)
Includes options issued to consultants.
c)
Reflects weighted average exercise price.

(1)
Represents the sale of 10,000,000 shares of our common stock in this offering.
(2)
The estimated fair value of the warrants issued in this offering was deducted from the equity amount from this offering

GOVERNMENT REGULATION

The FDA and other regulatory authorities at federal, state and local levels and in foreign countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing and post-approval monitoring and reporting of biologics such as those we are developing. We, along with third party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Food and Drug Administration Approval

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually;

approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is initiated;

performance of adequate and well-controlled human clinical trials in compliance with Good Clinical Practice, or GCP, regulations to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;

preparation of and submission to the FDA of a Biologics License Application, or BLA, after completion of clinical trials;

satisfactory completion of an FDA Advisory Committee review, if applicable;

a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with GCPs; and

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FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to commencing the first clinical trial with a product candidate in the U.S., we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to commence a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of approval of a Biologics License Application, or BLA, human clinical trials are typically conducted in three or four sequential phases that may overlap.

Phase 1— The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

Phase 2— The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3— The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Phase 4— In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial User Fee to the FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP

requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete but the application is not ready for approval. A Complete Response Letter may request additional information or clarification, including new clinical studies. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory approval of our products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA’s review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established the new Breakthrough Therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-phase 2 meeting with the FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment.

Fast Track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP, which impose certain procedural and documentation requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements on manufacturers. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If we are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the BLA.

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The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

fines, warning letters or holds on post-approval clinical studies;

refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;

product seizure or detention, or refusal to permit the import or export of products; or

injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer’s communications on the subject of off-label use of their products.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of 7 years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Other Health Care Laws

Our sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs must comply with the anti-kickback provisions of the Social Security Act, the Foreign Corrupt Practices Act, the False Claims Act, the Physician Payments Sunshine Act, the Veterans Health Care Act and similar state laws.

Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, exclusion from government health care programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private “qui tam” actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products and new drug classes, including biosimilars such as our product candidates. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

DESCRIPTION OF SECURITIES

Common stock

The material terms and provisions of our common stock are described under the caption “Description of Securities” in the accompanying prospectus. As of February 17, 2017, we had 190,965,450 shares of our common stock outstanding. Our common stock is listed on the NYSE MKT under the symbol “CVM”.

Rights Agreement

In November 2007, we declared a dividend of one Series A Right and one Series B Right, or collectively the Rights, for each share of our common stock which was outstanding on November 9, 2007. When the Rights become exercisable, each Series A Right will entitle the registered holder, subject to the terms of a Rights Agreement, to purchase from us one share of our common stock at a price equal to 20% of the market price of our common stock on the exercise date, although the price may be adjusted pursuant to the terms of the Rights Agreement. If after a person or group of affiliated persons has acquired 15% or more of our common stock or following the commencement of a tender offer for 15% or more of our outstanding common stock (i) we are acquired in a merger or other business combination and we are not the surviving corporation, (ii) any person consolidates or merges with us and all or part of our common shares are converted or exchanged for securities, cash or property of any other person, or (iii) 50% or more of our consolidated assets or earning power are sold, proper provision will be made so that each holder of a Series B Right will thereafter have the right to receive, upon payment of the exercise price of $100 (subject to adjustment), that number of shares of common stock of the acquiring company which at the time of such transaction has a market value that is twice the exercise price of the Series B Right.

The description and terms of the Rights are set forth in a Rights Agreement between the Company and Computershare Trust Company, N.A., as Rights Agent.

Distribution of Rights

Initially, stockholders will not receive separate certificates for the Rights as the Rights will be represented by outstanding common stock certificates. Until the exercise date, the Rights cannot be bought, sold or otherwise traded separately from the common stock. Certificates for common stock carry a notation that indicates that Rights are attached to the common stock and incorporate the terms of the Rights Agreement.

Separate certificates representing the Rights will be distributed as soon as practicable after the earliest to occur of:

15 business days following a public announcement that a person or group of affiliated or associated persons has acquired beneficial ownership of 15% or more of the outstanding common stock, or

15 business days (or such later date as may be determined by action of our board of directors prior to such time as any person or group of affiliated persons has acquired 15% or more of our common stock) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of such outstanding common stock.

The earlier of such dates described above is called the “distribution date.”

Until the distribution date (or earlier redemption or expiration of the Rights), the surrender for transfer of any certificates for common stock outstanding as of the record date, even without such notation, will also constitute the transfer of the Rights associated with the common stock represented by such certificate. As soon as practicable following the distribution date, separate certificates evidencing the Rights will be mailed to holders of record of the common stock as of the close of business on the distribution date and such separate right certificates alone will evidence the Rights.

Exercise and Expiration

The holders of the Rights are not required to take any action until the Rights become exercisable. The Rights are not exercisable until the distribution date. Holders of the Rights will be notified by us that the Rights have become exercisable. The Rights will expire on October 30, 2020, unless the expiration date is extended or unless the Rights are earlier redeemed by us as described below.

Redemption

At any time prior to the distribution date, our board of directors may redeem the Rights in whole, but not in part, at a price of $0.0001 per Right. Subject to the foregoing, the redemption of the Rights may be made effective at such time, on such basis and with such conditions as our board of directors in its sole discretion may establish. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only entitlement of the holders of Rights will be to receive the redemption price.

Exchange Option

At any time after a person or group of affiliated persons has acquired 15% or more of our common stock or following the commencement of a tender offer for 15% or more of our outstanding common stock, and prior to the acquisition by such person of 50% or more of the outstanding common stock, our board of directors may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment).

Other Provisions

The terms of the Rights may be amended by our board of directors without the consent of the holders of the Rights, except that from and after such time a person or group of affiliated persons has acquired 15% or more of our common stock no such amendment may adversely affect the interests of the holders of the Rights.

Until a Right is exercised, the holder of the Right, as such, will not have any rights as a stockholder, including, without limitation, the right to vote or to receive dividends.

The Rights may have certain anti-takeover effects. The Rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by our board of directors. However, the Rights should not interfere with any merger or other business combination approved by a majority of our board of directors because the Rights may be redeemed by us at any time prior to the distribution date. Thus, the Rights are intended to encourage persons who may seek to acquire control of us to initiate such an acquisition through negotiations with our board of directors. However, the effect of the Rights may be to discourage a third party from making a partial tender offer or otherwise attempting to obtain a substantial position in the equity securities of, or seeking to obtain control of, us. To the extent any potential acquisition is deterred by the Rights, the Rights may have the effect of preserving incumbent management in office.

Attorneys' Fees in Stockholder Actions

CEL-SCI's bylaws which include a fee-shifting provision in Article X for stockholder claims. Article X provides that in the event that any stockholder initiates or asserts a claim against us, or any of our officers or directors, including any derivative claim or claim purportedly filed on our behalf, and the stockholder does not obtain a judgment on the merits that substantially achieves, in substance and amount, the full remedy sought, then the stockholder will be obligated to reimburse us and any of our officers or directors named in the action, for all fees, costs and expenses of every kind and description, including but not limited to all reasonable attorneys' fees and other litigation expenses, that we or our officers or directors who were named in the action may incur in connection with such claim.

Our fee-shifting provision is not limited to specific types of actions, but is rather potentially applicable to the fullest extent permitted by law. There are several types of remedies that a stockholder may seek in connection with an action or proceeding against us, including declaratory or injunctive relief, or monetary damages. If a stockholder is not successful in obtaining a judgment that substantially achieves in substance, such as in the case of a claim for declaratory or injunctive relief, or amount, such as in the case of a claim for monetary damages, our and our officers' and directors' litigation expenses may be shifted to the stockholder.

Fee-shifting provisions are relatively new and untested. The case law and potential legislative action on fee shifting bylaws are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such bylaws. For example, it is unclear whether our ability to invoke our fee-shifting bylaw in connection with claims under the federal securities laws, including claims related to this offering, would be pre-empted by federal law. Similarly, it is unclear how courts might apply the standard that a stockholder must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of our fee shifting bylaw in connection with such claims, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting bylaw in any particular dispute, including any claims related to this offering.

If a stockholder that brings any such claim is unable to obtain the required judgment, the attorneys' fees and other litigation expenses that might be shifted to such a stockholder are potentially significant. This fee-shifting bylaw, therefore, may dissuade or discourage stockholders (and their attorneys) from initiating lawsuits or claims against us or our directors and officers. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our stockholders or otherwise discourage plaintiffs' attorneys from representing our stockholders at all. As a result, this bylaw may limit the ability of stockholders to affect the management and direction of our company, particularly through litigation or the threat of litigation.

PRIVATE PLACEMENT TRANSACTION AND WARRANTS

Concurrently with the closing of the sale of shares of common stock in this offering, we also expect to issue and sell to the investors warrants (Series GG) to purchase an aggregate of 10,000,000 shares of our common stock, at an initial exercise price equal to $0.12 per share (the "Warrants").

Each Warrant shall be first exercisable on the six month anniversary of the issuance date and have a term of exercise equal to five and a half years (51/2) from the date on which first exercisable. Subject to limited exceptions, a holder of Warrants will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise.

In connection with a fundamental transaction the holder of the warrants shall be entitled to the Black Scholes value of the warrants

Such securities will be issued and sold without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(a)(2) of the Act and/or Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the investors may exercise those warrants and sell the underlying shares only pursuant to an effective registration statement under the Securities Act covering the resale of those shares, an exemption under Rule 144 under the Securities Act, or another applicable exemption under the Securities Act.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement dated February 12, 2017, we have engaged Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering of our shares of common stock pursuant to this prospectus supplement and accompanying prospectus. Under the terms of the engagement agreement, the placement agent has agreed to be our exclusive placement agent, on a reasonable best efforts basis, in connection with the issuance and sale by us of our shares of common stock in this takedown from our shelf registration statement. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The engagement agreement does not give rise to any commitment by the placement agent to purchase any of our shares of common stock or the private placement warrants, and the placement agent will have no authority to bind us by virtue of the engagement agreement. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offering. The placement agent may engage sub-agents or selected dealers to assist with the offering.

We will enter into securities purchase agreements directly with investors in connection with this offering, and we will only sell to investors who have entered into securities purchase agreements.

We expect to deliver the shares of our common stock being offered pursuant to this prospectus supplement, as well as the warrants offered in the concurrent private placement, on or about February 23, 2017, subject to customary closing conditions.

We have agreed to pay the placement agent a total cash fee equal to 7% of the gross proceeds of this offering. We will also pay the placement agent aggregate expenses of $75,000. We estimate our total expenses associated with the offering, excluding Placement Agent commissions, will be approximately $100,000.

The following table shows per share and total cash placement agent’s fees we will pay to the placement agent in connection with the sale of the shares of common stock pursuant to this prospectus supplement and the accompanying prospectus assuming the purchase of all of the shares of common stock offered hereby:

Per share placement agent fee	$0.007
Total	$70,000

Placement Agent Warrants

In addition, we have agreed to issue to the placement agent warrants to purchase up to 500,000 shares of common stock (which represents 5% of the aggregate number of shares of common stock sold in this offering) at an exercise price of $0.125 per share (representing 125% of the offering price for a share of common stock offered in this offering). The placement agent warrants will have substantially the same terms as the warrants being sold to the investors in this offering. Pursuant to FINRA Rule 5110(g), the placement agent warrants and any shares issued upon exercise of the placement agent warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time

period.

Right of First Refusal