

VistaGen Therapeutics, Inc.

Form S-1/A

July 07, 2014

As filed with the Securities and Exchange Commission on July 3, 2014

Registration No. 333-195901

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

FORM S-1/A  
(Amendment No. 2)

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

VISTAGEN THERAPEUTICS, INC.  
(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation or organization)	3841 (Primary Standard Industrial Classification Code Number)	20-5093315 (I.R.S. Employer Identification Number)
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VistaGen Therapeutics, Inc.  
343 Allerton Avenue  
South San Francisco, CA 94080  
(650) 577-3600

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Shawn K. Singh, J.D.  
Chief Executive Officer  
VistaGen Therapeutics, Inc.  
343 Allerton Avenue  
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

(Do not check if a smaller reporting company)

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CALCULATION OF REGISTRATION FEE

Title Of Each Class Of Securities To Be Registered	Proposed Maximum Aggregate Offering Price	Amount Of Registration Fee (2)
Up to _____ shares of common stock, \$0.001 par value (2)	\$	\$2,447.20 (3)

(1) The Registration Statement shall also cover any additional shares of common stock that become issuable by reason of any stock dividend, stock split or other similar transaction effected without the receipt of consideration that results in an increase in the number of the outstanding shares of common stock of the Registrant.

(2) Calculated pursuant to Rule 457(o) of the rules and regulations under the Securities Act of 1933, as amended.

(3) \$1,288 was previously paid.

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

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Subject to Completion, dated July \_\_\_, 2014

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

Preliminary Prospectus

\_\_\_\_\_ shares

We are offering up to \_\_\_\_\_ shares of our common stock pursuant to this prospectus (the Offering).

Our securities are not listed on a national securities exchange. Our common stock is quoted on the OTC Markets (OTCQB) under the symbol "VSTA". On July \_\_\_, 2014 the closing price for our common stock was \$0.\_\_\_\_ per share.

	Per share	Total
Price to the public	\$	\$
Placement agent commission(1)(3)	\$	\$
Proceeds, before expenses, to us(2)(3)	\$	\$

(1) For the purpose of estimating the placement agent's commissions, we have assumed they will receive their maximum commission on all sales made in the Offering. The placement agent will also be entitled to reimbursement of certain expenses related to this Offering, including blue-sky fees and expenses.

(2) We estimate the total expenses of this Offering, excluding the placement agent commissions, will be approximately \$\_\_\_\_\_. Because there is no minimum offering amount required as a condition to closing in this Offering, the actual public offering amount, placement agent commissions, and proceeds to us, if any, are not presently determinable and may be substantially less than the total Offering price set forth above. Once the Offering price has been determined, the common stock offering price will remain fixed for the duration of the Offering. See "Plan of Distribution" beginning on page 40 of this prospectus for more information on this Offering and the placement agent arrangements.

(3) Of the total number of shares of common stock that may be issued in connection with this Offering, assuming the Offering results in minimum gross proceeds of \$10.0 million, up to \_\_\_\_\_ shares may be issued in exchange for certain promissory notes of the Company that automatically convert into shares of Common Stock issued in connection with the Offering, unless the holders of such notes elect to receive cash in lieu of such shares. See "Use of Proceeds" and "Note Conversions". The placement agent will not be paid a commission in connection with the issuance of such shares, nor will the Company receive any proceeds from the issuance thereof.

Geller Biopharm (Geller Biopharm or Agent), a healthcare investment banking division of Financial West Group, has agreed to act as our placement agent in connection with this Offering. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of securities. However, Geller Biopharm will use their best efforts to arrange for the sale of the securities offered by us in this Offering. We have agreed to pay the placement agent a cash fee equal to 8% of the gross proceeds of the securities sold by us in this Offering, as well as certain expenses.

This Offering will terminate on August 31, 2014, unless the maximum number of shares offered is fully subscribed before that date or we decide to terminate the Offering prior to that date. In either event, the Offering may be closed and we may conduct multiple closings without further notice to you. All costs associated with the registration will be borne by us. As there is no minimum purchase requirement, no funds are required to be escrowed and all net proceeds will be available to us at closing for use as set forth in “Use of Proceeds” beginning on page 37.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” beginning on page 7 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

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

The date of this prospectus is July\_\_\_\_, 2014

Sole Placement Agent

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## ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with additional information or information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

On July \_\_, 2014, our board of directors approved an amendment to our Articles of Incorporation, as amended (Articles), to authorize a reverse stock split of our authorized and issued and outstanding shares of common stock at a ratio of up to one-for-\_\_\_\_twenty, with the exact ratio to be determined by our board of directors (Stock Consolidation). Although no assurances can be give, the purpose of the Stock Consolidation is to make our shares more attractive to institutional investors and to facilitate a possible listing of our shares on the NASDAQ Capital Market or other national securities exchange. The Stock Consolidation is anticipated to be effective prior to August 31, 2014. Each reference to shares of common stock in this prospectus is pre-Stock Consolidation, and does not reflect the up to one-for-\_\_\_\_ adjustment anticipated as a result of the Stock Consolidation. See also “Risk Factors” beginning on page 7.

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PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus and does not contain all the information you should consider before investing in our common stock. You should carefully read this prospectus in its entirety before investing in our common stock, including the section entitled “Risk Factors” and our financial statements and related notes included elsewhere in this prospectus.

Overview

Unless the context otherwise requires, the words “VistaGen Therapeutics, Inc.,” “VistaGen,” “we,” “the Company,” “us” and “our” refer to VistaGen Therapeutics, Inc., a Nevada corporation. “VistaGen California” refers to VistaGen Therapeutics, Inc., a California corporation and our wholly owned subsidiary.

We are a stem cell company headquartered in South San Francisco, California, focused on drug rescue and regenerative medicine. We believe better cells lead to better medicines™ and that the key to making better cells is precisely controlling the differentiation of human pluripotent stem cells, which are the building blocks of all cells of the human body. Our stem cell technology platform, which we refer to as Human Clinical Trials in a Test Tube, is based on a combination of proprietary and exclusively licensed technologies for controlling the differentiation of human pluripotent stem cells and producing multiple types of mature, functional, adult human cells that we use, or plan to use, to reproduce complex human biology and disease. We have used the human heart cells and liver cells we produce to design and develop CardioSafe 3D and LiverSafe 3D, our customized in vitro biological assay systems for assessing, respectively, the potential cardiac toxicity and liver toxicity of small molecule new drug rescue candidates. We believe our Human Clinical Trials in a Test Tube platform, anchored by CardioSafe 3D and LiverSafe 3D, offer a new paradigm for evaluating potential heart and liver toxicity early in drug development, long before costly, high risk human clinical trials. We believe using CardioSafe 3D and LiverSafe 3D for small molecule drug rescue is the highest-value near term commercial application of the human cells we produce and the cellular assay systems we have developed.

Our stem cell technology-based drug rescue activities involve therapeutically and commercially promising new drug candidates, each of which was previously discovered, optimized and tested for efficacy by pharmaceutical companies and others but failed in development due to unexpected cardiac toxicity and/or liver toxicity. We refer to these failed but still-promising new drug candidates as Drug Rescue Candidates™. Our drug rescue strategy involves leveraging our Human Clinical Trials in a Test Tube platform to attempt to significantly reduce the toxicity that caused the Drug Rescue Candidates to be terminated, and bring new, potentially safer versions of them back into development, protected by new intellectual property. We refer to the new, potentially safer versions of Drug Rescue Candidates we intend to produce as Drug Rescue Variants™. We anticipate that Drug Rescue Variants optimized for cardiac and/or liver safety using CardioSafe 3D and/or LiverSafe 3D will be suitable as promising new drug development programs, either internally or under revenue-generating out-license arrangements with pharmaceutical companies.



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Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully under the caption “Risk Factors” and include, but are not limited to, the following:

We have incurred significant losses since inception, and anticipate that we will continue to incur substantial losses for the foreseeable future. We may never achieve or sustain profitability, which would depress the market price of our common stock, and could cause you to lose all or a part of your investment.

If we are unable to develop products that achieve sufficient market acceptance, our revenue will be adversely affected.

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Our future success is highly dependent upon our ability to produce, validate and license to pharmaceutical and biotechnology companies novel Drug Rescue Variants, which are intended to be potentially safer, proprietary chemical variants of once-promising small molecule drug candidates which pharmaceutical companies and others discovered, determined to have therapeutic and commercial potential, and ultimately discontinued due to heart or liver safety concerns after substantial investment and prior to receiving FDA approval.

Our human heart cell- and liver cell-based bioassay systems may not be meaningfully more clinically predictive of human biology than surrogate safety models currently used in drug development.

The life sciences field undergoes rapid technological changes, frequent new product introductions, changing needs and preferences, emerging competition, evolving standards and strong competition.

We utilize certain technologies that are licensed to us. If we are unable to maintain our licenses, our business could be adversely affected.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and we may be involved in lawsuits to protect or enforce our patents and proprietary rights or to defend against intellectual property infringement claims.

Corporate information

VistaGen Therapeutics, Inc. (formerly Excaliber Enterprises, Ltd.), a Nevada corporation, is the parent of VistaGen Therapeutics, Inc., a California corporation founded in 1998. Our principal executive offices are located at 343 Allerton Avenue, South San Francisco, California 94080, and our telephone number is (650) 577-3600. Our website address is [www.vistagen.com](http://www.vistagen.com). The information on our website is not part of this prospectus. We have included our website address as a factual reference and do not intend it to be an active link to our website.

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## THE OFFERING

Common stock offered	Up to _____ shares
Common stock outstanding after Offering, assuming the sale of all shares registered hereunder	Up to _____ shares
Use of proceeds	<p>We estimate that we will receive up to \$__ million in net proceeds from the sale of common stock in this Offering, based on a price of \$____ per share of common stock, assuming that (i) the maximum Offering amount is sold, and (ii) all holders of subordinated convertible promissory notes aggregating approximately \$2.5 million in principal and accrued interest at July 1, 2014 (Convertible Notes) elect to waive their right to receive payment of principal and accrued interest for their Convertible Notes and in lieu thereof receive shares of common stock in connection with this Offering (Automatic Conversion), and after deducting the placement agent’s commission and estimated Offering expenses payable by us. However, this is a best efforts offering, with no minimum, and no assurances can be given that we will receive significant proceeds. In the event certain holders of the Convertible Notes elect to receive cash in lieu of Automatic Conversion, and assuming gross proceeds from this Offering of at least \$10.0 million, the net proceeds available to us will decrease by an amount calculated based on the total amount of principal and accrued interest due and payable to those holders of Convertible Notes who elect to receive cash in lieu of Automatic Conversion. In either event, we will use net proceeds from the sale of the shares of common stock in this Offering for research and development, working capital needs, capital expenditures, extinguishment of indebtedness totaling approximately \$_____, and other general corporate purposes. See “Use of Proceeds” for additional information regarding the intended use of proceeds from the Offering and “Note Conversions” for additional information regarding the terms of the Automatic Conversion.</p>
Stock consolidation	<p>On July __, 2014, our board of directors approved an amendment to our Articles to a reverse split of our authorized and issued and outstanding shares of common stock at a ratio of up to one-for-_____, with the exact ratio to be determined by our board of directors (Stock Consolidation), which Stock Consolidation is anticipated to be effective prior to August 31, 2014. Each reference to shares of common stock in this prospectus is pre-Stock Consolidation, and does not reflect the up to one-for-_____ adjustment anticipated as a result of the Stock Consolidation.</p>
Dividend policy	<p>We have never declared or paid and do not anticipate declaring or paying any cash dividends on our common stock in the near future. You should read the “Dividend policy” section of this prospectus for more information on future declarations and payments of dividends.</p>
OTCQB symbol	VSTA
Risk factors	<p>See “Risk Factors” beginning on page 7 of this prospectus for a discussion of factors you should carefully consider before investing in our securities.</p>



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The number of shares of common stock to be outstanding after this Offering is based on 25,506,877 shares outstanding as of July 1, 2014, and does not include, as of that date:

4,227,357 shares issuable upon the exercise of outstanding options under our 1999 Stock Incentive Plan and 2008 Stock Incentive Plan;

735,200 shares of our common stock reserved for issuance in connection with future awards under our stock 2008 Stock Incentive Plan;

18,981,490 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants;

15,000,000 shares of our common stock issuable upon the exchange of our Series A Preferred Stock (Series A Preferred);

7,500,000 shares of our common stock issuable upon the exercise of warrants issuable upon the exchange of our Series A Preferred; and

up to approximately [ ] shares of our common stock reserved for issuance upon the conversion of newly created Series B Convertible Preferred Stock (Series B Preferred), which Series B Preferred will be issued upon conversion of outstanding convertible promissory notes and related accrued interest upon consummation of the Offering, assuming gross proceeds from the Offering of at least \$10.0 million.

NOTE CONVERSIONS

Unit Notes

Between March 2014 and July 2014, we issued Convertible Notes to certain investors to provide for our working capital requirements. Under the terms of the Convertible Notes, the principal and accrued interest due thereunder, totaling approximately \$2.5 million at July 1, 2014 (Conversion Amount) automatically converts at the closing of the Offering, assuming the Offering results in gross proceeds to us of at least \$10.0 million, into common stock (Automatic Conversion), the number of shares of which are determined by multiplying the Conversion Amount by 1.25, and dividing the resulting number by the price per share of common stock sold in the Offering. Notwithstanding the Automatic Conversion, holders of Convertible Notes may elect a cash payment option in lieu of Automatic Conversion by delivering written notice to us of their election to receive cash within three business days after receive by such holders of a written notice delivered to them prior to consummation of the Offering. Assuming all holders of Convertible Notes decline to elect to receive cash in lieu of shares of common stock, we anticipate issuing approximately \_\_\_\_ shares of Common Stock in the Offering to such holders, based on a price of \$\_\_\_\_\_ per share of common stock sold in the Offering.

Platinum Notes

We have issued certain senior secured convertible promissory notes to Platinum Long Term Growth VII, LLC (Platinum) in the aggregate principal amount of \$3,522,600 (Platinum Notes). Platinum and the Company have agreed to convert the Platinum Notes, including all accrued interest thereon, into shares of newly created Series B Preferred Stock (Series B Preferred) upon consummation of the Offering, assuming the Offering results in gross proceeds to us of at least \$10.0 million. See “Description of Securities – Series B Preferred Stock”. Upon conversion of the Platinum Notes, the security agreement executed by the parties securing all obligations under the terms of the Platinum Notes terminates, and is no further force and effect. In addition, upon consummation of the Offering, assuming the Offering results in gross proceeds to us of at least \$10.0 million, in addition to certain other changes, the

exercise price of certain warrants issued to Platinum are to be fixed at the price per share of common stock sold in the Offering.

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## SUMMARY FINANCIAL DATA

The following table presents summary financial data for the periods indicated. The summary statements of operations data for the years ended March 31, 2014 and 2013 and the balance sheet data as of March 31, 2014 and 2013 have been derived from our audited financial statements and notes thereto, which are included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future, and our interim results are not necessarily indicative of the results to be expected for the full fiscal year. You should read this information together with our financial statements and related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Use of Proceeds" and "Capitalization" included elsewhere in this prospectus.

	Fiscal Year Ended March	
	2014	31, 2013
(Dollars in thousands, except share and per share data)		
Revenues:		
Grant revenue	\$-	\$200
Total revenues	-	200
Operating expenses:		
Research and development	2,481	3,431
General and administrative	2,548	3,562
Total operating expenses	5,029	6,993
Loss from operations	(5,029 )	(6,793 )
Other expenses, net:		
Interest expense, net	(1,503 )	(921 )
Change in warrant liabilities	3,567	(1,636 )
Loss on early extinguishment of debt	-	(3,568 )
Other income	-	35
Loss before income taxes	(2,965 )	(12,883 )
Income taxes	(3 )	(4 )
Net loss	(2,968 )	(12,887 )
Deemed dividend on Series A Preferred Stock	-	(10,193 )
Net loss attributable to common stockholders	\$(2,968 )	\$(23,080 )
Basic net loss attributable to common stockholders per common share	\$(0.14 )	\$(1.27 )
Diluted net loss attributable to common stockholders per common share	\$(0.19 )	\$(1.27 )
Weighted average shares used in computing:		
Basic net loss attributable to common stockholders per common share	21,973,149	18,108,444
Diluted net loss attributable to common stockholders per common share	21,973,149	18,108,444

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes, before deciding whether to purchase shares of our common stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Our Business and Strategy

We are a development stage biotechnology company with no current revenues or approved products, and limited experience developing new drug, biological and/or regenerative medicine candidates, including conducting clinical trials and other areas required for the successful development and commercialization of therapeutic products, which makes it difficult to assess our future viability.

We are a development stage biotechnology company. Since inception in 1998, we have generated approximately \$16.4 million of revenues from strategic collaborations and grant awards. However, we currently have no approved products and generate no revenues, and we have not yet fully demonstrated an ability to overcome many of the fundamental risks and uncertainties frequently encountered by development stage companies in new and rapidly evolving fields of technology, particularly biotechnology. To execute our business plan successfully, we will need to accomplish the following fundamental objectives, either on our own or with strategic collaborators:

produce product candidates;

develop and obtain required regulatory approvals for commercialization of products we produce;

maintain, leverage and expand our intellectual property portfolio;

establish and maintain sales, distribution and marketing capabilities;

gain market acceptance for our products; and

obtain adequate capital resources and manage our spending as costs and expenses increase due to research, production, development, regulatory approval and commercialization of product candidates.

Our future success is highly dependent upon our ability to produce product candidates, including Drug Rescue Variants, using stem cell technology, human cells derived from stem cells, our proprietary human cell-based bioassay systems and medicinal chemistry, and we cannot provide any assurance that we will successfully produce Drug Rescue Variants or other product candidates, or that, if produced, any of our Drug Rescue Variants or other product candidates will be developed and commercialized.

Research programs designed to identify and produce product candidates, including Drug Rescue Variants, require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified and produced. In particular, our drug rescue programs may initially show promise in identifying potential Drug Rescue Variants, yet fail to yield lead Drug Rescue Variants suitable for preclinical, clinical development or commercialization for many reasons, including the following:

our research methodology may not be successful in identifying potential Drug Rescue Candidates;



competitors may develop alternatives that render our Drug Rescue Variants obsolete;

a Drug Rescue Variant may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

a Drug Rescue Variant may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or

a Drug Rescue Variant may not be accepted as safe and effective by regulatory authorities, patients, the medical community or third-party payors.

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In addition, we do not have a sales or marketing infrastructure, and we, including our executive officers, do not have any significant sales, marketing or distribution experience. We will be opportunistic in seeking to collaborate with others to develop and commercialize Drug Rescue Variants and future products if and when they are developed and approved. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our Drug Rescue Variants or other product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, in collaboration with third parties, we will not be successful in commercializing our product candidates.

We have limited operating history with respect to the identification and assessment of potential Drug Rescue Candidates and no operating history with respect to the production of Drug Rescue Variants, and we may never be able to produce a Drug Rescue Variant.

If we are unable to identify suitable Drug Rescue Candidates for our drug rescue programs, including AV-101, or produce suitable lead Drug Rescue Variants for internal development or out-license to pharmaceutical companies and others, we may not be able to generate sufficient revenues in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. There are a number of factors, in addition to the utility of CardioSafe 3D, that may impact our ability to identify and assess Drug Rescue Candidates and produce, develop or out-license and commercialize Drug Rescue Variants, independently or with strategic partners, including:

our ability to identify potential Drug Rescue Candidates in the public domain, obtain sufficient quantities of them, and assess them using our bioassay systems;

if we seek to rescue Drug Rescue Candidates that are not available to us in the public domain, the extent to which third parties may be willing to out-license or sell certain Drug Rescue Candidates to us on commercially reasonable terms;

our medicinal chemistry collaborator's ability to design and produce proprietary Drug Rescue Variants based on the novel biology and structure-function insight we provide using CardioSafe 3D or LiverSafe 3D; and

financial resources available to us to develop and commercialize lead Drug Rescue Variants internally, or, if we out-license them to strategic partners, the resources such partners choose to dedicate to development and commercialization of any Drug Rescue Variants they license from us.

Even if we do produce a Drug Rescue Variant, we can give no assurance that we will be able to develop and commercialize it as a marketable drug, on our own or in a strategic collaboration. Before we generate any revenues from product sales, we must produce additional product candidates through drug rescue and we or our potential strategic collaborator must complete preclinical and clinical development of one or more of our product candidates, conduct human subject research, submit clinical and manufacturing data to the FDA, qualify a third party contract manufacturer, receive regulatory approval in one or more jurisdictions, satisfy the FDA that our contract manufacturer is capable of manufacturing the product in compliance with cGMP, build a commercial organization, make substantial investments and undertake significant marketing efforts ourselves or in partnership with others. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.



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Our CardioSafe 3D internal studies have not been subjected to extensive external peer review or validation.

Our proprietary internal studies conducted to correlate our CardioSafe 3D results with reported clinical results of reference compounds, and our ability to use CardioSafe 3D to predict the cardiac effects, both toxic and nontoxic, of Drug Rescue Candidates, have not been subjected to extensive external peer review or validation. It is possible, therefore, that the results we have obtained from our successful internal validation studies may not be replicable by external peer reviewers. We are currently focused on identifying and assessing Drug Rescue Candidates available in the public domain. However, should we seek to license or acquire Drug Rescue Candidates from third-parties, and such third-parties cannot replicate our results or do not have confidence in the capabilities of CardioSafe 3D, it may be difficult for us to in-license or acquire from them certain Drug Rescue Candidates which might be of interest to us in the future. In addition, such third-parties may conclude that their current screening models are better than our CardioSafe 3D assay system and that granting a license to the Drug Rescue Candidate we seek from them is not warranted.

If CardioSafe 3D fails to predict accurately and efficiently the cardiac effects, both toxic and nontoxic, of Drug Rescue Candidates and Drug Rescue Variants, then our drug rescue business will be adversely affected.

Our success is highly dependent on our ability to use CardioSafe 3D to identify and predict, accurately and efficiently, the potential toxic and nontoxic cardiac effects of Drug Rescue Candidates and Drug Rescue Variants. If CardioSafe 3D is not capable of providing physiologically relevant and clinically predictive information regarding human cardiac biology, our drug rescue business will be adversely affected.

We have not yet fully validated LiverSafe 3D for potential drug rescue applications, and we may never do so.

We have successfully developed proprietary protocols for controlling the differentiation of human pluripotent stem cells to produce functional, mature, adult liver cells. However, we have not yet fully validated our ability to use the human liver cells we produce for LiverSafe 3D to predict important biological effects, both toxic and nontoxic, of reference drugs, Drug Rescue Candidates or Drug Rescue Variants on the human liver, including drug-induced liver injury and adverse drug-drug interactions. Furthermore, we may never be able to do so, which could adversely affect our business and the potential applications of LiverSafe 3D for drug discovery, drug rescue and regenerative medicine.

CardioSafe 3D, and, when validated, LiverSafe 3D may not be meaningfully more predictive of the behavior of human cells than existing methods.

The success of our drug rescue business is highly dependent, in the first instance, upon CardioSafe 3D, and, in the second instance, when validated, LiverSafe 3D, being more accurate, efficient and clinically predictive than long-established surrogate safety models, including animal cells and live animals, and immortalized, primary and transformed cells, currently used by pharmaceutical companies and others. We cannot give assurance that CardioSafe 3D, and, when validated, LiverSafe 3D, will be more efficient or accurate at predicting the heart or liver safety of new drug candidates than the testing models currently used. If CardioSafe 3D and LiverSafe 3D fail to provide a meaningful difference compared to existing or new models in predicting the behavior of human heart and liver cells, respectively, their utility for drug rescue will be limited and our drug rescue business will be adversely affected.

We may invest in producing Drug Rescue Variants for which there proves to be no demand.

To generate revenue from our drug rescue activities, we must produce Drug Rescue Variants for which there proves to be demand within the healthcare marketplace, and, if we intend to out-license a particular Drug Rescue Variant for development and commercialization prior to market approval, then also among pharmaceutical companies and other potential strategic collaborators. However, we may produce Drug Rescue Variants for which there proves to be no or

limited demand in the healthcare market and/or among pharmaceutical companies and others. If we misinterpret market conditions, underestimate development costs and/or seek to rescue the wrong Drug Rescue Candidates, we may fail to generate sufficient revenue or other value, on our own or in collaboration with others, to justify our investments, and our drug rescue business may be adversely affected.

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We may experience difficulty in producing human cells and our future stem cell technology research and development efforts may not be successful within the timeline anticipated, if at all.

Our human pluripotent stem cell technology is new and technically complex, and the time and resources necessary to develop new cell types and customized bioassay systems are difficult to predict in advance. We intend to devote significant personnel and financial resources to research and development activities designed to expand, in the case of drug rescue, and explore, in the case of drug discovery and regenerative medicine, potential applications of our Human Clinical Trials in a Test Tube platform. In particular, we are planning to conduct development programs related to producing and using functional, mature adult liver cells to validate LiverSafe 3D as a novel bioassay system for drug rescue, as well as exploratory nonclinical regenerative medicine programs involving blood, bone, cartilage, heart, liver and insulin-producing pancreatic beta-islet cells. Although we and our collaborators have developed proprietary protocols for the production of multiple differentiated cell types, we may encounter difficulties in differentiating particular cell types, even when following these proprietary protocols. These difficulties may result in delays in production of certain cells, assessment of certain Drug Rescue Candidates and Drug Rescue Variants, design and development of certain human cellular assays and performance of certain exploratory nonclinical regenerative medicine studies. In the past, our stem cell research and development projects have been significantly delayed when we encountered unanticipated difficulties in differentiating human pluripotent stem cells into heart, liver and pancreatic cells. Although we have overcome such difficulties in the past, we may have similar delays in the future, and we may not be able to overcome them or obtain any benefits from our future stem cell technology research and development activities. Any delay or failure by us, for example, to produce functional, mature blood, bone, cartilage, liver and insulin-producing pancreatic beta-islet cells could have a substantial and material adverse effect on our potential drug discovery, drug rescue and regenerative medicine business opportunities and results of operations.

If we are unable to keep up with rapid technological changes in our field, we will be unable to operate profitably.

We are engaged in activities in the life sciences field, which is characterized by rapid technological changes, frequent new product introductions, changing needs and preferences, emerging competition, and evolving industry standards. If we fail to anticipate or respond adequately to technological developments, our business, revenue, financial condition and operating results could suffer materially. Although we believe we are the first stem cell technology company focused primarily on drug rescue, we anticipate that we will face increased competition in the future as competitors develop or access new or improved bioassay systems and explore and enter the drug rescue market with new technologies. Competitors may have significantly greater financial, manufacturing, sales and marketing resources and may be able to respond more quickly and effectively than we can to new opportunities. In light of these advantages, even if our technology is effective in producing Drug Rescue Variants, potential development partners might prefer new drug candidates available from others or develop their own new drug candidates in lieu of licensing or purchasing our Drug Rescue Variants. We may not be able to compete effectively against these organizations. Our failure to compete effectively could materially and adversely affect our business, financial condition and results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing product candidates before, or more successfully, than we do.

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of Drug Rescue Variants. Our competitors may succeed in developing product candidates for the same indications we are pursuing before we do, obtaining regulatory approval for competing products or gaining acceptance of their products within the same markets that we are targeting for our Drug Rescue Variants. If, either on our own or in collaboration with a strategic partner, we are not "first to market" with one of our Drug Rescue Variants, our competitive position could be compromised because it may be more difficult for us or our partner to obtain marketing approval for our Drug Rescue Variant and successfully market it as a second competitor. We expect any Drug Rescue Variants that we commercialize, either internally or in collaboration with

others, will compete with products from other companies in the biotechnology and pharmaceutical industries.

Many of our competitors have substantially greater research and development and commercial infrastructures and financial, technical and personnel resources than we have. We will not be able to compete successfully unless we:

design, develop, produce and commercialize, either on our own or with collaborators, Drug Rescue Variants that are superior to other products in development or in the market;

attract qualified scientific, medical, sales and marketing and commercial personnel or collaborators;

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obtain patent and/or other proprietary protection for our Drug Rescue Variants; and

obtain, either on our own or in collaboration with strategic partners, required regulatory approvals for our Drug Rescue Variants.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our Drug Rescue Variants obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Other companies, academic institutions, government agencies and other public and private research organizations are conducting research, seeking patent protection and establishing collaborative arrangements for research, development and marketing of assays similar to ours and Drug Rescue Variants we may produce. These companies and institutions also compete with us in recruiting and retaining qualified scientific and management personnel, obtaining collaborators and licensees, as well as in acquiring technologies complementary to our programs.

As a result of the foregoing, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization than we will. Most significantly, competitive products may render any technologies and Drug Rescue Variants that we develop obsolete, which would negatively impact our business and ability to sustain operations.

With respect to drug rescue of Drug Rescue Candidates not otherwise available to us in the public domain, the licensing and acquisition of proprietary small molecule compounds, even compounds that have failed in development due to heart or liver safety concerns, is a highly competitive area, and a number of more established companies may also pursue strategies to license, acquire, rescue and develop small molecule compounds that we may consider to be Drug Rescue Candidates. These established companies have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to sell or license Drug Rescue Candidate rights to us. We have limited experience in negotiating licenses to drug candidates and there can be no assurances that we will be able to acquire or obtain licenses to Drug Rescue Candidates in the future, on commercially reasonable terms, if at all, should we elect to pursue such third-party licenses. If we are unable to acquire or obtain licenses to Drug Rescue Candidates we seek, our business may be adversely affected.

Restrictions on research and development involving human embryonic stem cells and political commentary regarding such research and development could impair our ability to conduct or sponsor certain potential collaborative research and development programs and adversely affect the market price of our common stock and our business model.

Some of our most important ongoing and planned research and development programs involve the use of human cells derived from our controlled differentiation of human embryonic stem cells (hESCs). Some believe the use of hESCs gives rise to ethical and social issues regarding the appropriate use of these cells. Our research related to differentiation of hESCs may become the subject of adverse commentary or publicity, which could significantly harm the market price of our common stock. Although now substantially less than in years past, certain political and religious groups in the United States and elsewhere voice opposition to hESC technology and practices. We use hESCs derived from excess fertilized eggs that have been created for clinical use in in vitro fertilization (IVF) procedures and have been donated for research purposes with the informed consent of the donors after a successful IVF procedure because they are no longer desired or suitable for IVF. Certain academic research institutions have adopted policies regarding the ethical use of human embryonic tissue. These policies may have the effect of limiting the scope of future collaborative research opportunities with such institutions, thereby potentially impairing our ability



to conduct certain research and development in this field that we believe is necessary to expand the drug rescue capabilities of our technology, which would have a material adverse effect on our business.

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The use of embryonic or fetal tissue in research (including the derivation of hESCs) in other countries is regulated by the government, and varies widely from country to country. Government-imposed restrictions with respect to use of hESCs in research and development could have a material adverse effect on us by harming our ability to establish critical collaborations, delaying or preventing progress in our research and development, and causing a decrease in the market interest in our stock. These potential ethical concerns do not apply to induced pluripotent stem cells (iPSCs), or our plans to pursue exploratory nonclinical regenerative medicine studies involving human cells derived from iPSCs, because their derivation does not involve the use of embryonic tissues.

We have assumed that the biological capabilities of induced pluripotent stem cells (iPSCs) and hESCs are likely to be comparable. If it is discovered that this assumption is incorrect, our exploratory research and development activities focused on potential regenerative medicine applications of our Human Clinical Trials in a Test Tube platform could be harmed.

We use both hESCs and iPSCs for drug rescue purposes. However, we anticipate that our future exploratory research and development focused on potential regenerative medicine applications of our Human Clinical Trials in a Test Tube platform primarily will involve iPSCs. With respect to iPSCs, we believe scientists are still somewhat uncertain about the clinical utility, life span, and safety of such cells, and whether such cells differ in any clinically significant ways from hESCs. If we discover that iPSCs will not be useful for whatever reason for potential regenerative medicine applications of our Human Clinical Trials in a Test Tube platform, this would negatively affect our ability to explore expansion of our platform, including, in particular, where it would be preferable to use iPSCs to reproduce rather than approximate the effects of certain specific genetic variations.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully produce, develop trials and commercialize our Drug Rescue Variants.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific and technical personnel. We are highly dependent upon our senior management, as well as other employees, consultants and scientific collaborators. As of June 1, 2014, we had 10 full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. Although none of our key scientific personnel or members of our senior management has informed us that he or she intends to resign or retire in the near future, the loss of services of any of these individuals could delay or prevent the successful development of potential expansions and applications of our Human Clinical Trials in a Test Tube platform and our production and assessment of Drug Rescue Variants or disrupt our administrative functions.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our research and development activities. We may not be able to attract and retain quality personnel on acceptable terms.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in designing our research and development strategy, including our drug rescue strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our proposed CardioSafe 3D drug rescue programs, produce and develop Drug Rescue Variants, and develop and validate LiverSafe 3D, we will need to expand our research and development capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need

to manage additional relationships with various strategic partners and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our research and development efforts effectively and hire, train and integrate additional management, administrative and technical personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming for us because we have fewer resources than a larger organization. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing the Company.

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If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

If we produce and develop Drug Rescue Variants or regenerative medicine products, either on our own or in collaboration with others, we will face an inherent risk of product liability as a result of the required clinical testing of such product candidates, and will face an even greater risk if we or our collaborators commercialize any such products. For example, we may be sued if any Drug Rescue Variant or regenerative medicine product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, 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, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our Drug Rescue Variants or other products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients;

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

loss of revenue;

the inability to commercialize our product candidates; and

a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we maintain liability insurance, 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 product liability claim for which we have no coverage. We will 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.

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To the extent we enter into licensing or collaboration agreements to develop and commercialize our product candidates, including Drug Rescue Variants, our dependence on such relationships may adversely affect our business.

We may enter into strategic partnerships in the future, including collaborations with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our product candidates. Our strategy to produce, develop and commercialize our product candidates, including any Drug Rescue Variants, may depend on our ability to enter into such agreements with third-party collaborators. We face significant competition in seeking appropriate strategic partners. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in entering into one or more strategic collaboration agreements with third-parties, such collaborations may involve greater uncertainty for us, as we may have less control over certain aspects of our collaborative programs than we do over our proprietary internal development and commercialization programs. We may determine that continuing a collaborative arrangement under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could also delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized.

Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to certain other products that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting preclinical studies, clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our future collaborative arrangements may not be successful.

We cannot provide any assurance that our future collaborations will not terminate development before achievement of revenue-generating milestones or market approval, that our future collaborative arrangements will result in successful development and commercialization of Drug Rescue Variants, or that we will derive any revenues from such future arrangements.

Our and our collaborators' relationships with customers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

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 product candidates for which we may obtain marketing approval. Our or

our future collaborator's arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we or they obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

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the federal healthcare anti-kickback statute 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

the federal False Claims Act imposes criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, 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 and also includes provisions allowing for private, civil whistleblower or "qui tam" actions;

the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA and HITECH also regulate the use and disclosure of identifiable health information by health care providers, health plans and health care clearinghouses, and impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of identifiable health information as well as requiring notification of regulatory breaches. HIPAA and HITECH violations may prompt civil and criminal enforcement actions as well as enforcement by state attorneys general;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures; and

analogous anti-kickback, fraud and abuse and healthcare laws and regulations in foreign countries.

Efforts to ensure that our and our future collaborators' business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our or their business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our or their operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we or our collaborators expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.





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If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could have a material adverse effect on our operations.

To the extent our research and development activities involve using induced pluripotent stem cells, we will be subject to complex and evolving laws and regulations regarding privacy and informed consent. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our research and development programs and objectives, increased cost of operations or otherwise harm the Company.

To the extent that we pursue research and development activities involving iPSCs, we will be subject to a variety of laws and regulations in the United States and abroad that involve matters central to such research and development activities, including obligations to seek informed consent from donors for the use of their blood and other tissue to produce, or have produced for us, iPSCs, as well as state and federal laws that protect the privacy of such donors. United States federal and state and foreign laws and regulations are constantly evolving and can be subject to significant change. If we engage in iPSC-related research and development activities in countries other than the United States, we may become subject to foreign laws and regulations relating to human subjects research and other laws and regulations that are often more restrictive than those in the United States. In addition, both the application and interpretation of these laws and regulations are often uncertain, particularly in the rapidly evolving stem cell technology sector in which we operate. These laws and regulations can be costly to comply with and can delay or impede our research and development activities, result in negative publicity, increase our operating costs, require significant management time and attention and subject us to claims or other remedies, including fines or demands that we modify or cease existing business practices.

Legal, social and ethical concerns surrounding the use of iPSCs, biological materials and genetic information could impair our operations.

To the extent that our future stem cell research and development activities involve the use of iPSCs and the manipulation of human tissue and genetic information, the information we derive from such iPSC-related research and development activities could be used in a variety of applications, which may have underlying legal, social and ethical concerns, including the genetic engineering or modification of human cells, testing for genetic predisposition for certain medical conditions and stem cell banking. Governmental authorities could, for safety, social or other purposes,

call for limits on or impose regulations on the use of iPSCs and genetic testing or the manufacture or use of certain biological materials involved in our iPSC-related research and development programs. Such concerns or governmental restrictions could limit our future research and development activities, which could have a material adverse effect on our business, financial condition and results of operations.

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Our human cellular bioassay systems and human cells we derive from human pluripotent stem cells, although not currently subject to regulation by the FDA or other regulatory agencies as biological products or drugs, could become subject to regulation in the future.

Our human cells and human cell-based bioassay systems, including CardioSafe 3D and LiverSafe 3D, are not currently sold, for research or any other purpose, to biotechnology or pharmaceutical companies, government research institutions, academic and nonprofit research institutions, medical research organizations or stem cell banks, and they are not therapeutic procedures. As a result, they are not subject to regulation as biological products or drugs by the FDA or comparable agencies in other countries. However, if, in the future, we seek to include cells we derive from human pluripotent stem cells in therapeutic applications or product candidates, such applications and/or product candidates would be subject to the FDA's pre- and post-market regulations. For example, if we seek to develop and market human cells we produce for use in performing cell therapy or for other regenerative medicine applications, such as tissue engineering or organ replacement, we would first need to obtain FDA pre-market clearance or approval. Obtaining such clearance or approval from the FDA is expensive, time-consuming and uncertain, generally requiring many years to obtain, and requiring detailed and comprehensive scientific and clinical data. Notwithstanding the time and expense, these efforts may not result in FDA approval or clearance. Even if we were to obtain regulatory approval or clearance, it may not be for the uses that we believe are important or commercially attractive.

We intend to rely on third-party contract manufacturers to produce our product candidate supplies and to produce commercial supplies of any approved product candidates we develop on our own. Any failure by a third-party manufacturer to produce for us supplies of product candidates we elect to develop on our own may delay or impair our ability to initiate or complete clinical trials, commercialize our product candidates, or continue to sell any products we commercialize.

We do not currently own or operate any manufacturing facilities, and we lack sufficient internal staff to produce product candidate supplies ourselves. As a result, we have worked with, and plan to continue to work with, third-party contract manufacturers to produce sufficient quantities of our product candidates for future preclinical and clinical testing and commercialization. If we are unable to arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms or on a timely basis, we or our potential strategic partner may not be able to successfully produce, develop, and market our product candidates or may be delayed in doing so.

Reliance on third-party manufacturers entails risks to which we or our potential collaborators would not be subject if we or they manufactured product candidates ourselves or themselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications), the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us, or misappropriation of proprietary formulas or protocols. We will be, and our potential strategic partners may be, dependent, on the ability of these third-party manufacturers to produce adequate supplies of drug product to support development programs and future commercialization of our product candidates. In addition, the FDA and other regulatory authorities require that all product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our or our collaborators' third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval for trial initiation or marketing of any product candidates we may produce, including Drug Rescue Variants. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.



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We will, and our potential strategic partners may, rely on contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for required studies. There may be a small number of suppliers for certain capital equipment and materials that we or our collaborators use to manufacture our product candidates. Such suppliers may not sell these materials to our manufacturers at the times we or they need them or on commercially reasonable terms. We will not have any control over the process or timing of the acquisition of these materials by our manufacturers. Although we and our collaborators generally will not begin a required study unless we or they believe a sufficient supply of a product candidate exists to complete the study, any significant delay in the supply of a product candidate or the material components thereof for an ongoing study due to the need to replace a third-party manufacturer could considerably delay completion of the studies, product testing and potential regulatory approval. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

In addition, we or our potential strategic partner may need to optimize the manufacturing processes for a particular drug substance and/or drug product so that certain product candidates may be produced in sufficient quantities of adequate quality, and at an acceptable cost, to support required development activities and commercialization. Contract manufacturers may not be able to adequately demonstrate that an optimized product candidate is comparable to a previously manufactured product candidate which could cause significant delays and increased costs to our or our collaborators' development programs. Our manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If we successfully commercialize any of our drugs, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, assuming that our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing, third party manufacturers with whom we work will need to increase their scale of production or we will need to secure alternate suppliers.

### Risks Related to Production, Development, and Regulatory Approval of Product Candidates

Even if we are able to begin clinical trials for a Drug Rescue Variant, we may encounter considerable delays and/or expend considerable resources without producing a marketable product capable of generating revenue.

We may never generate revenues from sales of a Drug Rescue Variant or any other product because of a variety of risks inherent in our business, including the following:

clinical trials may not demonstrate the safety and efficacy of any Drug Rescue Variant, other new drug candidate, biological candidate or regenerative medicine product candidate;

completion of nonclinical or clinical trials may be delayed, or costs of nonclinical or clinical trials may exceed anticipated amounts;

we may not be able to obtain regulatory approval of any Drug Rescue Variant, other new drug candidate, biological candidate or regenerative medicine product candidate; or we may experience delays in obtaining any such approval;

we may not be able to manufacture, or have manufactured for us, Drug Rescue Variants, other new drug candidates, biological candidates or regenerative medicine product candidates economically, timely and on a commercial scale;

we and any licensees of ours may not be able to successfully market Drug Rescue Variants, other new drug candidates, biological candidates or regenerative medicine product candidates;

physicians may not prescribe our products, or patients or third party payors may not accept our Drug Rescue Variants, other drug candidates, biological candidates or regenerative medicine product candidates;

others may have proprietary rights which prevent us from marketing our Drug Rescue Variants, other new drug candidates, biological candidates or regenerative medicine product candidates; and

competitors may sell similar, superior or lower-cost products.

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In the event we are able to begin a clinical trial of a Drug Rescue Variant, our or our collaborator's future clinical trials may be delayed or halted for many reasons, including:

delays or failure reaching agreement on acceptable terms with prospective contract manufacturing organizations (CMOs), contract research organizations (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;

failure of third-party contractors, such as CROs and CMOs, or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;

delays or failure in obtaining the necessary approvals from regulators or institutional review boards (IRBs) in order to commence a clinical trial at a prospective trial site;

inability to manufacture, or obtain from third parties, a supply of drug product sufficient to complete preclinical studies and clinical trials;

the FDA requiring alterations to study designs, preclinical strategy or manufacturing plans;

delays in patient enrollment, and variability in the number and types of patients available for clinical trials, or high drop-out rates of patients;

clinical trial sites deviating from trial protocols or dropping out of a trial and/or the inability to add new clinical trial sites;

difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

poor effectiveness of our product candidates during clinical trials;

safety issues, including serious adverse events associated with our product candidates and patients' exposure to unacceptable health risks;

receipt by a competitor of marketing approval for a product targeting an indication that one of our product candidates targets, such that we are not "first to market" with our product candidate;

governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or

varying interpretations of data by the FDA and similar foreign regulatory agencies.

We or our collaborator could also encounter delays if a clinical trial is suspended or terminated by us, our collaborator, the IRBs of the institutions in which a trial is being conducted, by the Data Safety Monitoring Board (DSMB) for a trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, if we or our collaborators are able to complete a clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. For any such trial, if the FDA disagrees with the choice of

primary endpoint or the results for the primary endpoint are not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including overall survival or complete response rate, the FDA may refuse to approve a BLA or NDA. The FDA may require additional clinical trials as a condition for approving our product candidates.



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If we or our collaborator experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow our product candidate development and approval process. Delays in completing clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This drug candidate development risk is heightened by any changes in planned clinical trials compared to completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for later stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

For example, the results of planned clinical trials may be adversely affected if we or our collaborator seek to optimize and scale-up production of a product candidate. In such case, we will need to demonstrate comparability between the newly manufactured drug substance and/or drug product relative to the previously manufactured drug substance and/or drug product. Demonstrating comparability may cause us to incur additional costs or delay initiation or completion of our clinical trials, including the need to initiate a dose escalation study and, if unsuccessful, could require us to complete additional preclinical or clinical studies of our product candidates.

We, as well as any future strategic partner, will need to receive regulatory approval for any new drug candidate, including each Drug Rescue Variant, biological candidate or regenerative medicine product before it may be marketed and distributed, and such regulatory approval may never occur.

Our future success depends heavily on our ability to use stem cell technology, human cells derived from stem cells, proprietary human cell-based bioassay systems, especially CardioSafe 3D, and medicinal chemistry to produce Drug Rescue Variants and, develop, obtain regulatory approval for, and commercialize lead Drug Rescue Variants, on our own or in strategic collaborations. We have not previously submitted a new drug application or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we

may not generate significant revenues from sales of such products, if approved.

Regulatory approval will require, among numerous other things, completing carefully controlled and well-designed clinical trials demonstrating the safety and efficacy of each new product candidate. This process is lengthy, expensive and uncertain. If we encounter delays in the regulatory approval process beyond our control, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

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If we, or our potential strategic partners, experience delays in the enrollment of patients in clinical trials involving our product candidates, our receipt of necessary regulatory approvals could be delayed or prevented.

We or our potential strategic partners may not be able to initiate or continue clinical trials for our product candidates if we or they are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the 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 or our collaborators may be investigating. If we or they fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested is safe and effective. Additionally, enrollment delays in clinical trials may result in increased development costs for our product candidates, which would cause the value of our common stock to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials, and, therefore, product candidates, altogether.

Even if we receive regulatory approval for any of our Drug Rescue Variants or other product candidates, we and/or our potential strategic partners will be subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our potential strategic partners receive for our Drug Rescue Variants or other product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate, all of which could adversely affect the product's commercial potential and our revenues. In addition, if the FDA approves any of our product candidates, the manufacturing processes, testing, packaging, labeling, storage, distribution, field alert or biological product deviation reporting, adverse event reporting, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, as well as continued compliance with cGMP for commercial manufacturing and good clinical practices, or GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

warning letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;

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

injunctions, fines or the imposition of other civil or criminal penalties.



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Risks Related to Our Financial Position and Capital Requirements

We have incurred significant net losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability, which would depress the market price of our common stock, and could cause you to lose all or a part of your investment.

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of \$3.0 million and \$12.9 million during the fiscal years ending March 31, 2014 and 2013, respectively. As of March 31, 2014, we had an accumulated deficit of \$70.6 million. We do not know whether or when we will become profitable. To date, although we have generated approximately \$16.4 million in revenues, we have not commercialized any products or generated any revenues from product sales. Our losses have resulted principally from costs incurred in our research and development programs and from general and administrative expenses. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our drug rescue, stem cell technology research and development, drug development and potential commercialization activities. Additionally, we expect that our general and administrative expenses will increase in the event we achieve our goal of obtaining a listing on a national securities exchange. The net losses we incur may fluctuate from quarter to quarter.

If we do not successfully develop, out-license, sell or obtain regulatory approval for our future product candidates and effectively manufacture, market and sell, or collaborate to accomplish such activities, any product candidates that are approved, we may never generate revenues from product sales, and even if we do generate product sales revenues, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our common stock also could cause you to lose all or a part of your investment.

As of July 1, 2014, we had outstanding indebtedness in the aggregate principal amount of approximately \$11.3 million, including up to \$9.0 million of which may be converted into, or is payable with, our equity securities. Unless we are able to convert such indebtedness into our equity securities, according to existing agreements or otherwise restructure such indebtedness, we may be unable to pay approximately \$4.2 million of such indebtedness when due in the next twelve months.

At July 1, 2014, we had outstanding indebtedness in the aggregate principal amount of approximately \$11.3 million, including up to \$9.0 million of convertible promissory notes that may be converted into our equity securities upon the consummation of this Offering, or extinguished upon the exercise of warrants to purchase shares of our common stock associated with certain of such indebtedness. Approximately \$4.2 million of our outstanding indebtedness is due or will become due from time to time during the next 12 months, to the extent it is not otherwise (i) restructured or (ii) converted into our equity securities in connection with the consummation of this Offering, or otherwise in accordance with certain agreements evidencing, or related to, such indebtedness. No assurances can be given that such conversions or extinguishment of indebtedness will occur within the next twelve months, or at all. In the event our indebtedness is not restructured or converted into our equity securities, we cannot assure you that we will generate sufficient revenue to repay this indebtedness in full when due. Unless we are able to restructure the terms of such indebtedness, we may be required to raise additional capital through debt and/or equity financing to continue our operations. No assurances can be given that any such financing will be available to us on favorable terms, if at all. Our inability to obtain debt or equity financing in a timely manner and in amounts sufficient to fund our operations, if necessary, would have an immediate and substantial adverse impact on our business, financial condition or results of operations.



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Our independent auditors have expressed substantial doubt about our ability to continue as a going concern.

Our consolidated financial statements for the year ended March 31, 2014 included in this prospectus have been prepared assuming we will continue to operate as a going concern. However, due to our ongoing operating losses and our accumulated deficit, there is doubt about our ability to continue as a going concern. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities or obtaining loans and grants from financial institutions and/or government agencies where possible. Our continued net operating losses increase the difficulty in completing such sales or securing alternative sources of funding, and there can be no assurances that we will be able to obtain such funding on favorable terms or at all. If we are unable to obtain sufficient financing from the sale of our securities or from alternative sources, we may be required to reduce, defer, or discontinue certain of our research and development activities or we may not be able to continue as a going concern.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since our inception, most of our resources have been dedicated to research and development of the drug rescue capabilities of our human pluripotent stem cell technology. In particular, we have expended substantial resources developing CardioSafe 3D and LiverSafe 3D, and we will continue to expend substantial resources for the foreseeable future developing LiverSafe 3D and CardioSafe 3D Drug Rescue Variants. These expenditures will include costs associated with general and administrative costs, facilities costs, research and development, acquiring new technologies, manufacturing product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale. Furthermore, we expect to incur additional costs associated with operating as a public company.

We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, we out-license a Drug Rescue Variant and/or AV-101 to a third party, obtain approval from the FDA or other regulatory authorities and successfully commercialize, on our own or through a future collaboration, one or more of our compounds. As the outcome of our proposed drug rescue and AV-101 development activities and future 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, on our own or in collaboration with others. In addition, other unanticipated costs may arise. As a result of these and other factors, we will need to seek additional capital in the near term to meet our future operating requirements, and may seek additional capital in the event there exists favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

the number and characteristics of the product candidates we pursue, including Drug Rescue Candidates;

the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies;

the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;

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

the cost of manufacturing our product candidates and any products we successfully commercialize;

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

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market acceptance of our products;

the effect of competing technological and market developments;

our ability to obtain government funding for our programs;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims necessary to preserve our freedom to operate in the stem cell industry, including litigation costs associated with any claims that we infringe third-party patents or violate other intellectual property rights and the outcome of such litigation;

the timing, receipt and amount of potential future licensee fees, milestone payments, and sales of, or royalties on, our future products, if any; and

the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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 drug rescue programs, preclinical studies, clinical trials or other research and development activities for one or more of our product candidates, or cease or reduce our operating activities and/or sell or license to third parties some or all of our intellectual property, any of which could harm our operating results.

Raising additional capital will cause substantial dilution to our existing stockholders and may restrict our operations or require us to relinquish rights to our technologies or product candidates.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of the new capital may include liquidation or other preferences that adversely affect existing stockholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Some of our programs have been partially supported by government grants, which may not be available to us in the future.

Since inception, we have received substantial funds under grant award programs funded by state and federal governmental agencies, such as the NIH, the NIH's National Institute of Neurological Disease and Stroke and the California Institute for Regenerative Medicine. To fund a portion of our future research and development programs, we may apply for additional grant funding from such or similar governmental organizations. However, funding by these governmental organizations may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive funds under future grants because of budgeting constraints of the agency administering the program. Therefore, we cannot assure you that we will receive any future grant funding from any government organization or otherwise. A restriction on the government funding available to us could reduce the resources that we would be able to devote to future research and development efforts. Such a reduction could delay the introduction of new products

and hurt our competitive position.

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Our ability to use net operating losses to offset future taxable income is subject to certain limitations.

If we do not generate sufficient taxable income we may not be able to use a material portion, or any portion, of our existing net operating losses (NOLs). Furthermore, our existing NOLs may be subject to limitations under Section 382 of the Internal Revenue Code of 1986, as amended, which in general provides that a corporation that undergoes an “ownership change” is limited in its ability to utilize its pre-change NOLs to offset future taxable income. Our existing NOLs are subject to limitations arising from previous ownership changes, and if we undergo an ownership change, in connection with a future equity-based financing, series of equity-based financings or otherwise, our ability to utilize NOLs could be further limited by Section 382 of the Internal Revenue Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Internal Revenue Code.

## Risks Related to Intellectual Property

We utilize certain technologies that are licensed to us, including key aspects of our Human Clinical Trials in a Test Tube platform. If the licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position and market share will be harmed, and our business could be adversely affected.

We currently use certain licensed technologies to produce cells that are material to our research and development programs, including our drug rescue programs, and we may enter into additional license agreements in the future. Our rights to use such licensed technologies are subject to the negotiation of, continuation of and compliance with the terms of the applicable licenses, including payment of any royalties and diligence, insurance, indemnification and other obligations. If a licensor believes that we have failed to meet our obligations under a license agreement for non-payment of license fees, non-reimbursement of patent expenses, or otherwise, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products could be significantly and negatively affected.

Our license rights are further subject to the validity of the owner’s intellectual property rights. As such, we are dependent on our licensors to defend the viability of these patents and patent applications. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Legal action could be initiated by or against the owners of the intellectual property that we license. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent these other companies or institutions from continuing to license intellectual property that we may need to operate our business. In some cases, we do not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties.

Certain of our license agreements are subject to termination by the licensor in specific circumstances, including non-payment of license fees, royalties and patent-related expenses. Any such termination of these licenses could prevent us from producing cells for our research and development programs and future commercial activities, including selling or marketing products. Because of the complexity of our human pluripotent stem cell technology and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties or other amounts due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology would be severely adversely affected.

We may engage in discussions regarding possible commercial, licensing and cross-licensing agreements with third parties from time to time. There can be no assurance that these discussions will lead to the execution of commercial license or cross-license agreements or that such agreements will be on terms that are favorable to us. If these discussions are successful, we could be obligated to pay license fees and royalties to such third parties. If these discussions do not lead to the execution of mutually acceptable agreements, we may be limited or prevented from producing and selling our existing products and developing new products. One or more of the parties involved in such discussions could resort to litigation to protect or enforce its patents and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. In addition, if we enter into cross-licensing agreements, there is no assurance that we will be able to effectively compete against others who are licensed under our patents.

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If we seek to leverage prior discovery and development of Drug Rescue Candidates under in-license arrangements with academic laboratories, biotechnology companies, the NIH, pharmaceutical companies or other third parties, it is uncertain what ownership rights, if any, we will obtain over intellectual property we derive from such licenses to Drug Rescue Variants we may generate or develop in connection with any such third-party licenses.

If, instead of identifying Drug Rescue Candidates based on information available to us in the public domain, we seek to in-license Drug Rescue Candidates from biotechnology, medicinal chemistry and pharmaceutical companies, academic, governmental and nonprofit research institutions, including the NIH, or other third-parties, there can be no assurances that we will obtain material ownership or economic participation rights over intellectual property we may derive from such licenses or similar rights to the Drug Rescue Variants we may generate and develop. If we are unable to obtain ownership or substantial economic participation rights over intellectual property related to Drug Rescue Variants we generate, our business may be adversely affected.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain, and we could be unsuccessful in obtaining adequate patent protection for one or more of our product candidates.

Our commercial success will depend in part on our ability to protect our intellectual property and proprietary technologies. We rely on patents, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, license agreements and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Pending patent applications of ours or our licensors may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or maintain our competitive advantage. Any patents we have obtained or may obtain in the future, or the rights we have licensed, may be subject to re-examination, reissue, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid or unenforceable. In addition, competitors may be able to design alternative methods or products that avoid infringement of these patents or technologies. To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

The patent positions of companies in the life sciences industry can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. A number of life sciences, biopharmaceutical and other companies, universities and research institutions have filed patent applications or have been issued patents relating to stem cells, use of stem cells and other modified cells to treat disease, disorder or injury, and other technologies potentially relevant to or required by our existing and planned products. We cannot be certain that patents we have filed or may file in the future will be issued or granted, or that issued or granted patents will not later be found to be invalid and/or unenforceable. The standards applied by the United States Patent and Trademark Office (US PTO) and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending or future patent applications. As such, we do not know the degree of future protection that we will have on certain of our proprietary products and technology.

Our patents and patent applications may not be sufficient to protect our products, product candidates and technologies from commercial competition. Our inability to obtain adequate patent protection for our product candidates or platform technology could adversely affect our business.

Publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by at least several months and sometimes several years. Therefore, the persons or entities that we or our licensors name as inventors in our patents and patent applications may not have been the first to invent the inventions disclosed in the patent applications or patents, or the first to file patent applications for these inventions. As a result, we may not be able to obtain patents for discoveries that we otherwise would consider patentable and that we consider to be extremely significant to our future success.

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Where several parties seek U.S. patent protection for the same technology, the US PTO may declare an interference proceeding in order to ascertain the party to which the patent should be issued. Patent interferences are typically complex, highly contested legal proceedings, subject to appeal. They are usually expensive and prolonged, and can cause significant delay in the issuance of patents. Moreover, parties that receive an adverse decision in interference can lose patent rights. Our pending patent applications, or our issued patents, may be drawn into interference proceedings, which may delay or prevent the issuance of patents or result in the loss of issued patent rights. If more groups become engaged in scientific research related to hESCs, the number of patent filings by such groups and therefore the risk of our patents or applications being drawn into interference proceedings may increase. The interference process can also be used to challenge a patent that has been issued to another party.

Outside of the U.S., certain jurisdictions, such as Europe, Japan, New Zealand and Australia, permit oppositions to be filed against the granting of patents. Because we may seek to develop and commercialize our product candidates internationally, securing both proprietary protection and freedom to operate outside of the U.S. is important to our business. In addition, the European Patent Convention prohibits the granting of European patents for inventions that concern “uses of human embryos for industrial or commercial purposes”. The European Patent Office is presently interpreting this prohibition broadly, and is applying it to reject patent claims that pertain to hESCs. However, this broad interpretation is being challenged through the European Patent Office appeals system. As a result, we do not yet know whether or to what extent we will be able to obtain European patent protection for our proprietary hESC-based technology and systems.

Patent opposition proceedings are not currently available in the U.S. patent system, but legislation is pending to introduce them. However, issued U.S. patents can be re-examined by the US PTO at the request of a third party. Patents owned or licensed by us may therefore be subject to re-examination. As in any legal proceeding, the outcome of patent re-examinations is uncertain, and a decision adverse to our interests could result in the loss of valuable patent rights.

Successful challenges to our patents through interference, opposition or re-examination proceedings could result in a loss of patent rights in the relevant jurisdiction(s). As more groups become engaged in scientific research and product development areas of hESCs, the risk of our patents being challenged through patent interferences, oppositions, re-examinations or other means will likely increase. If we institute such proceedings against the patents of other parties and we are unsuccessful, we may be subject to litigation, or otherwise prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business.

Furthermore, if such challenges to our patent rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could materially harm our business.

Issued patents covering one or more of our product candidates or technologies could be found invalid or unenforceable if challenged in court.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or technologies, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the US PTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the patent validity, we cannot be certain, for example, that

there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology, Human Clinical Trials in a Test Tube. Such a loss of patent protection could have a material adverse impact on our business.



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Claims that any of our product candidates, including our Human Clinical Trials in a Test Tube, or, if commercialized, the sale or use of our products infringe the patent rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our product candidates, the use of our product candidates, or our platform technology, do not or will not infringe third party patents. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets. Such third parties might resort to litigation against us. The basis of such litigation could be existing patents or patents that issue in the future. Our failure to successfully defend against any claims that our product candidates or platform technology infringe the rights of third parties could also adversely affect our business. Failure to obtain any required licenses could restrict our ability to commercialize our products in certain territories or subject us to patent infringement litigation, which could result in us having to cease commercialization of our products and subject us to money damages in such territories.

It is also possible that we may fail to identify relevant patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

To avoid or settle potential claims with respect to any patent rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or any future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing one or more of our products, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other business.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation, and could result in unfavorable outcomes that could limit our research and development activities and/or our ability to commercialize certain products.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. Moreover, if third parties successfully assert intellectual property rights against us, we might be barred from using certain aspects of our platform technology, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations of patent infringement or misappropriation of trade secrets, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There

can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the patent owner to continue our research and development programs or to market our product(s). It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This could limit our research and development activities, our ability to commercialize certain products, or both.

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Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our internal research programs, conduct clinical trials, continue to in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to patents, we rely on trade secrets, technical know-how, and proprietary information concerning our business strategy in order to protect our competitive position in the field of stem cell research and product candidate development. In the course of our research and development activities and other business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement upon joining the Company. We take steps to protect our proprietary information, and our confidentiality agreements are carefully drafted to protect our proprietary interests. These confidentiality agreements may not effectively prevent disclosure of our technical know-how and proprietary information and may not provide an adequate remedy in the event of unauthorized disclosure of such technical know-how and proprietary information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we would not be able to assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

There can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development strategic partners may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.



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Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

Others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we may own or have exclusively licensed;

We or our licensors or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we may own or have exclusively licensed;

We or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;

Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

Others may be able to develop technologies around some of our issued patents without infringing such patents;

It is possible that our pending patent applications will not lead to issued patents;

Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

We may not develop additional proprietary technologies that are patentable; and

The patents of others may have an adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other development stage biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity. Therefore, obtaining and enforcing patents is costly, time-consuming and inherently uncertain. In addition, Congress has passed patent reform legislation which provides new limitations on attaining, maintaining and enforcing intellectual property. Further, the Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the US PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.



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If we are not able to obtain and enforce patent protection or other commercial protection for AV-101, the value of AV-101 will be harmed.

Commercial protection of AV-101, our small molecule drug candidate for neuropathic pain and other neurological conditions is important to our business. Our success related to AV-101 will depend in part on our or a potential collaborator's ability to obtain and enforce potential patents and maintain our trade secrets and secure New Drug Product Exclusivity provided by the FDA under section 505(c)(3)(E) and 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act.

Additional patents may not be granted, and potential U.S. patents, if issued, might not provide us with commercial benefit or might be infringed upon, invalidated or circumvented by others. The principle U.S. method of use patent and its foreign counterparts for AV-101 have expired. Although we have recently filed three new U.S. patent applications relating to AV-101, we or others with whom we may collaborate for the development and commercialization of AV-101 may choose not to seek, or may be unable to obtain, patent protection in a country that could potentially be an important market for AV-101.

We may become subject to damages resulting from claims that we or our future employees have wrongfully used or disclosed alleged trade secrets of our employees' former employers.

Our ability to execute on our business plan will depend on the talents and efforts of highly skilled individuals with specialized training in the field of stem cell research and bioassay development, as well as medicinal chemistry and in vitro drug candidate screening and nonclinical and clinical development. Our future success depends on our ability to identify, hire and retain these highly skilled personnel during our development stage. We may hire additional highly skilled scientific and technical employees, including employees who may have been previously employed at biopharmaceutical companies, including our competitors or potential competitors, and who may have executed invention assignments, nondisclosure agreements and/or non-competition agreements in connection with such previous employment. As to such future employees, we may become subject to claims that we, or these future employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

## Risks Related to the Offering and our Common Stock

Purchasers in this Offering will experience immediate and substantial dilution in the book value of their investment.

If we successfully sell all shares registered by this Offering, new investors will contribute approximately \_\_\_\_% of the total amount of equity capital raised by us through the date of this Offering, and will own approximately \_\_\_\_% of the outstanding shares. In addition, we may have issued options, warrants or other derivative securities to acquire common stock at prices below the public offering price. To the extent outstanding options, warrants or other derivative securities are ultimately exercised or converted, or if we issue restricted stock to our employees under our equity incentive plans, there will be further dilution to investors who purchase shares in this Offering. In addition, if we issue additional equity securities or derivative securities, investors purchasing shares in this Offering will experience additional dilution. For a further description of the dilution that you will experience immediately after this Offering, see "Dilution."





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We may allocate the net proceeds from this Offering in ways that differ from our estimates based on our current plans and assumptions discussed in the section titled "Use of Proceeds" and with which you may not agree.

The allocation of net proceeds of the offering set forth in the "Use of Proceeds" section of this prospectus represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, our future revenues and expenditures. The amounts and timing of our actual expenditures will depend on numerous factors, including market conditions, cash generated by our operations, business developments and related rate of growth. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes. Circumstances that may give rise to a change in the use of proceeds and the alternate purposes for which the proceeds may be used are discussed in the section in this prospectus entitled "Use of Proceeds". You may not have an opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use our proceeds. As a result, you and other stockholders may not agree with our decisions. See "Use of Proceeds" for additional information.

The number of shares of issued and outstanding common stock represents approximately 30% of our fully diluted shares of common stock. Additional issuances of shares of common stock upon conversion and/or exercise of convertible promissory notes, preferred stock, options to purchase common stock and warrants to purchase common stock will cause substantial dilution to existing stockholders.

At July 1, 2014, we had 25.5 million shares of common stock issued and outstanding. Up to an additional 61.0 million shares may be issued upon conversion of our Series A Preferred and all outstanding convertible promissory notes, and upon exercise of all outstanding options and warrants to purchase our common stock, which amount includes all reserves, resulting in a total of up to 86.5 million shares that may be issued and outstanding, assuming conversion of all outstanding convertible promissory notes, and exercise of all outstanding option and warrants to purchase our common stock. The issuance of any and all of the 61.0 million shares issuable upon exercise or conversion of our outstanding convertible securities will cause substantial dilution to existing stockholders and may depress the market price of our common stock.

You will experience future dilution as a result of future equity offerings, including in the event we consummate a financing a sale of our common stock to Autilion AG.

We may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock, including up to 72.0 million shares of common stock to Autilion AG (Autilion) under the terms of an existing Securities Purchase Agreement by and between the Company and Autilion (Autilion Financing). While Autilion is in default under the Securities Purchase Agreement, we have not formally terminated the Agreement. Although no assurances can be given that Autilion will consummate the Autilion Financing, in the event we elect to close, or in the event we sell shares of common stock or other securities convertible into shares of our common stock in the future, additional and substantial dilution will occur. In addition, investors purchasing shares or other securities in the future could have rights superior to investors in the Offering.

There may be additional issuances of shares of preferred stock in the future.

Following approval by our stockholders in October 2011, our Articles of Incorporation permit us to issue up to 10.0 million shares of preferred stock and our board of directors has authorized the issuance of 500,000 shares of Series A Preferred, all of which shares are currently outstanding. In addition, our board of directors has authorized the creation of a new series of preferred stock, to be designated Series B Convertible Preferred Stock, for issuance promptly following consummation of the Offering upon conversion of certain outstanding indebtedness. Our board of directors could authorize the issuance of additional series of preferred stock in the future and such preferred stock could grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be

declared to holders of our common stock, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. In the event and to the extent that we do issue additional preferred stock in the future, the rights of holders of our common stock could be impaired thereby, including without limitation, with respect to liquidation.

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In the event we complete a reverse split of our authorized and issued and outstanding common stock, the market price for our shares may decline.

On July \_\_\_\_, 2014, our board of directors authorized a reverse split of our authorized and issued and outstanding common stock at a ratio of up to one-for-\_\_\_\_, with the exact ratio to be determined by our board of directors (Stock Consolidation). If consummated, no assurances can be given that the Stock Consolidation will have a long-term positive effect on the market price of our common stock, facilitate our ability to consummate acquisitions or financing arrangements in the future or our ability to list our shares on the NASDAQ Capital Market or other national exchange. The market price of our common stock is based on factors that may be unrelated to the number of shares outstanding. These factors include our performance, general economic and market conditions and other factors, many of which are beyond our control. The market price for our post-split shares may not rise or remain constant in proportion to the reduction in the number of pre-split shares outstanding before the Stock Consolidation. Accordingly, the total market capitalization of our common stock after the Stock Consolidation may be lower than the total market capitalization before the Stock Consolidation.

There is no assurance that an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Since we became a publicly traded company in May 2011, there has been a limited public market for shares of our common stock on the OTCQB Markets (OTCQB). We do not yet meet the initial listing standards of the New York Stock Exchange, the NASDAQ Capital Market, or other similar national securities exchanges. Until our common stock is listed on a broader exchange, we anticipate that it will remain quoted on the OTCQB, another over-the-counter quotation system, or in the “pink sheets.” In those venues, investors may find it difficult to obtain accurate quotations as to the market value of our common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect liquidity. This could also make it more difficult to raise additional capital.

We cannot predict the extent to which investor interest in our company will lead to the development of a more active trading market on the OTCQB, whether we will meet the initial listing standards of the New York Stock Exchange, the NASDAQ Capital Market, or other similar national securities exchanges, or how liquid that market might become. We and the placement agent determined the Offering price of our common stock through negotiation. This price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this Offering. If an active trading market does not develop, you may have difficulty selling any of the shares of our common stock that you buy. In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

actual or anticipated quarterly variation in our results of operations or the results of our competitors;

announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;

financial projections we may provide to the public, any changes to those projections, or our failure to meet those projections;

issuance of new or changed securities analysts’ reports or recommendations for our stock;

developments or disputes concerning our intellectual property or other proprietary rights;

commencement of, or our involvement in, litigation;

market conditions in the biopharmaceutical and life sciences sectors;

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failure to complete significant sales;

changes in legislation and government regulation;

public concern regarding the safety, efficacy or other aspects of our products;

entering into, changing or terminating collaborative relationships;

any shares of our common stock or other securities eligible for future sale;

any major change to the composition of our board of directors or management; and

general economic conditions and slow or negative growth of our markets.

The stock market in general, and small biotechnology-based companies like ours in particular, has from time to time experienced volatility in the market prices for securities that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In certain recent situations in which the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against such company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. Additionally, if the trading volume of our common stock remains low and limited there will be an increased level of volatility and you may not be able to generate a return on your investment.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. Future sales of shares by existing stockholders could cause our stock price to decline, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Prior to this date of this prospectus, there has been a limited public market for shares of our common stock on the OTCQB. Future sales of substantial amounts of shares of our common stock, including up to 72 million shares of common stock to Autilion and shares otherwise issued or issuable upon the exchange or conversion of our preferred stock, conversion of convertible promissory notes and exercise of outstanding options and warrants for common stock, in the public market, or the possibility of these issuances and sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

Our principal institutional stockholders may continue to have substantial control over us and could limit your ability to influence the outcome of key transactions, including changes in control.

Certain of our current institutional stockholders and their respective affiliates beneficially own approximately 46% of our outstanding capital stock, as beneficial ownership is defined by SEC rules and regulations. Accordingly, these stockholders may continue to have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. For information regarding the ownership of our outstanding stock by such stockholders,

refer to “Principal Stockholders” elsewhere in this prospectus.

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If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock may depend in part on the research and reports that securities or industry analysts publish about us and our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or too few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In the event we obtain analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. If one or more equity research analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. Securities and industry analysts do not currently, and may never, publish research on the Company. If no or too few securities or industry analysts commence coverage of the Company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In the event we obtain analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. If one or more equity research analysts cease coverage of the Company or fail to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Our common stock may be considered a “penny stock.”

Since we became a publicly traded company in May 2011, our common stock has traded on the OTCQB at a price of less than \$5.00 per share. The SEC has adopted regulations which generally define a “penny stock” as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. To the extent that the market price of our common stock is less than \$5.00 per share and, therefore, may be considered a “penny stock,” brokers and dealers effecting transactions in our common stock must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect your ability to sell shares of our common stock. In addition, as long as our common stock remains quoted only on the OTCQB, investors may find it difficult to obtain accurate quotations of the stock, and may find few buyers to purchase such stock and few market makers to support its price.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Any payment of cash dividends will depend upon our financial condition, contractual restrictions, financing agreement covenants, solvency tests imposed by corporate law, results of operations, anticipated cash requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may incur indebtedness that may severely restrict or prohibit the payment of dividends.





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We incur significant costs to ensure compliance with corporate governance, federal securities law and accounting requirements.

Since becoming a public company by means of a strategic reverse merger in 2011, we have been subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the Securities and Exchange Commission (SEC), the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act, and the Public Company Accounting Oversight Board, each of which imposes additional reporting and other obligations on public companies. We have incurred and will continue to incur significant costs to comply with these public company reporting requirements, including accounting and related audit costs, legal costs to comply with corporate governance requirements and other costs of operating as a public company. These legal and financial compliance costs will continue to require us to divert a significant amount of money that we could otherwise use to achieve our research and development and other strategic objectives.

The filing and internal control reporting requirements imposed by federal securities laws, rules and regulations are rigorous and we may not be able to continue to meet them, resulting in a possible decline in the price of our common stock and our inability to obtain future financing. Certain of these requirements may require us to carry out activities we have not done previously and complying with such requirements may divert management's attention from other business concerns, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Any failure to adequately comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, results of operations and financial condition.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We will continue to invest resources to comply with evolving laws, regulations and standards, however this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. All statements contained in this prospectus other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ

materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are under no duty to update any of these forward-looking statements after the date of this prospectus or to conform these statements to actual results or revised expectations. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

## USE OF PROCEEDS

We estimate that we will receive up to \$\_\_ million in net proceeds from the sale of common stock in this Offering, based on a price of \$\_\_\_\_ per share of common stock, assuming that (i) the maximum Offering amount is sold, and (ii) all holders of Convertible Notes aggregating approximately \$2.5 million in principal and accrued interest at July 1, 2014 elect to waive their right to receive payment of principal and accrued interest for their Convertible Notes in cash in lieu of Automatic Conversion, and after deducting the placement agent's commission and estimated Offering expenses payable by us. However, this is a best efforts offering, with no minimum, and no assurances can be given that we will receive significant proceeds. In the event certain holders of the Convertible Notes elect to receive cash in lieu of Automatic Conversion, and assuming gross proceeds from this Offering of at least \$10.0 million, the net proceeds available to us will decrease by an amount calculated based on the total amount of principal and accrued interest due and payable to those holders of Convertible Notes who elect to receive cash in lieu of Automatic Conversion, which, as of July 1, 2014, was approximately \$2.5 million.

The principal purposes of this Offering are to obtain additional capital for research and development, capital expenditures, extinguishment of indebtedness, and other general corporate purposes. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds of this Offering, especially since we are unable to determine whether and the extent to which any holders of Convertible Notes will elect to receive payment of principal and accrued interest otherwise due under the terms of such Convertible Notes in lieu of Automatic Conversion. However, assuming we receive gross proceeds from the Offering in the amount of \$15.0 million, the estimated use of proceeds is currently anticipated as follows, which illustrates the estimated use of proceeds assuming that all holders of Convertible Notes elect to receive cash in lieu of Automatic Conversion, and that no holders of Convertible Notes elect to receive cash:

(amounts in millions)	Assuming all holders of Convertible Notes: elect to receive cash in lieu of Automatic Conversion	elect Automatic Conversion of Convertible Notes
Assumed gross proceeds	\$15.0	\$15.0
Placement agent fees and offering expenses	(1.4 )	(1.4 )
Net proceeds	13.6	13.6
Research and development:		
Drug rescue programs, development of customized human cellular assay systems for drug discovery and drug rescue, and pilot nonclinical regenerative medicine programs	6.2	7.0
To extinguish, during the next twelve months, indebtedness related to prior research and development services, technology license fees and patent prosecution and maintenance	1.9	1.9

expenses

	8.1	8.9
New property, plant and equipment	0.5	0.5
Repayment of Convertible Notes	2.5	-
Working capital and other general and administrative purposes, including payment of approximately \$0.9 million of certain professional service accounts payable	\$2.5	\$4.2

Pending other uses, we intend to invest our proceeds in short-term investments or hold them as cash. We cannot predict whether the proceeds invested will yield a favorable return. Our management will have broad discretion in the use of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

#### DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock immediately after this Offering. As of March 31, 2014, our pro forma net tangible book value was approximately \$(\_\_\_\_) million, or \$(\_\_\_\_) per share of common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by shares of common stock outstanding, after giving effect, in connection with the completion of this Offering, to the conversion of \$\_\_\_\_\_ 2014 Unit Notes into \_\_\_\_\_ shares of common stock.

Dilution in pro forma net tangible book value per share represents the difference between the amount per share paid by buyers of shares of our common stock in this Offering and the pro forma net tangible book value per share of our common stock immediately following this Offering. After giving effect to the receipt of the net proceeds from our sale of shares of common stock in this Offering at an assumed public offering price of \$\_\_\_\_ per share, and after deducting estimated placement agent commissions and estimated Offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2014, would have been approximately \$\_\_\_\_ million, or \$\_\_\_\_ per share of common stock. This data represents an immediate increase in pro forma net tangible book value of \$\_\_\_\_ per share to existing stockholders and an immediate dilution of \$\_\_\_\_ per share to new investors purchasing shares at the public offering price.

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The following table illustrates the per share dilution to investors in this Offering:

Assumed public offering price per share	\$	
Historical net tangible book value per share as of March 31, 2014		
Conversion of promissory notes into common stock		
Pro forma net tangible book value per share as of March 31, 2014	\$	
Increase in pro forma net tangible book value per share attributable to investors in this Offering		
Pro forma net tangible book value per share as of March 31, 2014, as adjusted to give effect to this Offering	\$	
Less: Pro forma as adjusted dilution per share to investors in this Offering	\$	

The following table shows, on the pro forma basis described above, the difference between existing stockholders and new investors in this Offering with respect to the number of shares of common stock purchased from us, the total consideration paid and the average price paid per share, before deducting estimated offering expenses payable by us.

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount (in thousands)	Percent	
Existing stockholders		___%	\$		\$
New investors		___%	\$		\$
Total		___%	\$		\$

The outstanding share information set forth above is as of March 31, 2014 and excludes:

4,227,357 shares issuable upon the exercise of outstanding options under our 1999 Stock Incentive Plan and 2008 Stock Incentive Plan;

735,200 shares of our common stock reserved for issuance in connection with future awards under our stock 2008 Stock Incentive Plan;

18,981,490 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants;

15,000,000 shares of our common stock issuable upon the exchange of our Series A Preferred Stock (Series A Preferred);

7,500,000 shares of our common stock issuable upon the exercise of warrants issuable upon the exchange of our Series A Preferred; and

up to approximately [ ] shares of our common stock reserved for issuance upon the conversion of newly created Series B Convertible Preferred Stock (Series B Preferred), which Series B Preferred will be issued upon conversion of outstanding convertible promissory notes and related accrued interest upon consummation of the Offering, assuming gross proceeds from the Offering of at least \$10.0 million.



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## CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2014 that is derived from our audited financial information included elsewhere in this prospectus:

on an actual basis; and

on a pro forma basis giving effect to net proceeds from this Offering of approximately \$\_\_\_\_\_.

As of March 31, 2014 (Amounts in dollars)	Actual	Pro forma
Cash and cash equivalents	\$ -	\$ _____
Long-term debt, excluding current portion	4,784,500	_____
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; 500,000 Series A Preferred shares authorized, 500,000 Series A Preferred shares issued and outstanding, actual; _____ shares authorized, issued and outstanding, pro forma and pro forma as adjusted	500	_____
Common stock, \$0.001 par value, 200,000,000 shares authorized; 26,210,185 shares issued, 23,486,877 outstanding, actual; _____ shares issued and _____ shares outstanding, proforma	26,200	_____
Additional paid-in capital	61,976,500	_____
Treasury stock, at cost, 2,713,308 shares	(3,968,100)	_____
Note receivable from sale of common stock	(198,100)	_____
Accumulated deficit	(70,636,900)	_____
Total stockholders' deficit	(12,799,900)	_____
Total capitalization	\$ (8,015,400)	\$ _____

Common stock outstanding in the table above excludes the following shares as of March 31, 2014:

4,227,357 shares issuable upon the exercise of outstanding options under our 1999 Stock Incentive Plan and 2008 Stock Incentive Plan;

17,095,633 shares of our common stock issuable upon the exercise of outstanding warrants;

735,200 shares of common stock reserved for issuance under our 2008 Equity Incentive Plan;

15,000,000 shares of our common stock issuable upon exchange of our Series A Preferred;

7,500,000 shares of our common stock issuable upon the exercise of warrants issuable upon the exchange of our Series A Preferred; and

up to approximately [ ] shares of our common stock reserved for issuance upon the conversion of newly created Series B Preferred, which Series B Preferred will be issued upon conversion of outstanding convertible promissory notes and related

accrued interest promptly upon consummation of the Offering, assuming gross proceeds from the Offering of at least \$10.0 million.



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PLAN OF DISTRIBUTION

We have entered into a placement agency agreement, dated as of [\_\_\_\_], 2014, with Geller Biopharm (Geller Biopharm or Agent), a healthcare investment banking division of Financial West Group. Subject to the terms and conditions contained in the placement agency agreement, the placement agent has agreed to act as the placement agent in connection with the sale of our common stock. The placement agent may engage selected dealers to assist in the placement of the securities offered hereby. The placement agent is not purchasing or selling any securities offered by this prospectus, nor are they required to arrange the purchase or sale of any specific number or dollar amount of our securities. However, Geller Biopharm has agreed to use their best efforts to arrange for the sale of the securities offered hereby.

Investors wishing to participate in the Offering will be required to deliver an executed subscription agreement to the placement agent and immediately available funds via wire transfer [or check payable to [\_\_\_\_]] as escrow agent for the Company. All of the proceeds from the sale of the securities offered hereby will be deposited into an escrow account at the escrow agent. If the Company does not accept the subscription of a subscriber, all monies of such subscriber will be refunded promptly, without any earned interest, and without deduction for commissions or expenses, including costs of the escrow agent. The Offering period may continue until August 31, 2014 and may be extended by the placement agent and us until \_\_\_\_\_, 2014.

[The escrow agent will notify the placement agent when funds to pay for the securities offered hereby have been received. The placement agent shall inform the escrow agent in writing of the name, address, and the tax identification number of the subscriber, the amount of securities subscribed for by such subscriber, and the aggregate dollar amount of such subscription.] There is no minimum amount necessary for a closing, but the placement agent and we will provide written instructions to the escrow agent when to release funds. Upon closing, we will deliver to each purchaser delivering funds the number of shares of common stock purchased by such purchaser. [If the conditions to this Offering are not satisfied or waived, then all investor funds that were deposited into escrow will be returned promptly to investors, without any earned interest, and without deduction for commissions or expenses, including costs of the escrow agent and this Offering will terminate. We will pay the escrow agent a fee in connection with the escrow services.]

The placement agency agreement provides that the obligations of the placement agent and the purchasers are subject to certain conditions precedent, including, among other things, the absence of any material adverse change in our business and the receipt of customary legal opinions, letters and certificates.

We currently anticipate that the closing of the sale of the common stock offered hereby will take place on or before July 31, 2014.

We have agreed to pay the placement agents an aggregate fee equal to 8.0% of the gross proceeds (equivalent to 8.0% per share of the per share Offering price of \$[\_\_\_\_]) of this Offering and expect the net proceeds from this Offering to be approximately \$13.6 million, assuming the sale of the maximum Offering amount, after deducting up to approximately \$1,200,000 in placement agent fees and \$200,000 in our estimated Offering expenses. We have also agreed to pay the placement agent's expenses relating to the Offering.

We have paid a non-refundable deposit of \$10,000 to Geller Biopharm as placement agent.

We have agreed to indemnify the placement agent and certain other persons against certain liabilities, including civil liabilities under the Securities Act, and to contribute to payments that the placement agent may be required to make in respect of those liabilities.

The placement agent has informed us that they will not engage in over-allotment, stabilizing transactions or syndicate covering transactions in connection with this Offering.

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### Lock-Up Agreements

Pursuant to certain “lock-up” agreements, we, our named executive officers and directors, and certain of our stockholders have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the representative, for a period of one hundred and eighty (180) days after the date of the placement agency agreement.

The lock-up period described in the preceding paragraph will be automatically extended if: (1) during the last 17 days of the restricted period, we issue an earnings release or announce material news or a material event; or (2) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the date of the earnings release, unless the representative waives this extension in writing.

### Payments in Connection with Autillion AG

If we receive at least \$25 million of funding from Autillion pursuant to the Securities Purchase Agreement, dated as of April 8, 2013, as amended, between the Company and Autillion prior to the consummation of this Offering, then we will be required to pay Geller Biopharm a non-refundable financial advisory fee equal to \$500,000.

### Right of First Refusal

Upon the closing of the Offering, for a period of twelve months from the expiration or termination of its engagement, Geller Biopharm shall have a right of first refusal to participate in any public offering of our securities or sale in one or more transactions by our existing security holders of their securities.

### Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by one or more of the placement agents. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the placement agents should not be relied upon by investors.

### Other Relationships

From time to time in the ordinary course of business, the placement agents or their affiliates may in the future engage in investment banking, commercial banking and/or other services with us and our affiliates for which they may in the future receive customary fees and expenses.

### Exchange of Notes

Of the total number of share of common stock that may be issued in connection with this Offering, up to \_\_\_\_\_ shares may be issued in exchange for certain promissory notes of the Company. The placement agent will not be paid a commission in connection with the issuance of such shares, nor will the Company receive any proceeds from the issuance of such shares. Such shares will be issued directly by the Company to the holders of such promissory notes that elect to exchange such notes for shares of common stock in the Offering.



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DESCRIPTION OF SECURITIES

General

Our authorized capital stock consists of 200 million shares of our common stock, \$0.001 par value per share, and 10.0 million shares of preferred stock, \$0.001 par value per share. The following is a description of our common stock and certain provisions of our Articles, and our amended and restated bylaws (Bylaws), and certain provisions of Nevada law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Articles and our Bylaws, copies of which have been filed with the SEC as exhibits to our periodic filings under the Securities Exchange Act.

As of July 1, 2014, there were issued and outstanding, or reserved for issuance:

25,506,872 shares of our common stock held by approximately 300 stockholders of record;

15,000,000 shares of our common stock issuable upon exchange of our Series A Preferred held by one institutional investor;

4,227,357 shares of our common stock issuable upon exercise of outstanding stock options under our 1999 Stock Incentive Plan and 2008 Stock Incentive Plan;

26,481,490 shares of our common stock issuable upon exercise of outstanding warrants, including warrants to purchase 7,500,000 shares of common stock, which warrants are issuable upon exchange of our Series A Preferred for common stock; and

up to approximately [ ] shares of our common stock reserved for issuance upon the conversion of newly issued Series B Preferred, which Series B Preferred will be issued upon conversion of outstanding convertible promissory notes and related accrued interest promptly upon consummation of the Offering, assuming gross proceeds from the Offering of at least \$10.0 million.

Common Stock

Except as otherwise expressly provided in our Articles, or as required by applicable law, all shares of our common stock have the same rights and privileges and rank equally, share ratably and are identical in all respects as to all matters, including, without limitation, those described below. All outstanding shares of common stock are fully paid and nonassessable.

Voting rights

Each holder of our common stock is entitled to cast one vote for each share of common stock held on all matters submitted to a vote of stockholders. Cumulative voting for election of directors is not allowed under our Articles, which means that a plurality of the shares voted can elect all of the directors then outstanding for election. Except as otherwise provided under Nevada law or our Articles, and Bylaws, on matters other than election of directors, action on a matter is approved if the votes cast favoring the action exceed the votes cast opposing the action

Dividend rights

The holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available, if our board of directors, in its discretion, determines to issue dividend, and only at the times and in the amounts that

our board of directors may determine. Our board of directors is not obligated to declare a dividend. We have not paid any dividends in the past and we do not intend to pay dividends in the foreseeable future. See “Dividend Policy” for more information.

#### Liquidation rights

Upon our liquidation, dissolution or winding-up, the holders of our common stock will be entitled to share equally, identically and ratably in all assets remaining, subject to the prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

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### No preemptive or similar rights

Our common stock is not entitled to is not subject to conversion, redemption, sinking fund or similar provisions regarding the common stock.

### Preferred Stock

We are authorized, subject to limitations prescribed by Nevada law, to issue up to 10.0 million shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors can increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the Company and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

### Series A Preferred

#### General

In December 2011, our board of directors authorized the creation of a series of up to 500,000 shares of Series A Preferred. At July 1, 2014, there were 500,000 shares of Series A Preferred outstanding. By agreement with the sole holder thereof, each share of Series A Preferred is exchangeable at the option of the holder into thirty (30) shares of our common stock. The Series A Preferred ranks prior to our common stock for purposes of liquidation preference.

#### Dividend rights

The Series A Preferred has no separate dividend rights. However, whenever the board of directors declares a dividend on the common stock, each holder of record of a share of Series A Preferred, or any fraction of a share of Series A Preferred, on the date set by the board of directors to determine the owners of the common stock of record entitled to receive such dividend (Record Date) shall be entitled to receive out of any assets at the time legally available therefor, an amount equal to such dividend declared on one share of common stock multiplied by the number of shares of common stock into which such share, or such fraction of a share, of Series A Preferred could be exchanged on the Record Date.

#### Voting rights

Except with respect to transactions upon which the Series A Preferred shall be entitled to vote separately as a class, the Series A Preferred has no voting rights. The common stock into which the Series A Preferred is exchangeable shall, upon issuance, have all of the same voting rights as other issued and outstanding shares of our common stock.

#### Liquidation rights

In the event of the liquidation, dissolution or winding up of our affairs, after payment or provision for payment of our debts and other liabilities, the holders of Series A Preferred then outstanding shall be entitled to receive, out of our assets, if any, an amount per share of Series A Preferred calculated by taking the total amount available for distribution to holders of all of our outstanding common stock before deduction of any preference payments for the

Series A Preferred, divided by the total of (x), all of the then outstanding shares of our common stock, plus (y) all of the shares of our common stock into which all of the outstanding shares of the Series A Preferred can be exchanged before any payment shall be made or any assets distributed to the holders of the common stock or any other junior stock.



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### Series B Preferred

#### General

On July \_\_, our board of directors authorized the creation of a series of up to \_\_\_\_\_ shares of Series B Preferred. The Series B Preferred were authorized in order to provide for the conversion of certain promissory notes held by Platinum totally approximately \$\_\_\_\_\_ in principal and accrued interest at July 1, 2014 (Outstanding Balance) into Series B Preferred upon consummation of the Offering. We anticipate filing the certificate of designations for the Series B Preferred immediately prior to consummation of the Offering.

The number of shares of Series B Preferred to be issued will be calculated based on the liquidation preference for the Series B Preferred, which shall equal the Outstanding Balance as of the date of consummation of the Offering, divided by the lesser of (i) \$.50 and (ii) the per-share common stock price sold in the Offering.

By agreement with the sole holder thereof, each share of Series B Preferred will be exchangeable at the option of the holder into shares of our common stock at the price per-share of common stock sold in the Offering. The Series B Preferred will rank prior to our common stock for purposes of liquidation preference.

#### Dividend rights

The Series B Preferred will have no separate dividend rights. However, whenever the board of directors declares a dividend on the common stock, each holder of record of a share of Series B Preferred, or any fraction of a share of Series B Preferred, on the date set by the board of directors to determine the owners of the common stock of record entitled to receive such dividend (Record Date) shall be entitled to receive out of any assets at the time legally available therefor, an amount equal to such dividend declared on one share of common stock multiplied by the number of shares of common stock into which such share, or such fraction of a share, of Series B Preferred could be exchanged on the Record Date.

#### Voting rights

Except with respect to transactions upon which the Series B Preferred shall be entitled to vote separately as a class, the Series B Preferred shall have no voting rights. The common stock into which the Series B Preferred shall be exchangeable shall, upon issuance, have all of the same voting rights as other issued and outstanding shares of our common stock.

#### Liquidation rights

In the event of the liquidation, dissolution or winding up of our affairs, after payment or provision for payment of our debts and other liabilities, the holders of Series B Preferred then outstanding shall be entitled to receive, out of our assets, if any, an amount per share of Series B Preferred calculated by taking the total amount available for distribution to holders of all of our outstanding common stock before deduction of any preference payments for the Series B Preferred, divided by the total of (x), all of the then outstanding shares of our common stock, plus (y) all of the shares of our common stock into which all of the outstanding shares of the Series B Preferred can be exchanged before any payment shall be made or any assets distributed to the holders of the common stock or any other junior stock.

#### Options

As of July 1, 2014, we had options to purchase 4,227,357 shares of our common stock outstanding pursuant to our 1999 Plan and our 2008 Plan.

#### Warrants

As of July 1, 2014, warrants to purchase 18,981,490 shares of our common stock were outstanding, excluding warrants to purchase 7,500,000 shares of common stock issuable in connection with the exchange of our Series A Preferred for common stock.

#### Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Registrar and Transfer Company. The transfer agent's address is 10 Commerce Drive, Cranford, NJ 07016.

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## Securities Authorized for Issuance Under Equity Compensation Plans as of July 1, 2014

	Number of securities to be issued upon exercise of Outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans [excluding securities reflected in column (a)]
Equity Compensation plans approved by security holders	3,964,800	\$ 0.50	735,200
Equity Compensation plans not approved by security holders	262,557	0.58	-
Total	4,227,537	\$ 0.50	735,200

## Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Registrar and Transfer Company. The transfer agent's address is 10 Commerce Drive, Cranford, NJ 07016.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this Offering, there has a limited public market for shares of our common stock. Future sales of substantial amounts of shares of our common stock, including sales of shares issued upon the conversion of outstanding convertible promissory notes, exchange of outstanding preferred stock and exercise of outstanding options and warrants, in the public market after this Offering or the possibility of these issuances and sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

Upon the completion of this Offering, based on the number of shares outstanding as of July 1, 2014, we will have \_\_\_\_\_ shares of common stock outstanding, assuming exercise of outstanding options or warrants and conversion of our preferred stock and convertible promissory notes. Of these outstanding shares, all \_\_\_\_\_ shares of common stock sold by us in this Offering will be freely tradable in the public market without restriction or further registration under the Securities Act, and \_\_\_\_\_ shares of common stock held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below. The remaining \_\_\_\_\_ shares of common stock, and all shares of Series A Preferred and Series B Preferred outstanding after this Offering, will be deemed restricted under the Federal securities laws.

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Rule 144

In general, under Rule 144 as currently in effect, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person is entitled to sell those shares without complying with the requirements of Rule 144, subject to the availability of current public information about us.

In general, under Rule 144 as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon the expiration of the lock-up agreements described above, within any three month period, a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this Offering; or

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

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BUSINESS

We are a stem cell company headquartered in South San Francisco, California and focused on drug rescue and regenerative medicine. We believe better cells lead to better medicines™ and that the key to making better cells is precisely controlling the differentiation of human pluripotent stem cells, which are the building blocks of all cells of the human body. For over 15 years, our stem cell research and development teams and collaborators have focused on controlling the differentiation of pluripotent stem cells to produce multiple types of mature, functional, adult human cells, with emphasis on human heart and liver cells, and using such cells to design customized biological assay systems for drug discovery and drug rescue, as well as regenerative medicine applications.

Our stem cell technology platform - Human Clinical Trials in a Test Tube™

Our stem cell technology platform, which we refer to as Human Clinical Trials in a Test Tube, is based on a combination of proprietary and exclusively licensed technologies for controlling the differentiation of human pluripotent stem cells into multiple types of mature, functional, adult human cells that we use, or plan to develop, to reproduce complex human biology and disease. We are currently producing heart cells and liver cells for our drug rescue applications. Upon completion of this Offering, we intend to focus on the drug rescue applications utilizing human heart and liver cells, and further advance, through collaborative research projects, pharmaceutical applications of stem cell-derived blood, bone, cartilage, heart, liver and pancreatic beta-islet cells, including exploring opportunities to leverage our stem cell technology platform for regenerative medicine purposes. Our emphasis in the regenerative medicine arena will be on developing novel human disease models for discovery of small molecule drugs and biologics that activate the endogenous growth and healing processes enabling the body to repair tissue damage caused by certain degenerative diseases.

CardioSafe 3D™

Using mature cardiomyocytes (heart cells) differentiated from human pluripotent stem cells, we have developed CardioSafe 3D, as a novel, in vitro bioassay system used to assess new drug candidates for potential cardiac toxicity before they are tested in humans. We believe CardioSafe 3D is capable of predicting the in vivo cardiac effects, both toxic and non-toxic, of small molecule drug candidates with greater speed and precision than the long-established, surrogate safety models most often used in drug development, including models using animal cells or live animals, and cellular assays using cadaver, immortalized or transformed cells. Our pluripotent stem cell derived cardiomyocytes (heart cells) and CardioSafe 3D are key components of our Human Clinical Trials in a Test Tube platform and drug rescue programs.

LiverSafe 3D™

Using mature, functional adult hepatocytes (liver cells) derived from human pluripotent stem cells, we are currently correlating LiverSafe 3D, our second novel stem cell technology-based bioassay system, with reported clinical results of drugs with liver toxicity. We believe LiverSafe 3D will enable us to assess, early in development, new drug candidates for potential drug-induced liver injury and metabolism issues that can result in serious adverse drug-drug interactions, before animal or human testing. We plan to use LiverSafe 3D, and the clinically predictive liver biology insight we believe it will provide us, to expand the scope of our commercial opportunities related to drug rescue.

Drug Rescue

We believe drug rescue using CardioSafe 3D and LiverSafe 3D, the foundation of our Human Clinical Trials in a Test Tube platform, is the highest-value near term commercial application of the human cells we produce. Detailed information is available to us in the public domain regarding the efficacy, pharmacology, formulation and toxicity of

promising small molecule drug candidates developed by pharmaceutical and biotechnology companies which have failed due to unexpected heart or liver toxicity. These failed but still promising drug candidates, which we refer to as Drug Rescue Candidates, have already been optimized and tested by a pharmaceutical or biotechnology company and assessed preliminarily for efficacy and their commercial potential.

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We believe the human heart and liver cells we produce and use in CardioSafe 3D and LiverSafe 3D offer a new paradigm for evaluating potential heart and liver toxicity early in drug development, long before costly, high risk human clinical trials. While efforts of pharmaceutical and biotechnology companies to improve their prediction of such human toxicity for new drug candidates is ongoing, our access to Drug Rescue Candidates offers us an opportunity to use our stem cell technology platform to take advantage of prior third-party investment in Drug Rescue Candidates by attempting to significantly reduce the toxicity that caused them to be terminated, and bring new, potentially safer versions back into development protected by new intellectual property. We refer to the new, potentially safer versions of Drug Rescue Candidates we intend to produce as Drug Rescue Variants™.

By applying our stem cell technology platform to drug rescue opportunities, we intend to become a leading source of proprietary, small molecule drug candidates to the global pharmaceutical industry. We have designed our drug rescue model to leverage publicly available information and substantial prior investment by pharmaceutical companies and others in Drug Rescue Candidates. We believe the pre-existing public domain knowledge base supporting the therapeutic and commercial potential of Drug Rescue Candidates will provide us with a valuable head start as we launch our drug rescue programs. Leveraging the substantial prior investments by global pharmaceutical companies and others in discovery, optimization and efficacy validation of Drug Rescue Candidates is an essential component of our drug rescue strategy.

### Our Drug Rescue Strategy

We believe the pre-existing public domain knowledge base supporting the therapeutic and commercial potential of our Drug Rescue Candidates will provide us with a valuable head start as we launch our drug rescue programs. Leveraging the substantial prior investments by global pharmaceutical companies and others in discovery, optimization and in vitro efficacy validation of Drug Rescue Candidates is an essential component of our drug rescue strategy.

Our current drug rescue emphasis is on Drug Rescue Candidates discontinued prior to FDA market approval due to unexpected cardiac safety concerns. By using CardioSafe 3D assay platform to enhance our understanding of the cardiac liability profile of Drug Rescue Candidates, biological insight not previously available when the Drug Rescue Candidate was originally discovered and developed, we believe we can demonstrate in vitro proof-of-concept as to the efficacy and safety of Drug Rescue Variants earlier in development and with substantially less investment in discovery, in vitro efficacy optimization and development than was required of the pharmaceutical companies prior to their decision to terminate the Drug Rescue Candidates.

The key elements of our current CardioSafe 3D drug rescue strategy are as follows:

identify potential Drug Rescue Candidates with heart safety issues utilizing drug discovery and development information available in the public domain through open source, licensed databases, and published patents, as well as through our strategic relationships with our drug rescue and scientific advisors and consultants, including Synterys, Inc. and Cato Research Ltd., our providers of contract medicinal chemistry and contract clinical development services and regulatory expertise, respectively;

leverage substantial prior research and development investments made by global pharmaceutical companies and others to support the therapeutic and commercial potential of Drug Rescue Candidates, as important criteria for selection of Drug Rescue Candidates and potential lead Drug Rescue Variants;

use our CardioSafe 3D assay platform to enhance our understanding of the cardiac liability profile of Drug Rescue Candidates, important and more comprehensive biological insights not previously available when the Drug Rescue Candidates were originally discovered, optimized and developed by pharmaceutical companies;

leverage our internal knowledgebase about each Drug Rescue Candidate's specific chemistry to design and produce, with our contract medicinal chemistry collaborator, a portfolio of novel potential lead Drug Rescue Variants for each Drug Rescue Candidate;

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use CardioSafe 3D and pre-existing in vitro efficacy models to assess the efficacy and cardiac safety of potential Drug Rescue Variants and identify and validate a lead Drug Rescue Variant; and

internally develop optimized and validated lead Drug Rescue Variant or out-license them to a pharmaceutical or biotechnology company in a revenue-generating agreements providing for the development, market approval and commercial sale of the Drug Rescue Variant.

## Drug Rescue Candidates

Our current CardioSafe 3D Drug Rescue Candidates are set forth in the table below:

Drug Rescue Candidate	Indication	Developer	Terminated Reason for Termination	Mechanism
VSTA-1C05	Cancer	Pharma	Phase 1/2 Cardiotoxicity	Aurora kinase inhibitors
VSTA-1A08	Cancer	Biotech	Preclinical Cardiotoxicity	PI3 kinase inhibitor
VSTA-2A21	Dementia	Pharma	Preclinical Cardiotoxicity	Nicotinic a7 receptors
VSTA-5A03	HIV	Pharma	Preclinical Cardiotoxicity	Integrase inhibitor
VSTA-4E15	Type 2 Diabetes	Pharma	Post-NDA Cardiotoxicity	Insulin sensitizer; PPAR gamma agonist

We believe our exclusive focus on Drug Rescue Candidates with established, therapeutic and commercial potential, and our ability to build on that valuable head start using our expertise in human biology, will help us to generate Drug Rescue Variants without incurring certain high costs and risks typically inherent in drug discovery and development. Although we plan to continue to identify Drug Rescue Candidates in the public domain, we may also seek to acquire rights to Drug Rescue Candidates not available to us in the public domain by entering into contractual arrangements with third-parties.

## Strategic Development and Commercialization of Drug Rescue Variants

We believe many pharmaceutical companies are experiencing, and will continue to experience, critical research and development productivity issues, as measured by their lack of, or very low number of, FDA-approved products each year during the past decade. In 2013, the U.S. pharmaceutical industry invested over \$51 billion in research and development, while the FDA only approved 34 new treatments, including 27 medications approved by the FDA's Center for Drug Evaluation and Research (CDER). Considering CDER only approved an average of 26 medications per year between 2004 and 2012, we expect the disparity between annual spending on research and development by the U.S. pharmaceutical industry and the number of medications approved by CDER to continue.

As a result of research and development productivity issues and diminishing product pipelines, as well as generic competition for established products that are no longer patent protected, we believe there is and will continue to be a critical need among pharmaceutical companies to acquire or in-license the new, potentially safer Drug Rescue Variants we are focused on developing, including companies that originally discovered, developed and ultimately discontinued the Drug Rescue Candidates we select for our drug rescue programs.

Once we achieve proof-of-concept (POC) in vitro as to the efficacy and safety of a lead Drug Rescue Variant, we intend to announce the results of our internal POC studies and, at that time, consider whether we will seek to out-license that Drug Rescue Variant to a pharmaceutical company, including, potentially, the company that

developed the Drug Rescue Candidate, or further develop it internally. If we decide to out-license a lead Drug Rescue Variant to a pharmaceutical company, through a form of license arrangement we believe is generally accepted in the pharmaceutical industry, we anticipate that the pharmaceutical company will be responsible for all subsequent development, manufacturing, regulatory approval, marketing and sale of the Drug Rescue Variant and that we will receive licensing revenue through payments to us from the license upon signing the license agreement, achievement of development and regulatory milestones, and, if approved and marketed, upon commercial sales, although no assurances can be given that the terms of such a beneficial arrangement will be available or offered to us.

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### Regenerative Medicine and Drug Discovery

Although we believe the best and most valuable near term commercial application of our stem cell technology platform, Human Clinical Trials in a Test Tube, is for small molecule drug rescue, we also believe stem cell technology-based regenerative medicine has the potential to transform healthcare in the U.S. over the next decade by altering the fundamental mechanisms of disease. Upon completion of this Offering, we intend to explore opportunities to leverage our stem cell technology platform for regenerative medicine purposes, with emphasis on developing novel human disease models for discovery of small molecule drugs with regenerative and therapeutic potential. Our regenerative medicine focus will be based on our expertise in human biology, differentiation of human pluripotent stem cells to develop functional adult human cells and tissues involved in human disease, including blood, bone, cartilage, heart, liver and insulin-producing pancreatic beta-islet cells, and our expertise in designing novel, customized biological assay systems with the cells we produce. Upon completion of this Offering, among our key objectives will be to explore regenerative medicine opportunities through exploratory nonclinical POC studies, after which we intend to assess any potential opportunities for further development and commercialization of therapeutically and commercially promising regenerative medicine programs and novel, customized, disease-specific biological assay systems for drug discovery, either on our own or with strategic partners.

### AV-101 for Neuropathic Pain, Epilepsy and Depression

With \$8.8 million of grant funding awarded from the U.S. National Institutes of Health (NIH), we have successfully completed Phase 1 development of AV-101. AV-101, also known as “L-4-chlorokynurenine” and “4-Cl-KYN”, is an orally-available, non-sedating small molecule prodrug candidate aimed at the multi-billion dollar neurological disease and disorders market, including neuropathic pain, a serious and chronic condition causing pain after an injury or disease of the peripheral or central nervous system, epilepsy, depression and Parkinson’s disease. Our AV-101 IND application on file at the FDA covers clinical development for neuropathic pain. However, we believe the Phase 1 AV-101 safety studies we have completed to date will support development of AV-101 for multiple indications, including epilepsy, depression and Parkinson’s disease. Upon completion of this Offering, we intend to seek potential opportunities for further clinical development and commercialization of AV-101 for neuropathic pain, epilepsy, depression and Parkinson’s disease, either on our own or through one strategic partnering arrangements. In the event that we successfully complete one or more strategic partnering arrangements for AV-101, we plan to use the net proceeds from such arrangement(s) to expand our stem cell technology-based drug rescue and regenerative medicine programs.

### Scientific Background

#### Stem Cell Basics

Stem cells are the building blocks of all cells of the human body. They have the potential to develop into many different mature cell types. Stem cells are defined by a minimum of two key characteristics: (1) their capacity to self-renew, or divide in a way that results in more stem cells; and (2) their capacity to differentiate, or turn into mature, specialized cells that make up tissues and organs. There are many different types of stem cells that come from different places in the body or are formed at different times throughout our lives, including pluripotent stem cells and adult or tissue-specific stem cells, which are limited to differentiating into the specific cell types of the tissues in which they reside. We focus exclusively on human pluripotent stem cells.

Human pluripotent stem cells (hPSCs) can be differentiated into all of the more than 200 types of cells in the human body, can be expanded readily, and have diverse medical research, drug discovery, drug rescue, drug development and therapeutic applications. We believe hPSCs can be used to develop numerous cell types, tissues and customized assays that can mimic complex human biology, including heart and liver biology for drug rescue.



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Human pluripotent stem cells are either embryonic stem cells (hESCs) or induced pluripotent stem cells (iPSCs). Both hESCs and iPSCs have the capacity to be maintained and expanded in an undifferentiated state indefinitely. We believe these features make them highly useful research and development tools and as a source of normal, functionally mature cell populations. We use these mature cells as the basis to design and develop our novel, customized bioassay systems to test the safety and efficacy of new drug candidates in vitro. These cells also have potential for diverse regenerative medicine applications.

### Human Embryonic Stem Cells

According to the NIH, human embryonic stem cells are derived from excess embryos that develop from eggs that have been fertilized in an in vitro fertilization (IVF) clinic and then donated for research purposes with the informed consent of the parental donors after a successful IVF procedure. Human embryonic stem cells are not derived from eggs fertilized in a woman's body. Human ESCs are isolated when the embryo is approximately 100 cells, well before organs, tissues or nerves have developed.

Human embryonic stem cells have the potential to both self-renew and differentiate. They undergo increasingly tissue-restrictive developmental decisions during their differentiation. These "fate decisions" commit the hESCs to becoming only a certain type of mature, functional cells and ultimately tissues. At one of the first fate decision points, hESCs differentiate into epiblasts. Although epiblasts cannot self-renew, they can differentiate into the major tissues of the body. This epiblast stage can be used, for example, as the starting population of cells that develop into millions of blood, heart, muscle, liver and insulin-producing pancreatic beta-islet cells, as well as neurons. In the next step, the presence or absence of certain growth factors, together with the differentiation signals resulting from the physical attributes of the cell culture techniques, induce the epiblasts to differentiate into neuroectoderm or mesendoderm cells. Neuroectoderm cells are committed to developing into cells of the skin and nervous systems. Mesendoderm cells are precursor cells that differentiate into mesoderm and endoderm. Mesoderm cells develop into muscle, bone and blood, among other cell types. Endoderm cells develop into the internal organs such as the heart, liver, pancreas and intestines, among other cell types.

### Induced Pluripotent Stem Cells

It is also possible to obtain hPSC lines from individuals without the use of embryos. Induced pluripotent stem cells are adult cells, typically human skin or fat cells that have been genetically reprogrammed to behave like hESCs by being forced to express genes necessary for maintaining the pluripotential properties of hESCs. Although researchers are exploring non-viral methods, most early iPSCs were produced by using various viruses to express three or four genes required for the immature pluripotential property similar to hESCs. It is not yet precisely known, however, how each gene actually functions to induce cellular pluripotency, nor whether each of the three or four genes is essential for this reprogramming. Although hESCs and iPSCs are believed to be similar in many respects, including their pluripotential ability to form all cells in the body and to self-renew, scientists do not yet know whether they differ in clinically significant ways or have the same ability to self-renew.

Although there are remaining questions in the field about the lifespan, clinical utility and safety of iPSCs, we believe the biology and differentiation capabilities of hESCs and iPSCs are likely to be comparable for drug rescue purposes. There are, however, specific situations in which we may prefer to use one or the other type of hPSC. For example, we may prefer to use iPSCs for potential drug discovery applications based on the relative ease of generating iPSCs from:

individuals with specific inheritable diseases and conditions that predispose the individual to respond differently to drugs; or

individuals with specific variations in genes that directly affect drug levels in the body or alter the manner or efficiency of their metabolism, breakdown and/or elimination of drugs.

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Because they can significantly affect the therapeutic and/or toxic effects of drugs, these genetic variations have an impact on drug discovery and development. We believe iPSC technologies may allow the rapid and efficient generation of hPSCs from individuals with specific genetic variations. These hPSCs might then be used to produce cells to model specific diseases and genetic conditions for drug discovery and drug rescue purposes.

### Proprietary Stem Cell Differentiation Protocols

Over fifteen years of research, together with Dr. Gordon Keller, our co-founder and Chair of our Scientific Advisory Board, we have developed proprietary differentiation protocols covering key conditions involved in the differentiation of hPSCs into multiple types of mature human cells. The human cells generated by following these proprietary differentiation protocols are integral to our Human Clinical Trials in a Test Tube platform. We believe they support more clinically-predictive in vitro bioassay systems than animal testing or cellular assays currently used in drug discovery and development. Our strategic technology licenses from National Jewish Health in Denver, the Icahn School of Medicine at Mount Sinai in New York and the University Health Network in Toronto relate to proprietary stem cell differentiation protocols developed by Dr. Keller and involve precisely-coordinated temporal and quantitative conditions and interaction of biological molecules including the following:

- specific growth and differentiation factors used in the tissue culture medium, applied in specific combinations, at critical concentrations, and at critical times unique to each desired human cell type;

- the experimentally controlled regulation of developmental genes, which is critical for determining what differentiation path a human cell will take; and

- biological markers characteristic of precursor cells, which are committed to becoming specific human cells and tissues, and which can be used to identify, enrich and purify the desired mature human cell type.

We believe our Human Clinical Trials in a Test Tube platform will allow us to assess the toxicity profile of Drug Rescue Variants and other new drug candidates for a wide range of diseases and conditions with greater speed and precision than nonclinical surrogate safety models most often currently used in drug development.

### Growth Factors that Direct and Stimulate the Differentiation Process

The proprietary and licensed technologies underlying our Human Clinical Trials in a Test Tube platform allow us to direct and stimulate the differentiation process of hPSCs. As an example, for hESCs, the epiblast is the first stage in differentiation. One biological factor that controls the first fate decision of the epiblast is the relative concentrations of serum growth factors and activin, a protein involved in early differentiation and many cell fate decisions. Substituting explicit amounts of defined growth factors in place of ill-defined animal serum, and adding the optimal amount of activin is an important step in inducing the reproducible development of functional cells and, in our view, is essential for the development of a robust, efficient, and reproducible model of human cellular differentiation suitable for drug rescue. The use of activin in these applications is core to many of the claims in the patent applications underlying our licensed hPSC technology. Replacing activin with continuous exposure to ill-defined and variable animal serum results in an inefficient and variable differentiation of the human heart, liver, blood and cells of other organs. See “Intellectual Property – Icahn School of Medicine at Mount Sinai Exclusive Licenses.”

In addition to activin, Dr. Keller’s studies have identified a number of other growth and developmental factors that play important roles in the differentiation of hESCs. Some of the patents and patent applications underlying our licensed hPSC technology are directed to the use of a variety of specific growth factors that increase the efficiency

(yield) and reproducibility of the hPSC differentiation process. We have exclusive rights to certain patents and patent applications with claims relating to growth factor concentrations for hESC differentiation that we believe are core and essential for drug rescue and development. See “Intellectual Property – Icahn School of Medicine at Mount Sinai Exclusive Licenses” and “National Jewish Health Exclusive Licenses.”



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### Developmental Genes that Direct and Stimulate the Stem Cell Differentiation Process

For the purpose of creating our Human Clinical Trials in a Test Tube platform, we further control the differentiation process by controlling regulation of key developmental genes. By studying natural organ and tissue development, researchers have identified many genes that are critical to the normal differentiation, growth and functioning of tissues of the body. We engineer hESCs in a way that enables us to regulate genes that have been identified as critical to control and direct the normal development of specific types of cells. We can then mimic human biology in a way that allows us to turn on and off the expression of a selected gene by the addition of a specific compound to a culture medium. By adding specific compounds, we have the ability to influence the expression of key genes that are critically important to the normal biology of the cell.

### Cell Purification Approaches

The proprietary protocols we have licensed and developed internally for our Human Clinical Trials in a Test Tube platform also establish specific marker genes and proteins which can be used to identify, enrich, purify, and study important populations of intermediate precursor cells that have made specific fate decisions and are on a specific developmental pathway towards a certain type of functionally mature cell. These proprietary protocols enable a significant increase in the efficiency, reproducibility, and purity of final cell populations. For example, we are able to isolate millions of purified specific precursor cells which, together with a specific combination of growth factors, develop full culture wells of functional, beating human cardiomyocytes. Due to their functionality and purity, we believe these cell cultures are ideal for drug rescue.

### 3D “Micro-Organ” Culture Systems

In addition to standard two-dimensional (2D) cultures which work well for some cell types and cellular assays, the proprietary hPSC technologies underlying our Human Clinical Trials in a Test Tube platform enable us to grow large numbers of normal, non-transformed, mature human cells to produce novel in vitro 3D “micro-organ” culture systems. For example, for CardioSafe 3D, we grow large numbers of normal, non-transformed, human heart cells in vitro in 3D micro-organ culture systems. The 3D micro-organ cultures induce the cells to grow, mature, and develop 3D cell networks and tissue structures. We believe these 3D cell networks and structures more accurately reflect the structures and biology inside the human body than traditional flat, 2D, single cell layers grown on plastic, that are widely used by pharmaceutical companies today. We believe that the more representative human biology afforded by the 3D system will yield responses to drug candidates that are more predictive of human drug responses.

### Medicinal Chemistry

Medicinal chemistry involves designing, synthesizing, or modifying a small molecule compound or drug suitable for clinical development. It is a highly interdisciplinary science combining organic chemistry, biochemistry, physical chemistry, computational chemistry, pharmacology, and statistics. The combination of medicinal chemistry with the proprietary and licensed hPSC technologies underlying our Human Clinical Trials in a Test Tube platform are core components of our drug rescue business model. Working with our strategic contract medicinal chemistry partner, Synteris, Inc., we are focused on using our stem cell biology to generate a pipeline of effective and safe Drug Rescue Variants of once-promising company drug candidates in a more efficient and cost-effective manner than the processes currently used for drug development.

### CardioSafe 3D

The limitations of current preclinical drug testing systems used by pharmaceutical companies contribute to the high failure rate of drug candidates. According to articles published in the Journal of Applied Toxicology, Stem Cell

Research and Current Opinion in Cardiology, unexpected cardiotoxicity is one of the top two major safety-related reasons for failure of both drugs and drug candidates. Incorporating human pluripotent stem cell-derived cardiomyocyte (hPSC-CM) assays early in preclinical development offers the potential to improve clinical predictability, decrease rescue and development costs, and avoid adverse patient effects, late-stage clinical termination, and product recall from the market.

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With our proprietary human pluripotent stem cell technology, we can generate fully-functional hPSC-CMs at a high level of purity (>95%), without genetic modification or antibiotic selection. This is important because genetic modification and antibiotic selection can distort the ratio of cardiac cell types and have a direct impact on the ultimate results and clinical predictivity of the assay. In addition to expressing all of the key ion channels of the human heart (calcium, potassium and sodium) and various cardiomyocytic markers of the human heart, our hPSC-CMs function reliably in all cardiac toxicity assays relevant to cardiac drug effects developed and tested to date.

Utilizing fully functional hPSC-CMs that underlie our Human Clinical Trials in a Test Tube platform, we have validated our CardioSafe 3D assay system to screen for both cardiomyopathy (or direct cardiomyocyte cytotoxicity) and arrhythmogenesis (or development of irregular beating patterns). We believe CardioSafe 3D is sensitive, stable, reproducible and capable of generating data enabling a more accurate prediction of the in vivo cardiac effects of Drug Rescue Variants and other new drug candidates than is possible with existing preclinical testing systems.

We have developed and validated two functional components of our CardioSafe 3D screening system to assess multiple categories of cardiac toxicities. The first consists of a suite of five fluorescence or luminescence based high-throughput hPSC-CM assays. These five CardioSafe 3D assays measure drug-induced cardiomyopathy, including the following:

1. cell viability;
2. apoptosis;
3. mitochondrial membrane depolarization;
4. oxidative stress; and
5. energy metabolism disruption.

These five CardioSafe 3D biological assays were correlated to reported clinical results using reference compounds known to be cardiotoxic in humans versus compounds known to be safe in humans. These reference compounds were representative of eight different drug classes, including:

1. Ion channel blockers: amiodarone, nifedipine;
2. hERG trafficking blockers: pentamidine, amoxapine;
3.  $\alpha$ -1 adrenoreceptors: doxazosin;
4. Protein and DNA synthesis inhibitors: emetine;
5. DNA intercalating agents: doxorubicin;
6. Antibiotics: ampicillin, cefazolin;
7. NSAID: aspirin; and
8. Kinase inhibitors: staurosporine.

This suite of five CardioSafe 3D assays provided measurement of cardiac drug effects with high sensitivity that are consistent with the expected cardiac responses to each of these compounds. Based on our results, we believe our CardioSafe 3D assays provide valuable and more comprehensive bioanalytical tools for both assessing the effects of pharmaceutical compounds on cardiac cytotoxicity and for elucidating the specific mechanisms of cardiac toxicity, thereby laying what we believe is a solid foundation for our drug rescue programs.

The other component of our CardioSafe 3D assay system is a sensitive and reliable medium throughput multi-electrode array (MEA) assay developed to predict drug-induced alterations of electrophysiological function of the human heart. We have validated (correlated with reported clinical results) this key component of our CardioSafe 3D assay system with twelve drugs, each with known toxic or non-toxic cardiac effects in humans. These twelve validation compounds are as follows:

1. One FDA-approved drug (aspirin) without cardiac liability to serve as a negative control;
2. Five FDA-approved drugs (astemizole, sotalol, cisapride, terfenadine and sertindole) that were withdrawn from the market due to heart toxicity concerns;
3. Five FDA-approved drugs (fexofenadine, nifedipine, verapamil, lidocaine and propranolol) that have certain measurable clinical non-toxic cardiac effects. Note: fexofenadine is a non-cardiotoxic drug variant of terfenadine; and
4. One research compound (E-4031) failed in Phase I human clinical study before being discontinued due to heart toxicity concerns.

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We have validated that our CardioSafe 3D MEA assay was reproducible and consistent with the known human cardiac effects of all the twelve compounds studied, based on the mechanisms of action and dosage of the compounds. For instance, by using CardioSafe 3D, we were able to distinguish between the cardiac effects of terfenadine (Seldane<sup>TM</sup>), withdrawn by the FDA due to cardiotoxicity, and the cardiac effects of the close structurally related fexofenadine (Allegra<sup>TM</sup>), the non-cardiotoxic chemical variant of terfenadine, which remains on the market. Our validation data suggest that our CardioSafe 3D assay system provides valuable and more comprehensive bioanalytical tools for preclinical cardiac safety screening, which we believe will contribute to the efficient and rapid identification of novel, potentially safer Drug Rescue Variants in our drug rescue programs.

To further evaluate the potential of our CardioSafe 3D assay system to predict cardiac toxicity of drug candidates, including Drug Rescue Variants, we have assessed cardiac effects induced by small molecule kinase inhibitors (KIs), which belong to a new category of drugs that have revolutionized cancer therapy due to decreased systemic toxicity and an increased tumor cell specific effect compared to classic cancer drugs. Since 1998, the FDA has approved eighteen small molecule KIs for cancer therapy. However, many of these FDA-approved KIs have been implicated in causing serious adverse cardiac events in patients which were not identified during drug development.

In our KI-induced cardiotoxicity study, we evaluated well-known anti-cancer KIs with CardioSafe 3D, some of which are FDA-approved and have been documented as cardiotoxic. This important validation set of anti-cancer KI compounds is as follows:

1. Inhibitors to growth factor receptors: sunitinib, axitinib, imatinib, dasatinib, sorafenib, erlotinib, lapatinib, tyrphostin and AG1478;
2. Inhibitors to the mTOR pathway: everolimus, temsirolimus;
3. Inhibitors to cell cycle regulators: tozasertib, barasertib, alvocidib;
4. Inhibitors to the PI3K pathway : perifosine, LY294002, XL765;
5. Inhibitors to the MEK pathway: PD325901, AZD6264; and
6. Inhibitors to the JAK and other pathways: lestaurtinib.

Our validation data indicate that CardioSafe 3D successfully detected cardiotoxicity induced by each of the representative compounds, cardiotoxicity associated with clinical adverse cardiac events, in each of the foregoing six different KI categories. CardioSafe 3D assay system is able to distinguish between cardiotoxic and safe compounds, and even as between those compounds which inhibit the same kinase pathways. For instance, both sunitinib and axitinib inhibit VEGFR, PDGFR and c-Kit pathways, and our CardioSafe 3D assays indicate that sunitinib is cardiotoxic and axitinib is safe, which is consistent with the reported clinical outcomes.

Furthermore, the CardioSafe 3D profile of each KI provided clues to the potential mechanism(s) causing cardiotoxicity. For example, cardiotoxicity induced by perifosine showed apoptotic responses at lower concentrations, while imatinib was most active in the oxidative stress assays. In addition, no cardiac toxicity or alteration in electrophysiology was detected with drugs that do not have a cardiac liability, emphasizing the specificity of CardioSafe 3D. Having information on the pathways associated with the cardiotoxic effects of compounds provides important clues for novel medicinal chemistry approaches and compound modifications for our CardioSafe 3D drug rescue programs.

Our CardioSafe 3D assay system enables the sensitive measurement of drug effects with results that are consistent with reported clinical responses to the compounds. For example, our data indicated that sunitinib and dasatinib caused QT prolongation, arrhythmia, and/or altered contraction rates in hPSC-CMs, which are consistent with clinical observations.



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We believe our CardioSafe 3D correlation data demonstrated that CardioSafe 3D will improve clinical predictivity as an in vitro cardiac safety assay, helping not only to identify potential cardiac toxicities early in development, but also to discover important potential mechanisms of cardiotoxicity. We believe the results of our CardioSafe 3D validation studies indicate that CardioSafe 3D may be effectively used to identify novel Drug Rescue Variants with reduced heart toxicity. By providing more accurate and timely indications of alterations in electrophysiological activity, as well as direct heart toxicity of drug candidates, than animal models or cellular assay systems currently used by pharmaceutical companies, we believe the results of our CardioSafe 3D validation studies support the central premise of our drug rescue business model: by using our hPSC-derived human heart and liver cell bioassay systems at the front end of the drug development process, we have the opportunity to take advantage of substantial prior investment by pharmaceutical companies and others in drug discovery and in vitro efficacy optimization of once and still-promising drug candidates that have been terminated prior to FDA approval due to unexpected heart or liver toxicity concerns.

### LiverSafe 3D

LiverSafe 3D is a powerful new in vitro hepatotoxicity assay system that goes a step beyond the current commercially available gold standard primary (human cadaver cell-based) hepatocyte assays. By combining the flexibility of an in vitro, non-transformed human cell-based assay system with the renewable, reproducible sourcing of human pluripotent stem cells (hPSCs), the functional hPSC-derived hepatocytes we produce for LiverSafe 3D can be maintained in a healthy state for much longer than the current gold standard hepatocyte assays, greatly enhancing the reliability of hepatotoxicity testing for our drug rescue programs.

Until now, reliable human cell-based hepatotoxicity screening platforms have been difficult to establish for high throughput drug development with currently available primary hepatocyte systems. Primary hepatocytes have a short lifespan in culture, during which time they rapidly lose their drug metabolizing capabilities and develop signs of cellular stress. Furthermore, these commercially available primary hepatocytes have significant batch-to-batch genetic variation that alters the function of drug metabolism genes and their critical enzyme activity levels due to the use of hepatocytes from different sources. Additionally, primary hepatocytes are derived from individuals with significant differences in health status, with unknown effects on hepatocyte function. Consequently, it is difficult to maintain quantitative reproducibility using currently available primary hepatocyte assays, and this leads to limitations in the quality and clinical predictivity of the results and conclusions drawn from these assays.

The foregoing limitations have led many in the field to believe that hPSC-derived hepatocyte assays offer a better alternative to the current gold standard primary hepatocyte assays. This belief is mainly due to the fact that hepatocytes derived from the same hPSC line are genetically identical, normal, non-transformed (that is, not tumor-derived) human cells derived from hPSCs. Importantly, hPSC-derived hepatocytes can be indefinitely propagated and frozen down into large, uniform, quality-controlled cell banks. The challenge to using hPSC-derived hepatocytes has been differentiating the stem cells into mature hepatocytes that express a full complement of functional drug metabolizing enzymes, nuclear receptors, and transporters at least as well as primary hepatocytes. While many groups have taken on this challenge in recent years, published reports indicate that current hPSC differentiation protocols yield immature hepatocytes, especially with respect to extremely low expression of certain key drug metabolizing enzymes, such as CYP3A4. CYP3A4 is a critical liver enzyme responsible for metabolizing approximately 50% of the FDA-approved drugs currently available on the market. It is an important and well-accepted functional gene found almost exclusively in mature, adult hepatocytes. CYP3A4 is the key functional marker that we have used to optimize our hepatocyte differentiation cultures for LiverSafe 3D. We believe our optimized LiverSafe 3D assay system enables us to generate more mature hPSC-derived hepatocytes than are currently available from others in the field and that our LiverSafe 3D system provides the unique ability to specifically select for mature CYP3A4-expressing human hepatocytes.





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We developed LiverSafe 3D using hPSC differentiation protocols adapted from the laboratory of our co-founder, Dr. Gordon Keller, and our proprietary hPSC cell line, 3A4BLA. This 3A4BLA cell line is a human embryonic stem cell (hESC) line that contains a humanized BLA functional “reporter” that targets the CYP3A4 gene in a manner resulting in the expression of BLA only in cells that also express CYP3A4. This allows us to visualize by fluorescence cells that express CYP3A4 based on expression of the BLA reporter. By producing a cell line capable of tracking CYP3A4 expression, we have been able to optimize our hPSC differentiation protocols to increase expression of mature hepatocyte markers and drug metabolizing enzymes and to enrich for CYP3A4-expressing cells by cell sorting. However, even in the absence of cell sorting, our LiverSafe 3D hepatocyte populations contain greater than 80% ALBUMIN-positive cells and greater than 40% CYP3A4-positive cells, with CYP3A4 mRNA expression reaching levels nearly 60-fold higher than side-by-side 38-week human fetal liver controls. Our LiverSafe 3D hepatocytes secrete urea and ALBUMIN at levels that exceed commercially-available primary hepatocytes, and they also store both glycogen and lipids, characteristics that are required of functional, mature adult hepatocytes. Importantly, expression of fetal liver markers decreases over the time course of differentiation of our LiverSafe 3D hepatocytes. This decreased expression is expected and essential during maturation of hepatocytes, but it has rarely been reported by others in publications describing their hPSC-derived hepatocytes. With the addition of cell sorting, our LiverSafe 3D hepatocyte populations can be highly enriched for CYP3A4-BLA-positive cells, with CYP3A4 message in the positive cell population reaching greater than 30% that of an adult human liver pool control. To our knowledge, this level of CYP3A4 expression exceeds levels reported by others in the literature.

The most important capabilities of LiverSafe 3D relate to “Phase I” and “Phase II” drug metabolism, which are functional characteristics of mature adult hepatocytes. We have validated these capabilities of LiverSafe 3D by demonstrating its ability to metabolize known substrates, such as testosterone, and its ability to respond properly to known inducers of Phase I-mediated CYP3A4 metabolism, such as rifampicin. Moreover, our LiverSafe 3D hepatocytes demonstrate Phase II-mediated testosterone metabolism levels that exceed commercially available primary hepatocytes. These functional characteristics of mature adult hepatocytes are critical to the development of a reliable and clinically predictive hepatotoxicity screening platform for our drug rescue programs. We are currently focused on expanding our panel of validation assays and compounds to include more P450 substrates, inducers, and inhibitors, as well as adapting the cellular toxicity assays that have been developed for our CardioSafe 3D assay system to our LiverSafe 3D assay system and to apply specific hepatotoxic screening assays, such as ALBUMIN and urea secretion assays.

We believe LiverSafe 3D is a genetically identical, renewable, and reproducible hepatotoxicity assay system for drug rescue and development that provides advantages over currently available primary hepatocyte assays. We have demonstrated that our LiverSafe 3D hepatocyte populations, even in the absence of cell sorting, secrete adult hepatocyte levels of ALBUMIN and urea and contain greater than 40% CYP3A4-positive cells, historically difficult to achieve in hPSC differentiation cultures. The proprietary 3A4BLA cell line component of LiverSafe 3D allows us the unique opportunity to enrich CYP3A4-positive cells, resulting in CYP3A4 expression reaching greater than 30% of an adult human liver pool, and to the best of our knowledge, a level higher than described in current literature. Most importantly for drug rescue and development purposes, our hPSC-derived hepatocytes for LiverSafe 3D metabolize known substrates and respond to known inducers in a manner expected only of mature adult hepatocytes, paving the way for our final validation of LiverSafe 3D system as a novel hepatotoxicity assay system that can improve clinical predictivity, decrease the cost of drug rescue and development, reduce use of live animal studies, and improve drug safety.

## AV-101

We have successfully completed Phase I development of AV-101, also known as “L-4-chlorokynurenine” or “4-Cl-KYN”. AV-101 is a prodrug candidate for the treatment of neuropathic pain, epilepsy and depression. Our AV-101 IND application on file at the FDA covers our Phase I clinical development for neuropathic pain. However, we believe the safety studies done in Phase I development of AV-101 will support development of AV-101 for other indications,

including epilepsy, depression and potentially other neurological diseases, such as Parkinson's disease.

The NIH has awarded us \$8.8 million of grant funding for our preclinical and Phase 1 clinical development of AV-101. During 2014, we plan to seek strategic partnering arrangements for further clinical development and commercialization of AV-101 for neuropathic pain, epilepsy, depression and Parkinson's disease.

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AV-101 is an orally-available, non-sedating prodrug candidate that is converted in the brain into an active metabolite, 7-chlorokynurenic acid (7-Cl-KYNA), which regulates the N-methyl-D-aspartate (NMDA) receptors. 7-Cl-KYNA is a synthetic analogue of kynurenic acid, a naturally occurring neural regulatory compound, and is one of the most potent and selective blockers of the regulatory GlyB-site of the NMDA receptor. In preclinical studies, AV-101 has very good oral bioavailability, is rapidly and efficiently transported across the blood-brain barrier, and is converted into 7-Cl-KYNA in the brain and spinal cord, preferentially, at the site of seizures and potential neural damage.

The effect of AV-101 on chronic neuropathic pain due to inflammation and nerve damage was assessed in rats by using the Chung nerve ligation model. AV-101 effects were compared to either saline and MK-801, or gabapentin (Neurontin<sup>TM</sup>) as positive controls. Similar to the therapeutic effects seen in the acute formalin and thermal pain models, AV-101 had a positive effect on chronic neuropathic pain in the Chung model that were greater than two (2) standard deviations of the control, with no adverse behavioral observations. As expected, MK-801 and gabapentin also demonstrated reduced pain readouts in the Chung model. The effects observed by AV-101 in both the acute and chronic neuropathic pain model systems was dose dependent, and was not associated with any side effects at the range of doses administered. Preclinical AV-101 data demonstrated the potential clinical utility of AV-101 as an analgesic.

## Strategic Transactions and Relationships

Strategic collaborations are a cornerstone of our corporate development strategy. We believe that our strategic outsourcing and sponsorship of application-focused research gives us flexible access to medicinal chemistry, hPSC research and development, manufacturing, clinical development and regulatory expertise at a lower overall cost than developing and maintaining such expertise internally. In particular, we collaborate with the types of third parties identified below for the following functions:

- academic research institutions, such as the University Health Network (UHN) and Duke University, for hPSC technology research and development;

- contract medicinal chemistry companies, such as Synteris, Inc., to analyze Drug Rescue Candidates and design, produce and analyze Drug Rescue Variants; and

- contract clinical development and regulatory organizations (CROs), such as Cato Research, Ltd., for regulatory expertise and clinical development support.

## McEwen Centre for Regenerative Medicine, University Health Network

UHN in Ontario, Canada is a major landmark in Canada's healthcare system. UHN is one of the world's largest research hospitals, with major research in transplantation, cardiology, neurosciences, oncology, surgical innovation, infectious diseases and genomic medicine.

The McEwen Centre for Regenerative Medicine (McEwen Centre) is a world-renowned center for stem cell biology and regenerative medicine and a stem cell research facility affiliated with UHN. Dr. Gordon Keller, our co-founder and Chairman of our Scientific Advisory Board, is Director of the McEwen Centre. Dr. Keller's lab is considered one of the leaders in successfully applying principles from the study of developmental biology of many animal systems to the differentiation of pluripotent stem cell systems, resulting in reproducible, high-yield production of human heart, liver, blood and vascular cells. The results and procedures developed in Dr. Keller's lab are often quoted and used by academic scientists worldwide.



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In September 2007, we entered into a long-term sponsored stem cell research and development collaboration with UHN. In December 2010, we extended the collaboration to September 2017. The primary goal of this ten-year collaboration is to leverage the stem cell research, technology and expertise of Dr. Gordon Keller to develop and commercialize industry-leading human pluripotent stem cell differentiation technology and bioassay systems for drug rescue and development and regenerative cell therapy applications. This sponsored research collaboration builds on our existing strategic licenses from National Jewish Health and the Icahn School of Medicine at Mount Sinai to certain pluripotent stem cell technologies developed by Dr. Keller, and is directed to diverse human pluripotent stem cell-based research projects, including, as expanded and amended, strategic projects related to drug rescue and regenerative medicine. See “Sponsored Research Collaborations and Intellectual Property Rights – University Health Network, McEwen Centre for Regenerative Medicine, Toronto, Ontario”, “Intellectual Property – National Jewish Health Exclusive Licenses” and “Intellectual Property – Icahn School of Medicine at Mount Sinai Exclusive Licenses.”

### Cardiac Safety Research Consortium

We have joined the Cardiac Safety Research Consortium (CERC) as an Associate Member. The CSRC, which is sponsored in part by the FDA, was launched in 2006 through an FDA Critical Path Initiative Memorandum of Understanding with Duke University to support research into the evaluation of cardiac safety of medical products. CSRC supports research by engaging stakeholders from industry, academia, and government to share data and expertise regarding several areas of cardiac safety evaluation, including novel stem cell-based approaches, from preclinical through post-market periods.

### Cardiac Safety Technical Committee of the Health and Environmental Sciences Institute – FDA’s CIPA Initiative

We have also joined the Cardiac Safety Technical Committee, Cardiac Stem Cell Working Group, and Proarrhythmia Working Group of the Health and Environmental Sciences Institute (HESI) to help advance, among other goals, the FDA’s Comprehensive In Vitro Proarrhythmia Assay (CIPA) initiative, which is focused on developing innovative preclinical systems for cardiac safety assessment during drug development. HESI is a global branch of the International Life Sciences Institute (ILSI), whose members include most of the world’s largest pharmaceutical and biotechnology companies.

The goal of the FDA’s CIPA initiative is to develop a new paradigm for cardiac safety evaluation of new drugs that provides a more comprehensive assessment of proarrhythmic potential by (i) evaluating effects of multiple cardiac ionic currents beyond hERG and ICH S7B (inward and outward currents), (ii) providing more complete, accurate assessment of proarrhythmic effects on human cardiac electrophysiology, and (iii) focusing on Torsades de Pointes proarrhythmia rather than surrogate QT prolongation alone.

### Centre for Commercialization of Regenerative Medicine

The Toronto-based Centre for Commercialization of Regenerative Medicine (CCRM) is a not-for-profit, public-private consortium funded by the Government of Canada, six Ontario-based institutional partners and more than 20 companies representing the key sectors of the regenerative medicine industry. CCRM supports the development of foundational technologies that accelerate the commercialization of stem cell- and biomaterials-based products and therapies.

In December 2012, we formalized our membership in the CCRM’s Industry Consortium. Other members of CCRM’s Industry Consortium include such leading global companies as Pfizer, GE Healthcare and Lonza. The industry leaders that comprise the CCRM consortium benefit from proprietary access to certain licensing opportunities, academic rates on fee-for-service contracts at CCRM and opportunities to participate in large collaborative projects, among other advantages. Our CCRM membership reflects our strong association with CCRM and its core programs and objectives,

both directly and through our strategic relationships with Dr. Gordon Keller and UHN. We believe our long-term sponsored research agreement with Dr. Keller, UHN and UHN's McEwen Centre offers a solid foundation and unique opportunities for expanding the commercial applications of our Human Clinical Trials in a Test Tube platform by building multi-party collaborations with CCRM and members of its Industry Consortium. We believe these collaborations have the potential to transform medicine and accelerate significant advances in human health and wellness that stem cell technologies and regenerative medicine promise.

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Duke University

In November 2011, we entered into a strategic collaboration with Duke University, one of the premier academic research institutions in the U.S., aimed at combining our complementary expertise in cardiac stem cell technology, electrophysiology and tissue engineering. The initial goal of the collaboration is to explore the potential development of novel, engineered, stem cell-derived cardiac tissues to expand the scope of our drug rescue capabilities focused on heart toxicity. We expect that this collaboration, employing our human stem cell-derived heart cells combined with Duke's technology relating to cardiac electrophysiology and cardiac tissue engineering, will permit us to use micro-patterned cardiac tissue to expand the approaches available to us in our drug rescue programs to quantify drug effects on functional human cardiac tissue.

In May 2013, we announced that our scientists together with researchers at Duke University combined our human stem cell-derived heart cells with Duke's innovative tissue engineering and cardiac electrophysiology technologies to grow what is being called a "heart patch," which mimics the natural functions of native human heart tissue. We believe this is the closest man-made approximation of natural human heart muscle to date. This heart patch technology is being developed to aid in a better understanding of the biology critical to cardiac tissue engineering, for applications in regenerative cell therapy for heart disease, and as predictive in vitro assays for drug rescue and development. We believe the developed contractile forces and other functional properties of these cardiac tissues are remarkable and are significantly higher than any previous reports. The achievement of successfully growing a human heart muscle from cardiomyocytes derived from human pluripotent stem cells expands the scope of our drug rescue capabilities and reflects the advanced nature and potential of our collaboration with Duke University.

Achieving this capability represents a potentially significant breakthrough in heart cell-based therapies and in testing new medicines for potential heart toxicity and potential therapeutic benefits impacting heart disease.

The following are among several key development points from the study:

- The optimized 3D environment of a cardiac tissue patch yields advanced levels of structural and functional maturation of human cardiomyocytes that produce expected responses to drugs;
- Human cardiomyocyte maturation in an optimized 3D patch environment is enhanced relative to that found in industry standard 2D cultures;
- No genetic modifications were used to produce, purify, or mature cardiomyocytes, suggesting potential for future therapeutic applications;
- Cardiac tissue patches generated using VistaGen's cardiomyocytes exhibited 2.2-180 fold higher contractile force generation compared to previous studies;
- Based on a force per cardiomyocyte metric, cardiac tissue engineering methodology that used VistaGen's cardiomyocytes exhibited 4-700-fold higher efficiency than previously reported; and

Cardiac tissue patches generated using VistaGen's cardiomyocytes exhibited velocities of electrical signal propagation 5-fold higher compared to previous reports in human engineered cardiac tissues.

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### Cato Research and Cato BioVentures

#### Cato Research

Cato Research is a contract research and development organization (CRO), with international resources dedicated to helping biotechnology and pharmaceutical companies navigate the regulatory approval process in order to bring new biologics, drugs and medical devices to markets throughout the world. Cato Research has in-house capabilities to assist its sponsors with aspects of the drug development process including regulatory strategy, nonclinical and toxicology development, clinical development, data processing, data management, statistical analysis, regulatory applications, including INDs and NDAs, chemistry, manufacturing, and control programs, cGCP, cGLP and cGMP audit and compliance activities, and due diligence review of emerging technologies. Cato Research's senior management team, including co-founders Allen Cato, M.D., Ph.D. and Lynda Sutton, has over 25 years of experience interacting with the FDA and international regulatory agencies and a successful track record of product approvals. Should we elect to advance development of Drug Rescue Variants internally rather than license or sell them at an early-stage to pharmaceutical companies or others, we believe our long term strategic relationship with Cato Research provides us with real time access to the global connections, insight and knowledge necessary to effectively plan, execute and manage successful nonclinical and clinical development programs throughout the world without incurring the substantial expenses typically associated with establishing and maintaining a wide range of drug development capabilities in-house.

#### Cato BioVentures

Cato Holding Company, doing business as Cato BioVentures (Cato BioVentures), is the venture capital affiliate of Cato Research. Through strategic CRO service agreements with Cato Research, Cato BioVentures invests in therapeutics and medical devices, as well as platform technologies such as our stem cell technology-based Human Clinical Trials in a Test Tube platform, which its principals believe, based on their experience as management of Cato Research, are capable of transforming the traditional drug development process and the research and development productivity of the biotechnology and pharmaceutical industries.

#### Our Relationship with Cato Research and Cato BioVentures

Cato Research is our primary CRO for development of AV-101. Cato BioVentures is among our largest, long-term institutional investors.

As a result of the access Cato Research has to potential Drug Rescue Candidates from its biotechnology and pharmaceutical industry network, as well as Cato BioVentures' strategic long term equity interest in VistaGen, we believe that our relationships with Cato BioVentures and Cato Research may provide us with unique opportunities relating to our drug rescue efforts that will permit us to leverage both their industry connections and the CRO resources of Cato Research, either on a contract research basis or in exchange for economic participation rights, should we develop Drug Rescue Variants internally rather than out-license them to strategic partners.

#### United States National Institutes of Health

Since our inception in 1998, the U.S. National Institutes of Health (NIH) has awarded us \$11.3 million in non-dilutive research and development grants, including \$2.3 million to support research and development of our Human Clinical Trials in a Test Tube platform and \$8.8 million for nonclinical and Phase 1 clinical development of AV-101, our small molecule drug candidate which has successfully completed Phase 1 clinical development in the U.S. for neuropathic pain and other potential diseases and conditions, including epilepsy and depression.





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### California Institute for Regenerative Medicine

The California Institute for Regenerative Medicine (CIRM) funds stem cell research at academic research institutions and companies throughout California. CIRM was established in 2004 with the passage of Stem Cell Initiative (Proposition 71) by California voters. As a stem cell company based in California since 1998, we are eligible to apply for and receive grant funding under the Stem Cell Initiative. To date we have been awarded approximately \$1.0 million of non-dilutive grant funding from CIRM for stem cell research and development related to stem cell-derived human liver cells. This funded research and development focused on the improvement of techniques and the production of engineered human ES Cell lines used to develop mature functional human liver cells as a biological system for testing drugs.

### Celsis In Vitro Technologies

In March 2013, we entered into a strategic collaboration with Celsis In Vitro Technologies (Celsis IVT), a premier global provider of specialized in vitro products for drug metabolism, drug-drug interaction and toxicity screening, focused on characterizing and functionally benchmarking our human liver cell platform, LiverSafe 3D™ with Celsis IVT products for studying and predicting drug metabolism. We intend to utilize Celsis IVT's experience and expertise in in vitro drug metabolism to help validate LiverSafe 3D. We anticipate that Celsis IVT will not only validate our human liver cells in traditional pharmaceutical metabolism assays, but also will determine genetic variations in our human pluripotent stem cell lines that are important to drug development. In addition, we plan to utilize Celsis IVT's large inventory of cryopreserved primary human liver cells, currently used throughout the pharmaceutical industry for traditional and high-throughput liver toxicology and other bioassays, as reference controls with which to monitor and benchmark the functional properties of LiverSafe 3D.

Collaborating with Celsis IVT scientists, we are focused on the following four key objectives:

Optimize techniques to handle and maintain primary human cryopreserved primary liver cells as reference controls for various drug development assays;

Develop a stable supply of characterized and validated human cryopreserved primary liver cells to serve as internal controls and provide benchmark comparisons for the characterization of our pluripotent stem cell-derived liver cells;

Characterize our human pluripotent stem cell-derived liver cells using many of the same industry-standardized assays used to characterize primary human liver cells; and

Produce a joint publication of the characterization of our pluripotent stem cell-derived human liver cells.

As an industry leader in the development of in vitro primary hepatocyte technology, we believe Celsis IVT has extensive resources to aid us in the benchmarking LiverSafe 3D to industry standards. We anticipate this collaboration will lead to the further validation of LiverSafe 3D for predicting liver toxicity and drug metabolism issues before costly human clinical trials.

### Synteris, Inc.

We have entered into a strategic medicinal chemistry collaboration agreement with Synteris, Inc. (Synteris), a leading medicinal chemistry and collaborative drug discovery company. We believe this important collaboration will further our drug rescue initiatives with the support of Synteris' medicinal chemistry expertise. In addition to providing flexible, real-time contract medicinal chemistry services in support of our drug rescue programs, we anticipate potential collaborative opportunities with Synteris wherein we may jointly identify and develop Drug Rescue

Variants.

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### Intellectual Property

#### Intellectual Property Rights Underlying our Human Clinical Trials in a Test Tube Platform

We have established our intellectual property rights to the technology underlying our Human Clinical Trials in a Test Tube platform through a combination of exclusive and non-exclusive licenses, patents, and trade secret laws. To our knowledge, we are the first stem cell company focused primarily on stem cell technology-based drug rescue. We have assembled an intellectual property portfolio around the use of pluripotent stem cell technologies in drug discovery and development and with specific application to drug rescue. The differentiation protocols we have licensed direct the differentiation of pluripotent stem cells through:

a combination of growth factors (molecules that stimulate the growth of cells);

the experimentally controlled regulation of developmental genes, which is critical for determining what differentiation path a human cell will take; and

precise selection of immature cell populations for further growth and development.

By influencing key branch points in the cellular differentiation process, our pluripotent stem cell technologies can produce fully differentiated, non-transformed, highly functional human cells in vitro in an efficient, highly pure and reproducible process.

As of the date of this prospectus, we either own or license 43 issued U.S. patents and 12 U.S. patent applications and certain foreign counterparts relating to the stem cell technologies that underlie our Human Clinical Trials in a Test Tube platform. Our material rights and obligations with respect to these patents and patent applications are summarized below:

### Licenses

#### National Jewish Health (NJH) Exclusive License

We have exclusive licenses to seven issued U.S. patents held by NJH, certain of which are not essential to our current operations and will expire in November 2014. No foreign counterparts to these U.S. patents and patent application have been obtained. These U.S. patents contain claims covering composition of matter relating to specific populations of cells and precursors, methods to produce such cells, and applications of such cells for ES Cell-derived immature pluripotent precursors of all the cells of the mesoderm and endoderm lineages. Among other cell types, this covers cells of the heart, liver, pancreas, blood, connective tissues, vascular system, gut and lung cells.

This license agreement requires us to pay NJH 1% of our total revenues up to \$30 million in each calendar year and 0.5% of all revenues for amounts greater than \$30 million, with minimum annual payments of \$25,000. Additionally, this license agreement requires us to make certain royalty payments on sales of products based on NJH's patents or the sublicensing of such technology. However, the license agreement also includes anti-stacking provisions which reduce our payment obligations by a percentage of any royalty payments and fees paid to third parties, who have licensed necessary intellectual property to us. This agreement remains in force for the life of the patents so long as neither party elects to terminate the agreement upon the other party's uncured breach or default of an obligation under the agreement. We also have the right to terminate the agreement at any time without cause.



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Icahn School of Medicine at Mount Sinai School (MSSM) Exclusive License

We have an exclusive, field restricted, license to two U.S. patents and two U.S. patent applications, and their foreign counterparts filed by MSSM. Foreign counterparts have been filed in Australia (two), Canada (two), Europe (two), Japan (two), Hong Kong and Singapore. Two of the U.S. applications have been issued and the foreign counterparts in Australia and Singapore have been issued, while the two counterparts in Europe are pending. These patent applications have claims covering composition of matter relating to specific populations of cells and precursors, methods to produce such cells, and applications of such cells, including:

the use of certain growth factors to generate mesoderm (that is, the precursors capable of developing into cells of the heart, blood system, connective tissues, and vascular system) from hESCs;

the use of certain growth factors to generate endoderm (that is, the precursors capable of developing into cells of the liver, pancreas, lungs, gut, intestines, thymus, thyroid gland, bladder, and parts of the auditory system) from hESCs; and

applications of cells derived from mesoderm and endoderm precursors, especially those relating to drug discovery and testing for applications in the field of in vitro drug discovery and development applications.

This license agreement requires us to pay annual license and patent prosecution and maintenance fees and royalty payments that vary based on product sales and services that are covered by the MSSM patent applications, as well as for any revenues received from sublicensing. Any drug candidates that we develop, including any Drug Rescue Variants, will only require royalty payments to the extent they require the practice of the licensed technology. To the extent we incur royalty payment obligations from other business activities, the royalty payments are subject to anti-stacking provisions which reduce our payments by a percentage of any royalty payments or fees paid to third parties who have licensed necessary intellectual property to us. The license agreement will remain in force for the life of the patents so long as neither party terminates the agreement for cause (i) due to a material breach or default in performance of any provision of the agreement that is not cured within 60 days or (ii) in the case of failure to pay amounts due within 30 days.

Wisconsin Alumni Research Foundation (WARF) Non-Exclusive License

We have non-exclusive licenses to 28 issued stem cell-related U.S. patents, 14 stem cell-related U.S. patent applications, of which two have been allowed, and certain foreign counterparts held by WARF, for applications in the field of in vitro drug discovery and development. Foreign counterparts have been filed in Australia, Canada, Europe, China, India, Hong Kong, Israel, Brazil, South Korea, India, Mexico, and New Zealand. The subject matter of these patents includes specific hESC lines and composition of matter and use claims relating to hESCs important to drug discovery, and drug rescue screening. We have rights to:

use the technology for internal research and drug development;

provide discovery and screening services to third parties; and

market and sell research products (that is, cellular assays incorporating the licensed technology).

This license agreement requires us to make royalty payments that vary based on product sales and services that incorporate the licensed technology. We do not believe that any drug rescue candidates to be developed by us will incorporate the licensed technology and, therefore, no royalty payments will be payable. Nevertheless, there is a minimum royalty of \$20,000 per calendar year. There are also milestone fees related to the discovery of therapeutic

molecules, though no royalties are owed on such molecules. The royalty payments are subject to anti-stacking provisions which reduce our payments by a percentage of any royalty payments paid to third parties who have licensed necessary intellectual property to us. The agreement remains in force for the life of the patents so long as we pay all monies due and do not breach any covenants, and such breach or default is uncured for 90 days. We may also terminate the agreement at any time upon 60 days' notice. There are no reach through royalties on customer-owned small molecule or biologic drug products developed using the licensed technologies.

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## Our Patents

We have filed two U.S. patent applications on liver stem cells and their applications in drug development relating to toxicity testing; one patent has issued and a second patent application is pending. Of the related international filings, European, Canadian and Korean patents were issued. The European patent has been registered in 11 European countries. We have filed a U.S. patent application, with foreign counterpart filing in Canada and Europe, directed to methods for producing human pluripotent stem cell-derived endocrine cells of the pancreas, with a specific focus on beta-islet cells, the cells that produce insulin, and their uses in diabetes drug discovery and screening.

The material patents currently related to the generation of human heart and liver cells for use in connection with our drug rescue activities are set forth below:

Territory	Patent No.	General Subject Matter	Expiration
US	7,763,466	Method to produce endoderm cells	May 2025
US	7,955,849	Method of enriching population of mesoderm cells	May 2023
US	8,143,009	Toxicity typing using liver stem cells	June 2023

With respect to AV-101, we have filed three new U.S. patent applications.

## Trade Secrets

We rely, in part, on trade secrets for protection of some of our intellectual property. We attempt to protect trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in patents and copyrights arising from their work for us.

## Sponsored Research Collaborations and Intellectual Property Rights

University Health Network, McEwen Centre for Regenerative Medicine, Toronto, Ontario

We have a long-term strategic stem cell research collaboration with our co-founder, Dr. Gordon Keller, Director of the UHN's McEwen Centre, focused on, among other things, developing improved methods for differentiation of cardiomyocytes (heart cells) from pluripotent stem cells, and their uses in biological assay systems for drug discovery and drug development, including drug rescue. Pursuant to our sponsored research collaboration agreement with UHN, we have the right to acquire exclusive worldwide rights to any inventions arising from studies we sponsor, under pre-negotiated license terms. Such pre-negotiated terms provide for royalty payments equal to 3% of the first \$25.0 million of certain revenues received under the agreement, and 2% thereafter, based on product sales that incorporate the licensed technology and milestone payments based on the achievement of certain events. Any Drug Rescue Variants that we develop will not incorporate the licensed technology and, therefore, will not require any royalty payments. To the extent we incur royalty payment obligations from other business activities, the royalty payments will be subject to anti-stacking provisions, which reduce our payments by a percentage of any royalty payments paid to third parties who have licensed necessary intellectual property to us. These licenses will remain in force for so long as we have an obligation to make royalty or milestone payments to UHN, but may be terminated earlier upon mutual consent, by us at any time, or by UHN for our breach of any material provision of the license agreement that is not cured within 90 days.





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The sponsored research collaboration agreement with UHN, as amended, has a term of ten years, ending on September 18, 2017. Our 2012/2013 sponsored research project budget under the agreement ended on September 30, 2013. We are currently in discussions with Dr. Keller and UHN regarding the scope of our future sponsored research projects under the agreement. We anticipate finalizing such discussions following consummation of this Offering. The ten-year term of the agreement is subject to renewal upon mutual agreement of the parties. The agreement may be terminated earlier upon a material breach by either party that is not cured within 30 days. UHN may elect to terminate the agreement if we become insolvent or if any license granted pursuant to the agreement is prematurely terminated. We have the option to terminate the agreement if Dr. Keller stops conducting his research or ceases to work for UHN.

### UHN License for Stem Cell Culture Technology

In April 2012, we licensed stem cell culture technology from UHN's McEwen Centre. We intend to utilize the licensed technology to develop hematopoietic precursor stem cells from human pluripotent stem cells, with the goal of developing drug discovery screening and regenerative medicine applications for human blood system disorders. This technology is included in a United States patent application. The terms of this agreement provide for a royalty payment equal to 3% of the first \$25.0 million of certain revenues received from the licensed technology, and 2% thereafter. We believe this stem cell technology dramatically advances our ability to produce and purify this important blood stem cell precursor for both in vitro drug discovery screening and potential regenerative medicine applications. In addition to defining new cell culture methods for our use, the technology describes the surface characteristics of stem cell-derived adult hematopoietic stem cells. Most groups study embryonic blood development from stem cells, but, for the first time, we are now able to not only purify the stem cell-derived precursor of all adult hematopoietic cells, but also pinpoint the precise timing when adult blood cell differentiation takes place in these cultures. We believe these early cells have the potential to be the precursors of the ultimate adult, bone marrow-repopulating hematopoietic stem cells to repopulate the blood and immune system when transplanted into patients prepared for bone marrow transplantation. These cells have important potential therapeutic applications for the restoration of healthy blood and immune systems in individuals undergoing transplantation therapies for cancer, organ grafts, HIV infections or for acquired or genetic blood and immune deficiencies.

### AV-101-Related Intellectual Property

We have exclusive licenses to issued U.S. patents related to the use and function of AV-101, and various central nervous system (CNS)-active molecules related to AV-101. These patents are held by the University of Maryland, Baltimore, the Cornell Research Foundation, Inc. and Aventis, Inc. The principle U.S. method of use patent related to AV-101 has expired. Foreign counterparts to that U.S. patent also have expired. However, we have filed three U.S. patent applications relating to AV-101. In addition, among the key components of our commercial protection strategy with respect to AV-101 is the New Drug Product Exclusivity provided by the FDA under section 505(c)(3)(E) and 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (FDCA). The FDA's New Drug Product Exclusivity is available for new chemical entities (NCEs) such as AV-101, which, by definition, are innovative and have not been approved previously by the FDA, either alone or in combination. The FDA's New Drug Product Exclusivity protection provides the holder of an FDA-approved new drug application (NDA) up to five (5) years of protection from new competition in the U.S. marketplace for the innovation represented by its approved new drug product. This protection precludes FDA approval of certain generic drug applications under section 505(b)(2) of the FDCA, as well certain abbreviated new drug applications (ANDAs), during the up to five-year exclusivity period, except that such applications may be submitted after four years if they contain a certification of patent invalidity or non-infringement.

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The license agreement requires us to make royalty payments on 2% of net sales of products using the patent rights, including products containing compounds covered by the patent rights. Additionally, the license agreement requires us to pay a 1% royalty on net sales of combination products that use patent rights, or contain compounds covered by the patent rights. Consequently, future sales of AV-101 are subject to a 2% royalty obligation. There are no license, milestone or maintenance fees under the agreement. The agreement remains in force until the later of: (i) the expiration or invalidation of the last patent right; and (ii) 10 years after the first commercial sale of the first product that uses the patent rights or contains a compound covered by the patent rights. This agreement may also be terminated earlier at the election of the licensor upon our failure to pay any monies due, our failure to provide updates and reports to the licensor, our failure to provide the necessary financial and other resources required to develop the products, or our failure to cure within 90 days any breach of any provision of the agreement. We may also terminate the agreement at any time upon 90 days' written notice so long as we make all payments due through the effective date of termination.

## Competition

We believe that our human pluripotent stem cell (hPSC) technology platform, Human Clinical Trials in a Test Tube, the hPSC-derived human cells we produce, and the customized human cell-based assay systems we have formulated and developed are capable of being competitive in the diverse and growing global stem cell and regenerative medicine markets, including markets involving the sale of hPSC-derived cells to third-parties for their in vitro drug discovery and safety testing, contract predictive toxicology drug screening services for third parties, internal drug discovery, development and rescue of new molecular entities (NMEs), and regenerative medicine, including in vivo cell therapy research and development. A representative list of such biopharmaceutical companies pursuing one or more of these potential applications of adult and/or pluripotent stem cell technology includes the following: Acea Biosciences, Advanced Cell Technology, Athersys, BioTime, Cellectis Bioresearch, Cellular Dynamics, Cellerant Therapeutics, Cytori Therapeutics, HemoGenix, International Stem Cell, NeoStem, Neuralstem, Organovo Holdings, PluriStem Therapeutics, Stem Cells, and Stemina BioMarker Discovery. Pharmaceutical companies and other established corporations such as Bristol-Myers Squibb, GE Healthcare Life Sciences, GlaxoSmithKline, Life Technologies, Novartis, Pfizer, Roche Holdings and others have been and are expected to continue pursuing internally various stem cell-related research and development programs. Many of the foregoing companies have greater resources and capital availability and as a result, may be more successful in their research and development programs than us. We anticipate that acceptance and use of hPSC technology for drug development and regenerative medicine will continue to occur and increase at pharmaceutical and biotechnology companies in the future.

We believe the best and most valuable near term commercial application of our Human Clinical Trials in a Test Tube platform is internal production of NMEs, which we refer to as Drug Rescue Variants, through small molecule drug rescue. We believe that the stem cell technologies underlying our Human Clinical Trials in a Test Tube platform and our primary focus on opportunities to produce small molecule NMEs through drug rescue provide us substantial competitive advantages associated with application of human biology at the front end of the drug development process, before animal and human testing. Although we believe that our model for the application of human pluripotent stem cell technology for drug rescue is novel, significant competition may arise or otherwise increase considerably as the acceptance and use of hPSC technology, the sale of hPSC-derived human heart and liver cells, and the availability of hPSC-related contract predictive toxicology screening services, for drug discovery, development and rescue, as well as cell therapy and regenerative medicine, continue to become more widespread throughout the academic research community and the pharmaceutical and biotechnology industries. In addition, significant competition may arise from those academic research institutions, contract research organizations, and biopharmaceutical companies currently producing or capable of producing, currently using or capable of using, hPSC-derived heart cells and liver cells for third-party sales, contract screening or cell therapy research and development, that elect or their customers elect to transform their current business operations to include internal drug rescue and development of small molecule NMEs in a manner similar to our drug rescue model.



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With respect to AV-101, we believe that a range of pharmaceutical and biotechnology companies have programs to develop small molecule drug candidates for the treatment of neuropathic pain, epilepsy, depression, Parkinson's disease and other neurological conditions and diseases, including Abbott Laboratories, GlaxoSmithKline, Johnson & Johnson, Novartis, and Pfizer. We expect that AV-101 will have to compete with a variety of therapeutic products and procedures. With respect to each Drug Rescue Variant we are able to produce, we anticipate that a range of pharmaceutical and biotechnology companies will have programs to develop small molecule drug candidates or biologics for the treatment of the diseases or conditions targeted by each such Drug Rescue Variant.

### Government Regulation

#### United States

With respect to our stem cell research and development in the U.S., the U.S. government has established requirements and procedures relating to the isolation and derivation of certain stem cell lines and the availability of federal funds for research and development programs involving those lines. All of the stem cell lines that we are using were either isolated under procedures that meet U.S. government requirements and are approved for funding from the U.S. government, or were isolated under procedures that meet U.S. government requirements.

With respect to drug development, government authorities at the federal, state and local levels in the U.S. and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing, pricing and export and import of pharmaceutical products such as those we are developing. In the U.S., pharmaceuticals, biologics and medical devices are subject to rigorous FDA regulation. Federal and state statutes and regulations in the United States govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, export, record keeping, approval, marketing, advertising and promotion of our potential drug rescue variants. The information that must be submitted to the FDA in order to obtain approval to market a new drug varies depending on whether the drug is a new product whose safety and effectiveness has not previously been demonstrated in humans, or a drug whose active ingredient(s) and certain other properties are the same as those of a previously approved drug. Product development and approval within this regulatory framework takes a number of years and involves significant uncertainty combined with the expenditure of substantial resources.

Companies seeking FDA approval to sell a new prescription drug in the United States must test it in various ways. Currently, first are laboratory and animal tests. Next are tests in humans to see if the drug candidate is safe and effective when used to treat or diagnose a disease. After testing the drug candidate, the company developing it then sends the FDA an application called a New Drug Application (NDA). Some drug candidates are made out of biologic materials, including human cells, such as the human cells derived from human pluripotent stem cells. Instead of an NDA, new biologic drug candidates are approved using a Biologics License Application (BLA). Whether an NDA or a BLA, the application includes:

- the drug candidate's test results;

- manufacturing information to demonstrate the company developing the drug candidate can properly manufacture it; and

- the proposed label for the drug candidate, which provides necessary information about the drug candidate, including uses for which it has been shown to be effective, possible risks, and how to use it.

If a review by FDA physicians and scientists shows the drug candidate's benefits outweigh its known risks and the drug candidate can be manufactured in a way that ensures a quality product, the drug candidate is approved and can be marketed in the United States.

New drug and biological product development and approval takes many years, involves the expenditure of substantial resources and is uncertain to succeed. Many new drug and biological candidates appear promising in early stages of development but ultimately do not reach the market because they cannot meet FDA or other regulatory requirements. In addition, the current regulatory framework may change through regulatory, legislative or judicial actions or additional regulations may arise during development that may affect approval or delay the submission or review of an application.

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The activities required before a new drug or biological candidate may be approved for marketing in the U.S. begin with nonclinical testing, which includes laboratory evaluation and animal studies to assess the potential safety and efficacy of the product as formulated. Results of nonclinical studies are summarized in an Investigational New Drug (IND) application to the FDA. Human clinical trials may begin 30 days following submission of an IND application, unless the FDA requires additional time to review the application or raise questions.

Clinical testing involves the administration of the new drug or biological candidate to healthy human volunteers or to patients under the supervision of a qualified principal investigator, usually a physician, pursuant to an FDA-reviewed protocol. Each clinical study is conducted under the auspices of an institutional review board (IRB) at each of the institutions at which the study will be conducted. A clinical plan, or “protocol,” accompanied by the approval of an IRB, must be submitted to the FDA as part of the IND application prior to commencement of each clinical trial. Human clinical trials are conducted typically in three sequential phases. Phase I trials primarily consist of testing the product’s safety in a small number of patients or healthy volunteers. In Phase II trials, the safety and efficacy of the biological candidate is evaluated in a specific patient population. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded patient population at geographically dispersed sites. The FDA may order the temporary or permanent discontinuance of a nonclinical or clinical trial at any time for a variety of reasons, particularly if safety concerns exist.

All procedures we use to obtain clinical samples, and the procedures we use to isolate hESCs, are consistent with the informed consent and ethical guidelines promulgated by either the U.S. National Academy of Science, the International Society of Stem Cell Research (ISSCR), or the NIH. These procedures and documentation have been reviewed by an external Stem Cell Research Oversight Committee, and all cell lines we use have been approved under one or more of these guidelines.

The U.S. government and its agencies on July 7, 2009 published guidelines for the ethical derivation of hESCs required for receiving federal funding for hESC research. Should we seek NIH funding for our stem cell research and development, our request would involve the use of hESC lines that meet the NIH guidelines for NIH funding. In the U.S., the President’s Council on Bioethics monitors stem cell research, and may make recommendations from time to time that could place restrictions on the scope of research using human embryonic or fetal tissue. Although numerous states in the U.S. are considering, or have in place, legislation relating to stem cell research, including California whose voters approved Proposition 71 to provide up to \$3 billion of state funding for stem cell research in California, it is not yet clear what affect, if any, state actions may have on our ability to commercialize stem cell technologies.

## Canada

In Canada, stem cell research and development is governed by two policy documents and by one legislative statute: the Guidelines for Human Pluripotent Stem Cell Research (the Guidelines) issued by the Canadian Institutes of Health Research; the Tri-Council Statement: Ethical Conduct for Research Involving Humans (TCPS); and the Assisted Human Reproduction Act (Act). The Guidelines and the TCPS govern stem cell research conducted by, or under the auspices of, institutions funded by the federal government. Should we seek funding from Canadian government agencies or should we conduct research under the auspices of an institution so funded, we may have to ensure the compliance of such research with the ethical rules prescribed by the Guidelines and the TCPS.

The Act subjects all research conducted in Canada involving the human embryo, including hESC derivation (but not the stem cells once derived), to a licensing process overseen by a federal licensing agency. However, as of the date of this report, the provisions of the Act regarding the licensing of hESC derivation were not in force

We are not currently conducting stem cell research in Canada. We have, however, sponsored pluripotent stem cell research in Canada by Dr. Gordon Keller at UHN’s McEwen Centre. We anticipate conducting additional pluripotent

stem cell research (with both hESCs and hiPSCs), in collaboration with Dr. Keller and his research team, at UHN's McEwen Centre during 2014 and beyond pursuant to our long term sponsored research collaboration with Dr. Keller and UHN. Should the provisions of the Act come into force, we may have to apply for a license for all hESC research we may sponsor or conduct in Canada and ensure compliance of such research with the provisions of the Act.



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### Foreign

In addition to regulations in the U.S., we may be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the U.S. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

### Subsidiaries and Inter-Corporate Relationships

VistaGen Therapeutics, Inc., a California corporation, is our wholly-owned subsidiary and has the following two wholly-owned subsidiaries: VistaStem Canada Inc., a corporation incorporated pursuant to the laws of the Province of Ontario, intended to facilitate our stem cell-based research and development and drug rescue activities in Ontario, Canada including our collaboration with Dr. Keller and UHN should we elect to expand our U.S. operations into Canada; and Artemis Neuroscience, Inc., a corporation incorporated pursuant to the laws of the State of Maryland and focused on development of AV-101. The operations of VistaGen Therapeutics, Inc., a California corporation, and each of its two wholly owned subsidiaries are managed by our senior management team based in South San Francisco, California.

### Employees

We have ten full-time employees, four of whom have doctorate degrees. We anticipate adding up to ten additional employees, including at least two of whom will have a doctorate degree, within the twelve months following completion of the Offering. Currently, seven full-time employees work in research and development and laboratory support services and three full-time employees work in general and administrative roles. Staffing for all other functional areas is achieved through strategic relationships with service providers and consultants, each of whom provides services on an as-needed basis, including human resources and payroll, accounting and public company reporting, information technology, facilities, legal, stock plan administration, investor relations and web site maintenance, regulatory affairs, and FDA program management. In addition, we currently conduct some of our research and development efforts through sponsored research relationships with stem cell scientists at academic research institutions in the U.S. and Canada, including Dr. Keller's laboratories at UHN. See "Business – Strategic Transactions and Relationships."

None of our employees is represented by a labor union or is subject to a collective bargaining agreement. We believe that our current relationship with all of our employees is good.

### Facilities

Our principal executive offices and laboratories are located in South San Francisco, California, where we occupy approximately 10,000 square feet of office and laboratory space under a lease that expires in July 2017. Upon completion of this Offering, we anticipate leasing approximately 10,000 square feet of additional office and laboratory space to facilitate our growth plans.

### Legal Proceedings

From time to time, we may be a party to litigation and subject to claims incident to the ordinary course of business. We are not currently a party to any legal proceedings.



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## Autilion Securities Purchase Agreement

On April 8, 2013, we entered into a Securities Purchase Agreement with Autilion, as amended, pursuant to which we agreed to sell to Autilion 72.0 million shares of our common stock for \$0.50 per share, on or before April 30, 2013, resulting in gross proceeds to us of \$36.0 million. The Securities Purchase Agreement also provides for the election of one Autilion designee to the Company's Board of Directors. Prior to giving effect to the Offering, assuming consummation of the Autilion Financing, Autilion will beneficially own in excess of a majority of the our currently issued and outstanding common stock.

Contemporaneous with the execution of the Securities Purchase Agreement, Autilion entered into a Voting Agreement, pursuant to which Autilion agreed to vote all shares of capital stock held by Autilion consistent with the recommendation of a majority of the members of our board of directors. In addition, in the event of a Change in Control of the Company, as defined in the Voting Agreement, or an extraordinary transaction outside of the ordinary course of the Company's business, in each case approved by a majority of our board of directors, including the Autilion's designee to the board of directors, as well as by the holders of a majority of the outstanding shares of common stock held by stockholders unaffiliated with Autilion (Approved Transaction), Autilion is required to vote all shares of capital stock held by Autilion for such Approved Transaction.

To date, Autilion has completed only a nominal closing under the Securities Purchase Agreement. Autilion is therefore in default under the Securities Purchase Agreement, and no assurances can be given that Autilion will consummate any further investments under the Securities Purchase Agreement.

## MARKET FOR OUR COMMON STOCK

## Market Information and Dividend Policy

On June 21, 2011 our common stock began trading on the OTC Marketplace under the symbol "VSTA." There was no established trading market for our common stock prior to that date.

Shown below is the range of high and low sales prices for our common stock for the periods indicated as reported by the OTCQB. The market quotations reflect inter-dealer prices, without retail mark-up, markdown or commissions and may not necessarily represent actual transactions.

	High	Low
Year Ending March 31, 2014		
First quarter ending June 30, 2013	\$0.90	\$0.53
Second quarter ending September 30, 2013	\$0.89	\$0.50
Third quarter ending December 31, 2013	\$0.61	\$0.26
Fourth quarter ending March 31, 2014	\$0.50	\$0.28
Year Ending March 31, 2013		
First quarter ending June 30, 2012	\$2.80	\$0.16
Second quarter ending September 30, 2012	\$1.52	\$0.12
Third quarter ending December 31, 2012	\$0.95	\$0.53
Fourth quarter ending March 31, 2013	\$0.90	\$0.56

On July 1, 2014 the closing price of our common stock on the OTCQB was \$0.64 per share.

We have never declared or paid any dividend. We may, as our Board of Directors deems appropriate, continue to retain all earnings to use in our business or may consider paying dividends in the future.

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## Securities Authorized for Issuance Under Equity Compensation Plans at July 1, 2014

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,964,800	\$ 0.50	735,200
Equity compensation plans not approved by security holders	262,557	0.58	--
Total	4,227,537	\$ 0.50	735,200

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this prospectus. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in "Risk Factors."

Overview

We are a biotechnology company with expertise applying human pluripotent stem cell technology for drug rescue and regenerative medicine.

Our Human Clinical Trials in a Test Tube platform is based on a combination of proprietary and exclusively licensed stem cell technologies focused on controlling stem cell differentiation and production of multiple types of mature, functional, adult human cells from pluripotent stem cells, with emphasis on the human heart cells and liver cells, and using the cells we produce to design customized biological assay systems for drug discovery and drug rescue, as well as regenerative medicine applications.

With mature heart cells produced from stem cells, we have developed CardioSafe 3D, a novel bioassay system for assessing potential cardiotoxicity of new drug candidates. We believe CardioSafe 3D is capable of predicting the in vivo cardiac effects, both toxic and non-toxic, of small molecule drug candidates before they are ever tested in animals or humans. With mature, functional hepatocytes (liver cells) we have developed LiverSafe 3D, our novel human liver cell-based bioassay system, for assessing potential liver toxicity and adverse drug-drug interactions early in development. We are now focused on correlating LiverSafe 3D with small molecule drugs with reported clinical results involving liver toxicity, including drug-induced liver injury and metabolism issues that can result in serious adverse drug-drug interactions. We believe our novel, customized human pluripotent stem cell-derived bioassay systems will allow us to assess the heart and liver safety profile of new small molecule drug candidates with greater speed and precision than nonclinical surrogate safety testing models currently used in drug development.

Our drug rescue business model involves using our novel, in vitro bioassay systems, CardioSafe 3D and LiverSafe 3D, and medicinal chemistry to generate and either develop internally or out-license to third-parties, new, potentially safer proprietary variants of once-promising small molecule drug candidates that pharmaceutical companies and others have discovered, optimized for efficacy and evaluated as having commercial potential, but ultimately discontinued prior to market approval due to unexpected heart or liver safety concerns. We refer to these once-promising drug candidates we believe are now suitable for our drug rescue programs as Drug Rescue Candidates. And we refer to the new, potentially safer proprietary variants we intend to generate in our drug rescue programs as Drug Rescue Variants. Our drug rescue strategy is to leverage substantial prior investment in the discovery and optimization of Drug Rescue Candidates by pharmaceutical companies and others, unique and new heart and liver biology insight regarding such Drug Rescue Candidates we generate by screening them in CardioSafe 3D and/or LiverSafe 3D, and contract medicinal chemistry expertise to generate novel, proprietary Drug Rescue Variants for internal development or out-license to pharmaceutical companies and others for development and commercialization.

We are utilizing the vast amount of information available in the public domain with respect to identification of potential Drug Rescue Candidates. We may also seek to in-license or acquire rights to certain Drug Rescue Candidates from third-parties, including biotechnology, medicinal chemistry and pharmaceutical companies, contract research organizations, and academic, governmental and nonprofit research institutions. We anticipate having economic rights

in each lead Drug Rescue Variant we produce and internally develop or out-license, including, in the case of out-licensed Drug Rescue Variants, customary up-front payments, development milestone payments and, if approved for commercial sale, royalty payments on sales.

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In addition to our drug rescue programs, upon completion of this Offering, we are planning to initiate several exploratory nonclinical development programs with Dr. Gordon Keller, one of the world's most experienced stem cell research scientists, relating to differentiation and production of multiple cell types for regenerative medicine purposes, including stem cell-based small molecule drug discovery, with an emphasis on blood, bone, cartilage, heart, liver and pancreas (insulin-producing beta-islet) cells. Each of these exploratory regenerative medicine programs would be based on the proprietary controlled differentiation and production capabilities of our Human Clinical Trials in a Test Tube platform.

With grant funding from the U.S. National Institutes of Health (NIH), we have successfully completed Phase 1 development of AV-101. AV-101 is an orally-available, non-sedating small molecule prodrug candidate aimed at the multi-billion dollar neurological disease and disorders market, including neuropathic pain, a serious and chronic condition causing pain after an injury or disease of the peripheral or central nervous system, epilepsy, depression and Parkinson's disease. We were awarded over \$8.8 million of grant funding from the NIH to support our nonclinical and Phase I clinical development of AV-101 for neuropathic pain. We intend to seek potential strategic partnering alternatives for further clinical development and commercialization of AV-101 for neuropathic pain, epilepsy, depression and Parkinson's disease.

## Financial Operations Overview

### Net Loss

We are in the development stage and, since inception, have devoted substantially all of our time and efforts to hPSC research and bioassay development, small molecule drug development, creating, protecting and patenting intellectual property, recruiting personnel and raising working capital. As of March 31, 2014, we had an accumulated deficit of \$70.6 million. Our net loss for the years ended March 31, 2014 and 2013 was \$3.0 million and \$12.9 million, respectively. We expect these conditions to continue for the foreseeable future as we expand our drug rescue activities and the capabilities of our Human Clinical Trials in a Test Tube™ platform.

### Summary of Fiscal Year 2014

During fiscal 2014, our scientific personnel have continued to expand the drug rescue capabilities of CardioSafe 3D and further develop LiverSafe 3D. Our internal scientific operations were curtailed somewhat during our second fiscal quarter as we decommissioned our former lab space in preparation for our move to expanded lab and office facilities at the end of July 2013, and completed the corresponding relocation, recalibration and recertification of our laboratories and equipment following the move. Limited cash resources following the move, resulting in part from a third-party institutional investor's failure to close the financing described below, continued to restrict certain scientific activities and collaborations for the remainder of the fiscal year. Nevertheless, we have continued to advance the drug rescue capabilities of our heart and liver cells and cellular assay systems and pursue our internal evaluation of prospective Drug Rescue Candidates. We successfully completed Phase 1 clinical development of AV-101 during our fiscal year ended March 31, 2013 and directed effort during the first quarter of fiscal 2014 to finalizing AV-101 Phase 1b clinical study reports, as required under the terms of our NIH grant awards and to facilitate further collaborative development of AV-101.

Throughout fiscal 2014, our executive management has been significantly focused on providing sufficient operating capital to advance our research and development objectives while meeting our continuing operational needs. To that end, in April 2013, we entered into a Securities Purchase Agreement (as amended, Securities Purchase Agreement) with Autilion AG, an institutional investor organized and existing under the laws of Switzerland (Autilion), under which Autilion is contractually obligated to purchase an aggregate of 72.0 million restricted shares of our common stock at a purchase price of \$0.50 per share for aggregate cash proceeds to us of \$36.0 million (Autilion Financing).



To date, Autilion has completed only a nominal closing under the Securities Purchase Agreement. Autilion is therefore in default under the Securities Purchase Agreement, and no assurances can be given that Autilion will consummate any further investments under the Securities Purchase Agreement.

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To meet our working capital needs as a result of Autilion's default under the Securities Purchase Agreement, during June and July 2013, we offered certain warrant holders the opportunity to exercise outstanding warrants having an exercise price of \$1.50 per share to purchase shares of our restricted common stock at a reduced exercise price of \$0.50 per share. Participating warrant holders exercised modified warrants to purchase an aggregate of 528,370 restricted shares of our common stock and we received cash proceeds of \$264,200. In addition, certain long-term warrant holders exercised modified warrants to purchase 16,646 restricted shares of our common stock in lieu of payment by us in satisfaction of amounts due for professional services in the aggregate amount of \$8,300. Additionally, in July 2013, we issued to Platinum Long Term Growth Fund VII, LLC (Platinum), our largest institutional investor, a senior secured convertible note in the face amount of \$250,000 (the July 2013 Note) and a five-year warrant to purchase 250,000 restricted shares of our common stock at an exercise price of \$0.50 per share. Between August 2013 and March 14, 2014, we entered into securities purchase agreements with certain accredited investors pursuant to which we sold units of our securities (Units) consisting, in aggregate, of: (i) 10% convertible notes maturing on July 30, 2014 in the aggregate face amount of \$1,007,500; (ii) an aggregate of 2,015,000 restricted shares of our common stock; and (iii) warrants exercisable through July 30, 2016 to purchase an aggregate of 2,015,000 restricted shares of our common stock at an exercise price of \$1.00 per share. We received cash proceeds of \$1,007,500 from the sale of the Units, including \$50,000 in lieu of repayment of previous advances made to us by one of our executive officers.

Between late-March 2014 and July 1, 2014, we entered into subscription agreements with accredited investors, including Platinum, pursuant to which we sold Units consisting, in aggregate, of: (i) 10% convertible notes maturing on March 31, 2015 in the aggregate face amount of \$1,570,000; (ii) an aggregate of 1,570,000 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 1,570,000 restricted shares of our common stock at an exercise price of \$0.50 per share.

Given our working capital constraints during fiscal 2014, we attempted to minimize cash commitments and expenditures for external research and development and general and administrative services to the greatest extent possible, particularly during the later portion of the fiscal year. The following table summarizes the results of our operations for the fiscal years ended March 31, 2014 and 2013 (in thousands):

	Fiscal Years Ended March 31,	
	2014	2013
Revenues:		
Grant revenue	\$-	\$200
Operating expenses:		
Research and development	2,481	3,431
General and administrative	2,548	3,562
Total operating expenses	5,029	6,993
Loss from operations	(5,029 )	(6,793 )
Other expenses, net:		
Interest expense, net	(1,503 )	(921 )
Change in warrant liabilities	3,567	(1,636 )
Loss on early extinguishment of debt	-	(3,568 )
Other income	-	35
Loss before income taxes	(2,965 )	(12,883 )
Income taxes	(3 )	(4 )
Net loss	\$(2,968 )	\$(12,887 )
Deemed dividend on Series A Preferred Stock	-	(10,193 )

Net loss attributable to common stockholders	\$ (2,968 )	\$ (23,080 )
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### Revenue

We have successfully completed our Phase I development of AV-101, our prodrug candidate for the treatment of neuropathic pain and, potentially, depression, epilepsy and Parkinson's disease. Our NIH grant related to AV-101 expired in its normal course on June 30, 2012. We had drawn the maximum amount available under the grant prior to its expiration. Revenue associated with our earlier subcontract research arrangement terminated in May 2012. We had no other grant or contract revenue sources during the fiscal year ended March 31, 2014.

### Research and Development Expense

Research and development expense represented approximately 49% of our operating expenses for each of the years ended March 31, 2014 and 2013. Research and development costs are expensed as incurred. Research and development expense consists of both internal and external expenses incurred in sponsored stem cell research and drug development activities, costs associated with the development of AV-101 and costs related to the licensing, application and prosecution of our intellectual property. These expenses primarily consist of the following:

- salaries, benefits, including stock-based compensation costs, travel and related expense for personnel associated with research and development activities;

- fees to contract research organizations and other professional service providers for services related to the conduct and analysis of clinical trials and other development activities;

- fees to third parties for access to licensed technology and costs associated with securing and maintaining patents related to such licensed technology and our internally generated inventions;

- laboratory supplies and materials;

- leasing and depreciation of laboratory equipment; and

- allocated costs of facilities and infrastructure.

### General and Administrative Expense

General and administrative expense consists primarily of salaries and related expense, including stock-based compensation expense, for personnel in executive, finance and accounting, and other support functions. Other costs include professional fees for legal, investor relations and accounting services and other strategic consulting and public company expenses as well as facility costs not otherwise included in research and development expense.

### Other Expenses, Net

In both fiscal 2014 and 2013, we incurred interest expense, including discount amortization with respect to certain notes, on the outstanding balances of our Senior Secured Convertible Promissory Notes issued to Platinum during fiscal 2013 and in July 2013, on the new and modified notes issued to Morrison & Foerster, Cato Research Ltd. and University Health Network (UHN) during August and September 2012, and on various notes issued to certain service providers during fiscal years 2011 and 2012. Additionally, in fiscal 2014, we incurred interest expense and related discount amortization attributable to the convertible notes issued in connection with the sale of Units between August 2013 and March 2014. In fiscal 2013, we incurred non-cash losses on extinguishment of debt resulting from the modification of indebtedness to Platinum, Morrison & Foerster, Cato Research Ltd., and UHN, as well as the conversion by the holders of our 12% Convertible Promissory Notes issued in February 2012 into restricted shares of

our common stock and warrants in November 2012. In fiscal 2014 and 2013, we recorded income and expense, respectively, related to the changes in the fair values of the warrants issued or issuable in connection with the various Senior Secured Convertible Promissory Notes issued to Platinum during fiscal 2013 and 2014.

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In fiscal 2013, we also recorded a non-cash deemed dividend related to the modification of the exchange rights of our Series A Preferred Stock held by Platinum and the impact of the prospective issuance of a five-year warrant to purchase restricted shares of our common stock upon Platinum's exercise of its Series A Preferred Stock exchange rights.

### Critical Accounting Policies and Estimates

We consider certain accounting policies related to revenue recognition, impairment of long-lived assets, research and development, stock-based compensation, and income taxes to be critical accounting policies that require the use of significant judgments and estimates relating to matters that are inherently uncertain and may result in materially different results under different assumptions and conditions. The preparation of financial statements in conformity with United States generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes to the consolidated financial statements. These estimates include useful lives for property and equipment and related depreciation calculations, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

### Revenue Recognition

Although we do not currently have any such arrangements, we have historically generated revenue principally from collaborative research and development arrangements, technology access fees and government grants. We recognize revenue under the provisions of the SEC issued Staff Accounting Bulletin 104, Topic 13, Revenue Recognition Revised and Updated (SAB 104) and Accounting Standards Codification (ASC) 605-25, Revenue Arrangements-Multiple Element Arrangements (ASC 605-25). Revenue for arrangements not having multiple deliverables, as outlined in ASC 605-25, is recognized once costs are incurred and collectability is reasonably assured.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer. Consideration received is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.

We recognize revenue when the four basic criteria of revenue recognition are met: (i) a contractual agreement exists; (ii) the transfer of technology has been completed or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no objective and reliable evidence of the fair value of those obligations. We recognize non-refundable upfront technology access fees under agreements in which we have a continuing performance obligation ratably, on a straight-line basis, over the period in which we are obligated to provide services. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collectability is reasonably assured. Payments received related to substantive, performance-based "at-risk" milestones are recognized as revenue upon achievement of the milestone event specified

in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

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Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees and/or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of the continuing research and development efforts. Otherwise, revenue is recognized over the period of our continuing involvement.

Government grant awards, which support our research efforts on specific projects, generally provide for reimbursement of approved costs as defined in the terms of grant awards. We recognize grant revenue when associated project costs are incurred.

### Impairment of Long-Lived Assets

In accordance with ASC 360-10, Property, Plant & Equipment—Overall, we review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, we write down the assets to their estimated fair values and recognize the loss in the statements of operations.

### Research and Development Expenses

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses of scientific personnel and direct project costs. External research and development expenses consist of sponsored stem cell research and development costs, costs associated with clinical and non-clinical development of AV-101, our lead drug candidate, and costs related to application and prosecution of patents related to our stem cell technology platform, Human Clinical Trials in a Test Tube, and AV-101. All such costs are charged to expense as incurred.

### Stock-Based Compensation

We account for stock-based payment arrangements in accordance with ASC 718, Compensation-Stock Compensation and ASC 505-50, Equity-Equity Based Payments to Non-Employees which requires the recognition of compensation expense, using a fair-value based method, for all costs related to stock-based payments including stock options and restricted stock awards. We recognize compensation cost for all share-based awards to employees based on their grant date fair value. Share-based compensation expense is recognized over the period during which the employee is required to perform service in exchange for the award, which generally represents the scheduled vesting period. We have no awards with market or performance conditions. For equity awards to non-employees, we re-measure the fair value of the awards as they vest and the resulting value is recognized as an expense during the period over which the services are performed.

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards as of the grant date. The Black-Scholes model is complex and dependent upon key data input estimates. The primary data inputs with the greatest degree of judgment are the expected terms of the stock options and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding. We use the simplified method to estimate the expected term as an input into the Black-Scholes option pricing model. We determine expected volatility using the historical method, which, because of the limited period during which our stock has been publicly traded, is based on the historical daily trading data of the common stock of a peer group of public companies over the expected



term of the option.

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## Income Taxes

We account for income taxes using the asset and liability approach for financial reporting purposes. We recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established, when necessary, to reduce the deferred tax assets to an amount expected to be realized.

## Recent Accounting Pronouncements

See Note 3 to the consolidated financial statements included elsewhere in this prospectus for information on recent accounting pronouncements.

## Results of Operations

## Comparison of Years Ended March 31, 2014 and 2013

## Revenue

The following table compares our primary revenue sources between the periods (in thousands):

	Fiscal Years Ended March 31,	
	2014	2013
NIH - AV-101 grant	\$-	\$187
Subcontract revenue	-	13
Total Revenue	\$-	\$200

We have successfully completed our Phase I development of AV-101, our prodrug candidate for the treatment of neuropathic pain and, potentially, depression and other neurological conditions. Our NIH grant related to AV-101 expired in its normal course on June 30, 2012. We had drawn the maximum amount available under the grant prior to its expiration. Revenue associated with our earlier subcontract research arrangement terminated in May 2012.

## Research and Development Expense

Research and development expense decreased by 28% or \$900,000 to \$2.5 million in fiscal 2014 compared to \$3.4 million in fiscal 2013. The following table compares the primary components of research and development expense between the periods (in thousands):

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	Fiscal Years Ended March 31,	
	2014	2013
Salaries and benefits	\$902	\$792
Stock-based compensation	453	510
UHN research under SRCA	160	466
Consulting services	53	14
Technology licenses and royalties	484	136
Project-related third-party research and supplies:		
AV-101	51	1,079
All other including CardioSafe and LiverSafe	145	293
	196	1,372
Rent	185	115
Depreciation	44	26
All other	4	-
Total Research and Development Expense	\$2,481	\$3,431

The increase in research and development salaries and benefits expense reflects the impact of (i) the addition of a research technician in April 2013; (ii) the partial restoration in April 2013 of an earlier voluntary salary reduction to below his contractual pay rates taken by our President and Chief Scientific Officer; and (iii) general annual increases in employee benefits costs. In addition to the ratable amortization of stock-based compensation expense over the requisite service period of the respective grants made in fiscal 2014 and in prior years, stock-based compensation expense for fiscal 2014 includes approximately \$82,000 as the impact of October 2013 and December 2013 modifications to reduce the exercise price of certain outstanding option grants to \$0.40 per share or \$0.50 per share, as well as approximately \$157,000 attributable to the expense resulting from the March 2014 and March 2013 grants of warrants to our President and Chief Scientific Officer that vest over three years, subject to certain vesting acceleration events. Stock-based compensation expense for fiscal 2013 includes approximately \$89,000 from the impact of October 2012 modifications reducing the exercise price to \$0.75 per share and reducing any remaining vesting period to two years for certain option grants having exercise prices between \$1.13 per share and \$2.58 per share made to certain scientific employees and consultants in prior years and approximately \$268,000 attributable to the expense resulting from the March 2013 grant of a warrant to our President and Chief Scientific Officer. Our 2012/2013 sponsored research project budget under the collaboration agreement with Dr. Gordon Keller's laboratory at UHN ended on September 30, 2013. We are currently in discussions with Dr. Keller and UHN regarding the scope of our 2013/2014 sponsored research project budget under the agreement, and we anticipate finalizing such budget in the near term. The expense recorded in fiscal 2013 reflects our stem cell research collaboration in accordance with our agreements with UHN made in the third and fourth quarters of our fiscal year ended March 31, 2012 and in a further modification effective beginning in October 2012. Technology license expense increased significantly in fiscal 2014 as a result of costs for patent prosecution and protection that we are required to fund under the terms of certain of our license agreements. We recognize these costs as they are invoiced to us by the licensors and they do not occur ratably throughout the year or between years. We began Phase 1b clinical trials of AV-101 early in calendar 2012, completing them by mid-year 2012. We recorded significant expense related to the trials during fiscal 2013. AV-101 expenses in fiscal 2014 reflect the costs associated with finalizing the AV-101 clinical trial results, preparing the final clinical trial and other reports required under the terms of the NIH grant and monitoring for feedback related to the reports, activities performed primarily through our contract research collaborator, Cato Research Ltd. We do not track internal research and development expenses, including compensation costs, by project as we do not currently believe that such project accounting is necessary given the level and overlap of project resources, including staffing, that are dedicated to our internal research and development projects. The increase in rent expense and depreciation in fiscal 2014 reflects

increased rental costs and the amortization of tenant improvements related to our relocation to expanded facilities in late-July 2013.

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## General and Administrative Expense

General and administrative expense decreased by 29% or \$1.0 million to \$2.5 million in fiscal 2014 compared to \$3.6 million in fiscal 2013. The following table compares the primary components of general and administrative expense between the periods (in thousands):

	Fiscal Years Ended March 31,	
	2014	2013
Salaries and benefits	\$675	\$617
Stock-based compensation	684	731
Consulting Services	94	157
Legal, accounting and other professional fees	340	554
Investor relations	120	622
Insurance	130	122
Travel and entertainment	18	37
Rent and utilities	139	85
Warrant modification expense	205	507
All other expenses	143	130
<b>Total General and Administrative Expense</b>	<b>\$2,548</b>	<b>\$3,562</b>

The increase in administrative salaries and benefits expense reflects the impact of (i) the partial restoration in April 2013 of an earlier voluntary salary reduction to below his contractual pay rate taken by our Chief Executive Officer; (ii) the September 2012 conversion of our Chief Financial Officer from part-time consultant to full-time employee status; (iii) the April 2013 conversion of an administrative assistant from consultant to employee status, and (iv) general annual increases in employee benefits costs; all offset by the impact of voluntary resignations of certain administrative personnel. In addition to the ratable amortization of stock-based compensation expense over the requisite service period of the respective grants made in fiscal 2014 and in prior years, stock-based compensation expense for fiscal 2014 includes approximately \$170,000 as the impact of October 2013 and December 2013 modifications to reduce the exercise price of certain outstanding option grants to \$0.40 per share or \$0.50 per share, as well as approximately \$299,000 attributable to the expense resulting from the March 2014 and March 2013 grants of warrants vesting over three years, subject to certain vesting acceleration events, to certain members of our senior management and to the independent members of our Board of Directors. Stock-based compensation expense for fiscal 2013 includes approximately \$44,000 reflecting the impact of October 2012 modifications reducing the exercise price to \$0.75 per share and reducing any remaining vesting period to two years for certain option grants having exercise prices between \$1.13 per share and \$2.58 per share made to certain administrative employees and consultants in prior years, and approximately \$535,000 attributable to the expense resulting from the March 2013 grants of warrants to certain members of our senior management and to the independent members of our Board of Directors. The reduction in legal, accounting and other professional fees reflects the impact of converting our Chief Financial Officer from part-time consultant to full-time employee status, as noted above, a reduction in legal expenses and the absence in fiscal 2014 of non-cash expense related to the granting of warrants to certain administrative consultants and service providers. During fiscal 2013, we engaged third parties to provide us with investor relations services and to conduct market awareness initiatives, however, for strategic purposes, we significantly scaled back those initiatives during fiscal 2014. The fiscal 2014 increase in rent and utilities expenses reflects higher costs related to our relocation to expanded facilities in late-July 2013. Warrant modification expense for fiscal 2014 reflects the impact of October 2013, December 2013 and February 2014 strategic reductions in the exercise price of certain outstanding warrants, generally from \$1.75 per share or \$1.50 per share, to \$0.50 per share, and in certain cases, the extension of the term of

outstanding warrants by approximately one year. In fiscal 2013, we recorded warrant modification expense also related to the reduction of the exercise price of certain outstanding warrants. The increase in other expenses for 2013 includes one-time costs associated with our late-July 2013 relocation to new facilities.

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## Other Expenses, Net

In both fiscal 2014 and 2013, other expenses, net includes interest expense, including non-cash discount amortization, on our outstanding promissory notes, net of interest income, as well as the non-cash impact of changes in the fair value of the warrant liabilities related to warrants issued or issuable to Platinum as a result of the October 2012 Agreement with Platinum, as amended, and, in fiscal 2014, the warrant issued to Platinum in July 2013. In fiscal 2013, other expenses, net additionally includes the non-cash loss on extinguishment of debt resulting from the modification of indebtedness to Platinum, Morrison & Foerster, Cato Research Ltd., and University Health Network, as well as the conversion by the holders of our 12% Convertible Promissory Notes issued in February 2012 into restricted shares of our common stock and warrants in November 2012.

The following table compares the primary components of net interest expense between the periods (in thousands):

	Fiscal Years Ended March 31,	
	2014	2013
Interest expense on promissory notes, including discount amortization	\$1,547	\$796
Charge for fair value of replacement warrants issued in connection with exercise of modified warrants	-	36
Charge related to losses on accounts payable settled by issuance of common stock or notes payable	-	80
Charge for investment banker warrants related to February 2012 Convertible promissory notes	-	28
Charge for legal fees related to issuance of Senior Secured Promissory Notes to Platinum under June and October 2012 agreements	-	59
Other interest expense, including on capital leases and premium financing	15	5
	1,562	1,004
Effect of foreign currency fluctuations on notes payable	(49 )	(53 )
Interest Income	(10 )	(30 )
<b>Interest Expense, net</b>	<b>\$1,503</b>	<b>\$921</b>

The increase in interest expense is primarily attributable to the accrued interest and discount amortization recorded for the July 2012 through July 2013 issuances and restructuring of an aggregate of \$3.5 million of 10% senior secured convertible notes to Platinum, including the \$250,000 convertible note issued in July 2013, as well as the restructuring in September and October 2012 of an additional \$3.9 million of debt into new convertible notes to other service providers, including Morrison & Foerster, Cato Research Ltd., and University Health Network. These transactions are described in greater detail in Note 9, Convertible Promissory Notes and Other Notes Payable, in the Consolidated Financial Statements included elsewhere in this prospectus.

In conjunction with the issuance to Platinum, pursuant to the October 2012 Note Exchange and Purchase Agreement, of certain Senior Secured Convertible Promissory Notes and the related Exchange Warrant and Investment Warrants in October 2012, February 2013 and March 2013, and in connection with the similar senior secured convertible promissory note and related warrant issued to Platinum in July 2013, (as described more completely in Note 9, Convertible Promissory Notes and Other Notes Payable, in the Consolidated Financial Statements included elsewhere in this prospectus), and the contingent issuance of the Series A Exchange Warrant to Platinum upon Platinum's exchange of shares of our Series A Preferred held by Platinum into shares of our common stock, we determined that the warrants included certain exercise price adjustment features requiring the warrants to be treated as

liabilities. Accordingly, we recorded a non-cash warrant liability at its estimated fair value as of the date of warrant issuance or contract execution. During fiscal 2014, we recognized non-cash income of \$3,566,900 related to the net decrease in the estimated fair value of these liabilities since March 31, 2013, or issuance in the case of the warrant issued in July 2013, which resulted from a combination of both the decrease in the market price of our common stock during that period and an agreement with Platinum in May 2013 pursuant to which the stated exercise price of the warrants was reduced from \$1.50 per share to \$0.50 per share. During fiscal 2013, we recognized non-cash expense of \$1,635,800 attributable to the net increase in the fair value of these liabilities between the issuance date of the warrants and March 31, 2013, primarily as the result of the increase in the market price of our common stock during that period.



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During fiscal 2013, we recognized non-cash losses on the early extinguishment of debt in the aggregate amount of \$3.6 million primarily as a result of the restructuring of notes payable to Platinum and Cato Holding Company, and the restructuring of accounts payable to Cato Research, Ltd. and UHN that were converted into notes payable, as well as upon the conversion by the holders of our 12% Convertible Promissory Notes issued in February 2012 into restricted shares of our common stock and warrants, all of which were treated as extinguishment of debt for accounting purposes, all as described more completely in Note 9, Convertible Promissory Notes and Other Notes Payable, in the Consolidated Financial Statements included elsewhere in this prospectus.

In fiscal 2013, in connection with the October 2012 Note Exchange and Purchase Agreement we entered with Platinum, as described in Note 9, Convertible Promissory Notes and Other Notes Payable, and Note 10, Capital Stock, in the Consolidated Financial Statements included elsewhere in this prospectus, we recorded a non-cash deemed dividend of \$10.2 million as a result of the modification of the exchange rights for the Series A Preferred held by Platinum and the related contingent issuance of a five-year warrant to purchase shares of our common stock upon Platinum's exercise of its Series A Preferred exchange rights.

## Liquidity and Capital Resources

Since our inception in May 1998 through March 31, 2014, we have financed our operations and technology acquisitions primarily through the issuance and sale of equity and debt securities, including convertible promissory notes and short-term promissory notes, for aggregate cash proceeds of approximately \$26.0 million, as well as from an aggregate of approximately \$16.4 million of government research grant awards, strategic collaboration payments and other revenues. Additionally, we have issued equity securities with an approximate aggregate value at issuance of \$12.6 million, primarily as compensation for professional services rendered to us since inception. At March 31, 2014, we had negligible cash and cash equivalents. To meet our cash needs and fund our working capital requirements after March 31, 2014 and prior to the expected completion of the Autilion Financing or an alternate debt- or equity-based financing, through July 1, 2014, we entered into securities purchase agreements with accredited investors pursuant to which we sold to such accredited investors certain Units for aggregate cash proceeds of \$1,520,000, consisting of: (i) 10% subordinate convertible promissory notes in the aggregate face amount of \$1,520,000 maturing on March 31, 2015; (ii) an aggregate of 1,520,000 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 1,520,000 restricted shares of our common stock at an exercise price of \$0.50 per share. We anticipate that our cash expenditures during the next twelve months will be approximately \$4.0 to \$6.0 million.

In April 2013, we entered into the Securities Purchase Agreement with Autilion, under which Autilion is contractually obligated to purchase an aggregate of 72.0 million restricted shares of our common stock at a purchase price of \$0.50 per share for aggregate cash proceeds to us of \$36.0 million. To date, Autilion has completed only a nominal closing under the Securities Purchase Agreement. Autilion is therefore in default under the Securities Purchase Agreement, and no assurances can be given that Autilion will consummate additional investments under the Securities Purchase Agreement. In the event that Autilion does not complete a material closing under the Securities Purchase Agreement in the near term, we anticipate that we will need to raise between \$4.0 million and \$6.0 million from alternative financing sources to execute our current business plan, which we intend to obtain as a result of the consummation of the Offering, although no assurances can be given that we will raise the maximum Offering amount or a sufficient amount to fund our operations and satisfy our outstanding obligations. Substantial additional financing may not be available to us on a timely basis, on terms acceptable to us, or at all. In the event we are unable to obtain substantial additional financing on a timely basis, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, and we may not be able to continue as a going concern.

In the event Autilion completes a closing under the Securities Purchase Agreement in an amount exceeding \$13.0 million, and we issue to Autilion over 26 million shares of our restricted common stock in connection with such

closing, without giving effect to any closings in connection with the Offering, Autilion will control in excess of 50% of our issued and outstanding common stock, resulting in a change in control of the Company. In addition, substantial dilution to existing stockholders will occur upon completion of a material portion of the Autilion Financing, or completion of an alternate equity-based financing.

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If and as necessary, we may seek to complete a combination of additional private placements or public offerings of our securities, which may include both debt and equity securities, stem cell technology-based research and development collaborations, stem cell technology and drug candidate license fees and government grant awards. Although we have been successful since May 1998 with raising sufficient capital for our operations, and we will continue to pursue additional financing opportunities as necessary to meet our business objectives, there can be no assurance that substantial additional capital will be available to us in sufficient amounts, on terms favorable to us, and without substantial dilution to our current stockholders, if at all. If we are unable to complete one or more private placements or public offerings, or otherwise obtain sufficient financing through strategic collaborations or government grant awards, we may be required to delay, scale back or discontinue certain drug rescue and/or research and development activities, and this may adversely affect our ability to continue as a going concern. If we obtain additional financing by selling our equity or debt securities, we anticipate that substantial dilution to our existing stockholders will result. Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of strategic opportunities related to our stem cell technology platform, including drug rescue and cell therapy research and development efforts, the success of such programs, our ability to obtain government grant awards and our ability to enter into strategic collaborations with institutions on terms acceptable to us. To further advance drug rescue applications of our stem cell technology platform, as well as support our operating activities, we plan to continue to carefully manage our monthly operating costs associated with salaries and benefits, regulatory and public company consulting, contract research and development, legal, accounting and other working capital costs.

The following table summarizes changes in cash and cash equivalents for the periods stated (in thousands):

	Fiscal Years Ended March 31,	
	2014	2013
Net cash used in operating activities	\$(2,126 )	\$(3,463 )
Net cash used in investing activities	(10 )	(135 )
Net cash provided by financing activities	1,498	4,155
Net increase (decrease) in cash and cash equivalents	(638 )	557
Cash and cash equivalents at beginning of period	638	81
Cash and cash equivalents at end of period	\$-	\$638

## Off-Balance Sheet Arrangements

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retained or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity. VistaGen California has two inactive, wholly-owned subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation, and VistaStem Canada, Inc., an Ontario corporation.

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## MANAGEMENT

## Directors and Executive Officers

Our directors and executive officers are as follows:

Name	Age	Position
Shawn K. Singh, J.D.	51	Chief Executive Officer and Director Founder, President, Chief Scientific Officer and Director
H. Ralph Snodgrass, Ph.D.	64	Vice President, Chief Financial Officer and Secretary
Jerrold D. Dotson	60	Secretary
Jon S. Saxe (1)	77	Director
Brian J. Underdown, PhD. (2)	73	Director

(1) Chairman of the audit committee and member of the compensation committee and corporate governance and nominating committee

(2) Member of the audit committee and chairman of the compensation committee and corporate governance and nominating committee

## Executive Officers

Shawn K. Singh, J.D. has served as our Chief Executive Officer since August 2009; he joined our Board of Directors in 2000 and served on our management team (part-time) from late-2003, following our acquisition of Artemis Neuroscience, of which he was President, to August 2009. Mr. Singh has over 20 years of experience working with biotechnology, medical device and pharmaceutical companies, both private and public. From February 2001 to August 2009, Mr. Singh served as Managing Principal of Cato BioVentures, a life science venture capital firm, and as Chief Business Officer and General Counsel of Cato Research Ltd, a profitable global contract research organization (CRO) affiliated with Cato BioVentures. Mr. Singh served as President (part-time) of Echo Therapeutics (NASDAQ: ECTE), a medical device company, from September 2007 to June 2009, and as a member of its Board of Directors from September 2007 through December 2011. He also served as Chief Executive Officer (part-time) of Hemodynamic Therapeutics, a private biopharmaceutical company affiliated with Cato BioVentures, from November 2004 to August 2009. From late-2000 to February 2001, Mr. Singh served as Managing Director of Start-Up Law, a management consulting firm serving biotechnology companies. Mr. Singh also served as Chief Business Officer of SciClone Pharmaceuticals (NASDAQ: SCLN), a US-based, China-focused specialty pharmaceutical company with a substantial revenue-generating and profitable commercial business and a marketed product portfolio of differentiated therapies for oncology, infectious diseases and cardiovascular disorders, from late-1993 to late-2000, and as a corporate finance associate of Morrison & Foerster LLP, an international law firm, from 1991 to late-1993. Mr. Singh currently serves as a member of the Board of Directors of Armour Therapeutics, a private biotechnology company focused on prostate cancer. Mr. Singh earned a B.A. degree, with honors, from the University of California, Berkeley, and a J.D. degree from the University of Maryland School of Law. Mr. Singh is a member of the State Bar of California.

We selected Mr. Singh to serve on our Board of Directors due to his substantial practical experience and expertise in senior leadership roles with multiple private and public biotechnology, pharmaceutical and medical device companies, and his extensive experience in corporate finance, venture capital, corporate governance and strategic partnering.

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H. Ralph Snodgrass, Ph.D. co-founded VistaGen with Dr. Gordon Keller in 1998 and served as our Chief Executive Officer until August 2009. Dr. Snodgrass has served as our President and Chief Scientific Officer since August 2009. He has served as a member of our Board of Directors since 1998. Prior to founding VistaGen, Dr. Snodgrass served as a key member of the executive management team which lead Progenitor, Inc., a biotechnology company focused on developmental biology, through its initial public offering, and was its Chief Scientific Officer from June 1994 to May 1998, and its Executive Director from July 1993 to May 1994. He received his Ph.D. in immunology from the University of Pennsylvania, and has 20 years of experience in senior biotechnology management and over 10 years research experience as a professor at the Lineberger Comprehensive Cancer Center, University of North Carolina Chapel Hill School of Medicine, and as a member of the Institute for Immunology, Basel, Switzerland. Dr. Snodgrass is a past Board Member of the Emerging Company Section of the Biotechnology Industry Organization (BIO), and past member of the International Society Stem Cell Research Industry Committee. Dr. Snodgrass has published more than 50 scientific papers, is the inventor on more than 17 patents and a number of patent applications, is, or has been, the principal investigator on U.S. federal and private foundation sponsored research grants with budgets totaling more than \$14.5 million and is recognized as an expert in stem cell biology with more than 28 years' experience in the uses of stem cells as biological tools for research, drug discovery and development.

We selected Dr. Snodgrass to serve on our board of directors due to his expertise in biotechnology focused on developmental biology, including stem cell biology, his extensive senior management experience leading biotechnology companies at all stages of development, as well as his reputation and standing in the fields of biotechnology and stem cell research, allow him to bring to us and the Board of Directors a unique understanding of the challenges and opportunities associated with pluripotent stem cell biology, as well as credibility in the markets in which we operate.

Jerrold D. Dotson, CPA has served as our Chief Financial Officer since September 2011, as our Corporate Secretary since October 2013 and as a Vice President since February 2014. Mr. Dotson served as Corporate Controller for Discovery Foods Company, a privately held Asian frozen foods company from January 2009 to September 2011. From February 2007 through September 2008, Mr. Dotson served as Vice President, Finance and Administration (principal financial and accounting officer) for Calypte Biomedical Corporation (OTCBB: CBMC), a publicly held biotechnology company. Mr. Dotson served as Calypte's Corporate Secretary from 2001 through September 2008. He also served as Calypte's Director of Finance from January 2000 through July 2005 and was a financial consultant to Calypte from August 2005 through January 2007. Prior to joining Calypte, from 1988 through 1999, Mr. Dotson worked in various financial management positions, including Chief Financial Officer, for California & Hawaiian Sugar Company, a privately held company. Mr. Dotson is licensed as a CPA in California and received his BS degree in Business Administration with a concentration in accounting from Abilene Christian College.

Directors

Jon S. Saxe, J.D. has served as Chairman of our Board of Directors since 2000. He also serves as the Chairman of our Audit Committee. Mr. Saxe is the retired President and was a director of PDL BioPharma from 1989 to 2008. From 1989 to 1993, he was President, Chief Executive Officer and a director of Synergen, Inc. (acquired by Amgen). Mr. Saxe served as Vice President, Licensing & Corporate Development for Hoffmann-Roche from 1984 through 1989, and Head of Patent Law for Hoffmann-Roche from 1978 through 1989. Mr. Saxe currently is a director of SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN) and Durect Corporation (NASDAQ: DRRX), and six private life science companies, including Arbor Vita Corporation and Arcuo Medical, LLC. Mr. Saxe also has served as a director of other biotechnology and pharmaceutical companies, including ID Biomedical (acquired by GlaxoSmithKline), Sciele Pharmaceuticals, Inc. (acquired by Shionogi), Amalyte (acquired by Kemin Industries), Cell Pathways (acquired by OSI Pharmaceuticals), and other companies, both public and private. Mr. Saxe has a B.S.Ch.E. from Carnegie-Mellon University, a J.D. degree from George Washington University and an LL.M. degree from New York University.



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We selected Mr. Saxe to serve as Chairman of our Board of Directors due to numerous years of experience as a senior executive with major biopharmaceutical and biotechnology companies, including Protein Design Labs, Inc., Synergen, Inc. and Hoffmann-Roche, Inc., as well as his extensive experience serving as a director of numerous private and public biotechnology and pharmaceutical companies, serving as Chairman, and Chair and member of audit, compensation and governance committees of both private and public companies. Mr. Saxe provides us and our Board of Directors with highly valuable insight and perspective into the biotechnology and pharmaceutical industries, as well as the strategic opportunities and challenges that we face.

Brian J. Underdown, Ph.D. has served as a member of our Board of Directors since November 2009. Dr. Underdown has served as Managing Director of Lumira Capital Corp. since September 1997, having started in the venture capital industry in 1997 with MDS Capital Corporation (MDSCC). His investment focus has been on therapeutics in both new and established companies in both Canada and the United States. Prior to joining MDSCC, Dr. Underdown held a number of senior management positions in the biopharmaceutical industry and at universities. Dr. Underdown's past and current board positions include: ID Biomedical, Trillium Therapeutics, Cytochroma Inc., Argos Therapeutics, Nysa Membrane Technologies, Ception Therapeutics and Transmolecular Therapeutics. He has served on a number of Boards and advisory bodies of government sponsored research organizations including CANVAC, the Canadian National Centre of Excellence in Vaccines, Ontario Genomics Institute, Allergen, the Canadian National Centre of Excellence in Allergy and Asthma. Dr. Underdown obtained his Ph.D. in immunology from McGill University and undertook post-doctoral studies at Washington University School of Medicine.

We selected Dr. Underdown to serve on our Board of Directors due to his extensive background working in the biotechnology and pharmaceutical industries, as a director of numerous private and public companies, as well as his venture capital experience funding and advising start-up and established companies focused on therapeutics.

## Election of Executive Officers

Our executive officers are elected by, and serve at the discretion of, our board of directors. Each of our executive officers devotes his full time to our affairs. There are no family relationships among any of our directors or executive officers.

## Board Composition

Our Bylaws provide that the authorized number of directors of the Company shall be not less than one nor more than seven, with the exact number of directors currently fixed at seven. The exact number may be amended only by the vote or written consent of a majority of the outstanding shares of our voting stock. Our board of directors currently consists of four members. Accordingly, there are currently three vacancies on our board of directors. Our board of directors anticipates filling each of such vacancies as soon as practicable following the completion of this Offering. All actions of the board of directors require the approval of a majority of the directors in attendance at a meeting at which a quorum is present.

## Director Independence

Our securities are not currently listed on a national securities exchange or on any inter-dealer quotation system that has a requirement that directors be independent, or that a majority of our directors be independent. However, we evaluate independence by the standards for director independence established by applicable laws, rules, and listing standards, including, without limitation, the standards for independent directors established by the SEC, the New York Stock Exchange, Inc. and the NASDAQ Stock Market.





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Subject to some exceptions, these standards generally provide that a director will not be independent if (a) the director is, or in the past three years has been, an employee of ours; (b) a member of the director's immediate family is, or in the past three years has been, an executive officer of ours; (c) the director or a member of the director's immediate family has received more than \$120,000 per year in direct compensation from us other than for service as a director (or for a family member, as a non-executive employee); (d) the director or a member of the director's immediate family is, or in the past three years has been, employed in a professional capacity by our independent public accountants, or has worked for such firm in any capacity on our audit; (e) the director or a member of the director's immediate family is, or in the past three years has been, employed as an executive officer of a company where one of our executive officers serves on the compensation committee; or (f) the director or a member of the director's immediate family is an executive officer of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during the past three years, exceeds the greater of \$1,000,000 or two percent of that other company's consolidated gross revenues.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that Mr. Saxe and Dr. Underdown are "independent" as that term is defined under the applicable rules and regulations of the SEC. Our board of directors has also determined that Mr. Saxe and Dr. Underdown, who comprise our audit committee, compensation committee, corporate governance and nominating committee, satisfy the independence standards for those committees established by applicable SEC rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances that our board of directors deemed relevant.

### Board Committees

Our board of directors has established an audit committee, a compensation committee and a corporate governance and nominating committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our independent directors, Mr. Saxe and Dr. Underdown, are each members of the audit committee. Mr. Saxe and Dr. Underdown also currently serve as members of the compensation committee and the corporate governance and nominating committee.

### Audit Committee

Our audit committee is comprised of Mr. Saxe and Dr. Underdown. Mr. Saxe is the chairman of our audit committee and is our audit committee financial expert, as that term is defined under SEC rules implementing Section 407 of the Sarbanes Oxley Act of 2002, and possesses the requisite financial sophistication, as defined under applicable rules. The audit committee operates under a written charter. Our audit committee charter is available on our website. Under its charter, our audit committee is primarily responsible for, among other things,

overseeing our accounting and financial reporting process;

selecting, retaining and replacing our independent auditors and evaluating their qualifications, independence and performance;

reviewing and approving scope of the annual audit and audit fees;

monitoring rotation of partners of independent auditors on engagement team as required by law;

discussing with management and independent auditors the results of annual audit and review of quarterly financial statements;

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reviewing adequacy and effectiveness of internal control policies and procedures;

approving retention of independent auditors to perform any proposed permissible non-audit services;

overseeing internal audit functions and annually reviewing audit committee charter and committee performance; and

preparing the audit committee report that the SEC requires in our annual proxy statement.

Compensation Committee

Our compensation committee is comprised of Mr. Saxe and Dr. Underdown, who serves as the committee chairman. Our compensation committee charter is available on our website. Under its charter, the compensation committee is primarily responsible for, among other things,

Reviewing and approving our compensation programs and arrangements applicable to our executive officers (as defined in Rule I 6a-I (f) of the Exchange Act), including all employment-related agreements or arrangements under which compensatory benefits are awarded or paid to, or earned or received by, our executive officers, including, without limitation, employment, severance, change of control and similar agreements or arrangements;

Determining the objectives of our executive officer compensation programs;

Ensuring corporate performance measures and goals regarding executive officer compensation are set and determining the extent to which they are achieved and any related compensation earned;

Establishing goals and objectives relevant to CEO compensation, evaluating CEO performance in light of such goals and objectives, and determining CEO compensation based on the evaluation;

Endeavoring to ensure that our executive compensation programs are effective in attracting and retaining key employees and reinforcing business strategies and objectives for enhancing stockholder value;

Monitoring the administration of incentive-compensation plans and equity-based incentive plans as in effect and as adopted from time to time by the board;

Reviewing and approving any new equity compensation plan or any material change to an existing plan; and

Reviewing and approving any stock option award or any other type of award as may be required for complying with any tax, securities, or other regulatory requirement, or otherwise determined to be appropriate or desirable by the committee or board.

Corporate Governance and Nominating Committee

Our corporate governance and nominating committee is comprised of Mr. Saxe and Dr. Underdown, who serves as the committee chairman. Our corporate governance and nominating committee charter is available on our website. Under its charter, the corporate governance and nominating committee is primarily responsible for, among other things:

Monitoring the size and composition of the board;



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Making recommendations to the board with respect to the nominations or elections of our directors;

Reviewing the adequacy of our corporate governance policies and procedures and our Code of Business Conduct and Ethics, and recommending any proposed changes to the board for approval; and

Considering any requests for waivers from our Code of Business Conduct and Ethics and ensure that we disclose such waivers as may be required by the exchange on which we are listed, if any, and rules and regulations of the SEC.

## Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics applicable to our employees, officers and directors. Our Code of Business Conduct and Ethics is available on our website. We intend to disclose any future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of these provisions, on our website at [www.vistagen.com](http://www.vistagen.com) or in filings with the SEC under the Exchange Act.

## EXECUTIVE COMPENSATION

## Summary Compensation Table for Fiscal Years 2014 and 2013

This section provides compensation information about the following individuals:

Shawn K. Singh, J.D., our Chief Executive Officer (CEO) and director;  
H. Ralph Snodgrass, Ph.D., our President, Chief Scientific Officer (CSO) and director; and  
Jerrold D. Dotson, CPA, our Vice President, Chief Financial Officer (CFO) and Secretary

In the discussion below, we refer to this group of executives as the named executive officers (NEOs). This group includes the executive officers for whom disclosure is required under the applicable rules of the SEC.

The following table shows information regarding the compensation of our named executive officers for services performed in the fiscal years ended March 31, 2014 and 2013:

Name and Principal Position	Fiscal Year	Salary (\$)	Bonus (\$)	Option and Warrant Awards (7) (\$)	All Other Compensation (\$)	Total (\$)
Shawn K. Singh, J.D. (1) Chief Executive Officer	2014	250,000 (4)	-	159,802 (8)	-	409,802
	2013	201,646	-	802,411 (9)(10)	-	1,004,057
H. Ralph Snodgrass, Ph.D. (2) President, Chief Scientific	2014	250,000 (5)	-	102,353 (8)	-	352,353
	2013	203,086	-	534,941 (10)	-	738,027

Officer

Jerrold D. Dotson (3) Vice President, Chief Financial Officer, Secretary	2014	200,000	(6)	-	36,846	(8)	-	236,846
	2013	97,269		-	134,316	(11)	62,333 (12)	293,918

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- (1) Mr. Singh became VistaGen California's Chief Executive Officer on August 20, 2009 and our Chief Executive Officer in May 2011, in connection with the Merger. In our fiscal years ended March 31, 2014 and 2013, Mr. Singh's annual base cash salary, excluding potential cash bonus amounts, pursuant to his January 2010 employment agreement was contractually set at \$347,500. However, to conserve cash for our operations during our fiscal years ended March 31, 2014 and 2013, Mr. Singh voluntarily reduced his base cash salary in each of such fiscal years to the amounts indicated. In addition, pursuant to his employment agreement, Mr. Singh is eligible to receive an annual incentive bonus of up to fifty percent (50%) of his base cash salary. However to conserve cash for our operations during our fiscal years ended March 31, 2014 and 2013, Mr. Singh voluntarily refrained from receiving any cash bonus from us.
- (2) Through August 20, 2009, Dr. Snodgrass served as VistaGen California's President and Chief Executive Officer, at which time he became its President and Chief Scientific Officer. He became our President and Chief Scientific Officer in May 2011, in connection with the Merger. In our fiscal years ended March 31, 2014 and 2013, Dr. Snodgrass' annual base cash salary, excluding potential cash bonus amounts, pursuant to his January 2010 employment agreement was contractually set at \$305,000. However, to conserve cash for our operations during our fiscal years ended March 31, 2014 and 2013, Dr. Snodgrass voluntarily reduced his base cash salary in each of such fiscal years to the amounts indicated. In addition, pursuant to his employment agreement, Dr. Snodgrass is eligible to receive an annual incentive bonus of up to fifty percent (50%) of his base cash salary. However to conserve cash for our operations during our fiscal years ended March 31, 2014 and 2012, Dr. Snodgrass voluntarily refrained from receiving any cash bonus from us.
- (3) Mr. Dotson served as Chief Financial Officer on a part-time contract basis from September 19, 2011 through August 2012, at which time he became a full-time employee of the Company.
- (4) Of this amount, Mr. Singh received only \$125,000 in cash; the remaining balance has been accrued for future payment.
- (5) Of this amount, Dr. Snodgrass received only \$149,606 in cash; the remaining balance has been accrued for future payment.
- (6) Of this amount, Mr. Dotson received only \$143,333 in cash; the remaining balance has been accrued for future payment.
- (7) The amounts in Option and Warrant Awards column do not represent any cash payments actually received by Mr. Singh, Dr. Snodgrass or Mr. Dotson with respect to any of the options or warrants to purchase restricted shares of our common stock awarded to them or modified during the periods presented. Rather, the amounts in the Option and Warrant Awards column represent the deemed aggregate grant date fair value of options or warrants to purchase restricted shares of our common stock awarded to Mr. Singh, Dr. Snodgrass and Mr. Dotson or the effect of modifications to prior grants of options or warrants occurring during the fiscal year presented, computed in accordance with the Financial Accounting Standards Board's Accounting

Standards Codification Topic 718, Compensation – Stock Compensation (ASC 718). Except as indicated in note (9) below, to date, Mr. Singh, Dr. Snodgrass and Mr. Dotson have not exercised such options or warrants to purchase common stock, and there can be no assurance that any of them will ever realize any of the ASC 718 grant date fair value amounts presented in the Option and Warrant Awards column.



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The table below provides information regarding the option and warrant awards and modifications we granted to Mr. Singh, Dr. Snodgrass and Mr. Dotson during fiscal 2014 and the assumptions used in the Black Scholes Option Pricing Model to determine the grant date fair values of the respective awards and modifications:

	Option Grant 10/27/2013	Warrant Grant 3/19/2014	Option Modification 12/20/2013	Warrant Modification 12/20/2013	Option/ Warrant Exchange (a) 3/19/2014	Total		
Singh	\$ -	\$ -	\$ 134,436	\$ 25,366	\$ -	\$ 159,802		
Snodgrass	-	14,560	56,835	-	30,958	102,353		
Dotson	6,380	29,120	1,346	-	-	36,846		
	\$ 6,380	\$ 43,680	\$ 192,617	\$ 25,366	\$ 30,958	\$ 299,001		
			Before	After	Before	After	Before	After
Market price per share	\$ 0.40	\$ 0.46	\$ 0.40	\$ 0.40	\$ 0.40	\$ 0.40	\$ 0.46	\$ 0.46
Exercise price per share	\$ 0.40	\$ 0.50	\$0.75 to \$2.10	\$ 0.50	\$0.50 to \$1.75	\$ 0.50	\$ 0.50	\$ 0.50
Risk-free interest rate	1.675 %	1.750 %	0.7% to 2.68%	0.12% to 2.68%	0.07% to 1.18%	0.75% to 1.18%	0.106 %	1.750 %
Volatility	99.53 %	80.57 %	68.8% to 97.6%	68.8% to 97.6%	68.76% to 78.21%	76.51% to 78.21%	68.96 %	80.57 %
Expected term (years)	6.25	5.00	0.25 to 8.86	0.87 to 8.86	0.03 to 3.96	3.03 to 3.96	0.63	5.00
Dividend rate	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
Fair value per share	\$ 0.32	\$ 0.29	\$0.00 to \$0.32	\$0.07 to \$0.34	\$0.00 to \$0.11	\$0.18 to \$0.21	\$ 0.08	\$ 0.29
Aggregate shares	20,000	150,000	2,322,500	2,322,500	166,052	166,052	150,000	150,000

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(a) On March 19, 2014, the Board and Dr. Snodgrass agreed to cancel a fully-vested option to purchase 150,000 shares of our restricted common stock at a price of \$0.50 per share and expiring on November 4, 2014 in exchange for the grant of a five-year warrant to purchase 150,000 shares of our restricted common stock at a price of \$0.50 per share. Shares subject to the cancelled option grant were returned to the 2008 Stock Incentive Plan for potential future grants. The cancellation of the option and grant of the warrant was accounted for as a modification of an award under ASC 718 and, accordingly, the difference in the fair value of the two instruments at the modification date was recorded in stock compensation expense and is the amount reported in the table above.

(9) In June and October 2013, Mr. Singh exercised warrants granted to him in March 2013, described in Note 10, below, to purchase an aggregate of 60,000 shares of our restricted common stock at \$0.64 per share. Mr. Singh continues to hold the shares of our restricted common stock issued upon his exercise of the warrants.

(10) We used the Black Scholes Option Pricing Model and the following assumptions for determining the grant date fair value of the warrants to purchase shares of our common stock granted in March 2013.

Market price per share	\$	0.64
Exercise price per share	\$	0.64
Risk-free interest rate		1.86%
Expected Term (years)		10.0
Volatility		84.73%
Dividend rate		0.0%
Grant date fair value per share	\$	0.53

Mr. Singh, Dr. Snodgrass and Mr. Dotson were granted warrants to purchase 1,500,000, 1,000,000 and 200,000 restricted shares of our common stock, respectively.

(11) In October 2012, we modified the stock option award granted to Mr. Dotson in September 2011 to reduce the exercise price of the option from \$2.58 per share to \$0.75 per share and granted him a new stock option to purchase an additional 50,000 restricted shares of our common stock. We used the Black Scholes Option Pricing Model and the following assumptions to determine incremental fair value of the modified option and the grant date fair value of \$0.51 per share for the new option: market price per share: \$0.71; exercise price per share: \$0.75; risk-free interest rate: 1.00%; expected term: 6.25 years; volatility 85.35%; dividend rate: 0%. The figure reported includes (i) the grant date fair value of the warrant granted to Mr. Dotson, determined in accordance with the assumptions described in note 5 above, \$106,988; (ii) the fair value of the new option, \$25,385; and (iii) the incremental fair value resulting from the modification of the September 2011 stock option grant, \$1,943.

(12) Amount shown represent cash compensation paid to Mr. Dotson under the terms of the consulting agreement between us and Mr. Dotson for the period April 2012 through August 2012.

None of the NEOs is entitled to perquisites or other personal benefits that, in the aggregate, are worth over \$50,000 or over 10% of their base salary.

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## Options and Warrants Granted to Named Executive Officers

The following table provides information regarding each unexercised stock option and warrant to purchase restricted shares of our common stock held by each of the named executive officers as of March 31, 2014:

Name	Stock Options		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
Shawn K. Singh, J.D.	20,000	-	0.80	12/21/2016
	40,000	-	0.72	5/17/2017
	20,000	-	0.50	1/17/2018
	20,000	-	0.50	1/17/2018
	60,000	-	0.50	3/24/2019
	22,500	-	0.50	6/17/2019
	1,000,000	-	0.50	11/4/2019
	425,000	-	0.50	12/30/2019
	72,916	27,084	0.50	4/25/2021
	80,338	-	0.50	12/31/2016
	35,714	-	0.50	12/31/2016
	50,000	-	0.50	12/6/2017
	100,000	-	1.00	7/30/2016
	690,000	750,000 (1)	0.64	3/3/2023
<b>Total:</b>	<b>2,636,468</b>	<b>777,084</b>		
H. Ralph Snodgrass, Ph.D.	50,000	-	0.50	3/24/2019
	25,000	-	0.50	6/17/2014
	6,362	-	0.88	12/20/2016
	250,000	-	0.50	12/30/2019
	72,916	27,084	0.50	4/25/2021
	500,000	500,000 (1)	0.64	3/3/2023
	-	50,000 (2)	0.50	3/19/2024
	-	150,000 (2)	0.50	3/19/2024
<b>Total:</b>	<b>904,278</b>	<b>727,084</b>		
Jerrold D. Dotson	74,782	25,218	0.50	10/30/2022
	4,166	15,834	0.40	10/27/2023
	100,000	100,000 (1)	0.64	3/3/2023
	-	100,000 (2)	0.50	3/19/2024
<b>Total:</b>	<b>178,948</b>	<b>241,052</b>		

(1) Represents warrant to purchase restricted shares of our common stock granted on March 3, 2013 at the market price of our common stock on the grant date. At March 31, 2014, the warrant is exercisable for 50% of the shares and becomes exercisable

for 25% of the shares on April 1, 2014 and will become fully vested on April 1, 2015 or upon a change in control of the Company, as defined, or upon the consummation by the Company and a third party of a license or sale transaction involving at least one new Drug Rescue Variant.

- (2) Represents warrant to purchase restricted shares of our common stock granted on March 19, 2014 when the market price of our common stock was \$0.46 per share. The warrant becomes exercisable for 50% of the shares on April 1, 2014, 25% of the shares on April 1, 2015 and 25% of the shares on April 1, 2016, provided that the warrant will become fully vested upon a change in control of the Company, as defined, or upon the consummation by the Company and a third party of a license or sale transaction involving at least one new Drug Rescue Variant.

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### Employment or Severance Agreements

We have employment agreements with Mr. Singh and Dr. Snodgrass.

#### Singh Agreement

We entered into an employment agreement with Mr. Singh on April 28, 2010. Under the agreement, as amended on May 9, 2011, Mr. Singh's base salary is \$347,500 per year. However, Mr. Singh has not received his full base salary in any fiscal year since he entered into his agreement in 2010. In each of our fiscal years ended March 31, 2014, 2013, 2012 and 2011, Mr. Singh voluntarily reduced his base salary to \$250,000, \$201,646, 292,268 and \$168,274, respectively, to conserve cash for our operations. Although, under his agreement, Mr. Singh is eligible to receive an annual incentive cash bonus of up to 50% of his base salary, he has voluntarily foregone any such cash bonus payment to conserve cash for our operations. Payment of his annual incentive bonus is at the discretion of our board of directors. In the event we terminate Mr. Singh's employment without cause, he is entitled to receive severance in an amount equal to:

twelve months of his then-current base salary payable in the form of salary continuation;

a pro-rated portion of the incentive cash bonus that the board of directors determines in good faith that Mr. Singh earned prior to his termination; and

such amounts required to reimburse him for Consolidated Omnibus Budget Reconciliation Act (COBRA) payments for continuation of his medical health benefits for such twelve-month period.

In addition, in the event Mr. Singh terminates his employment with good reason following a change of control, he is entitled to twelve months of his then-current base salary payable in the form of salary continuation.

In December 2006, we accepted a full-recourse promissory note in the amount of \$103,411 from Mr. Singh in payment of the exercise price for options and warrants to purchase an aggregate of 126,389 shares of our common stock. On May 11, 2011, in connection with the Merger, the \$128,168 outstanding balance of the principal and accrued interest on this note was cancelled in accordance with Mr. Singh's employment agreement and was treated as additional compensation. In accordance with his employment agreement, Mr. Singh is entitled to an income tax gross-up payment on the compensation related to the note cancellation. At March 31, 2014 and 2013, we had accrued \$101,936 as an estimate of the gross-up amount. However, at Mr. Singh's suggestion, we have not yet paid such amount to Mr. Singh to conserve capital for our operations. See Notes 9 and 14 to our audited consolidated financial statements that are included elsewhere in this prospectus.

#### Snodgrass Agreement

We entered into an employment agreement with Dr. Snodgrass on April 28, 2010. As amended on May 9, 2011, under the agreement, Dr. Snodgrass's base salary is \$305,000 per year. However, Dr. Snodgrass has not received his full base salary in any fiscal year since he entered into his agreement in 2010. In each of our fiscal years ended March 31, 2014, 2013, 2012 and 2011, Dr. Snodgrass voluntarily reduced his annual salary to \$250,000, \$203,086, \$249,266 and \$141,486, respectively, to conserve cash for our operations. Dr. Snodgrass is eligible to receive an annual incentive cash bonus of up to 50% of his base salary. Payment of his annual incentive bonus is at the discretion of the board of directors. In the event we terminate Dr. Snodgrass's employment without cause, he is entitled to receive severance in an amount equal to

twelve months of his then-current base salary payable in the form of salary continuation;

a pro-rated portion of the incentive bonus that the board of directors determines in good faith that Dr. Snodgrass earned prior to his termination; and

such amounts required to reimburse him for COBRA payments for continuation of his medical health benefits for such twelve-month period.

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In addition, in the event Dr. Snodgrass terminates his employment with good reason, he is entitled to twelve months of his then-current base salary payable in the form of salary continuation.

### Change of Control Provisions

Pursuant to each of their respective employment agreements, Dr. Snodgrass is entitled to severance if he terminates his employment at any time for “good reason” (as defined below), while Mr. Singh is entitled to severance if he terminates his employment for good reason after a change of control. Under their respective agreements, “good reason” means any of the following events, if the event is effected by us without the executive’s consent (subject to our right to cure):

a material reduction in the executive’s responsibility; or

a material reduction in the executive’s base salary following the Merger except for reductions that are comparable to reductions generally applicable to similarly situated executives of the Company.

Furthermore, pursuant to their respective employment agreements and their stock option award agreements as amended, in the event we terminate the executive without cause within twelve months of a change of control, the executive’s remaining unvested shares become fully vested and exercisable. Upon a change of control in which the successor corporation does not assume the executive’s stock options, the stock options granted to the executive become fully vested and exercisable.

Pursuant to their respective employment agreements, a change of control occurs when: (i) any “person” as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (other than the Company, a subsidiary, an affiliate, or the Company employee benefit plan, including any trustee of such plan acting as trustee), becoming the “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company’s then outstanding securities; (ii) a sale of substantially all of the Company’s assets; or (iii) any merger or reorganization of the Company whether or not another entity is the survivor, pursuant to which the holders of all the shares of capital stock of the Company outstanding prior to the transaction hold, as a group, fewer than 50% of the shares of capital stock of the Company outstanding after the transaction.

In the event that following termination of employment amounts are payable to an executive pursuant to his employment agreement, the executive’s eligibility for severance is conditioned on executive having first signed a release agreement.

Pursuant to their respective employment agreements, the estimated amount that could be paid by us assuming that a change of control occurred on the last business day of our current fiscal year, is \$347,500 for Mr. Singh and \$305,000 for Dr. Snodgrass, excluding the imputed value of accelerated vesting of incentive stock options, if any.

### Employee Benefit Plans

#### Equity Grants

As of March 31, 2014, options to purchase a total of 4,249,271 shares of common stock are outstanding at a weighted average exercise price of \$0.50 per share, of which 3,655,061 options are vested and exercisable at a weighted average exercise price of \$0.50 per share and 593,867 are unvested and unexercisable at a weighted average exercise price of \$0.51 per share. These options were issued under our 2008 Plan and our 1999 Plan, each as more particularly described below. At March 31, 2014, an additional 735,200 shares remain available for future equity grants under our



2008 Plan.

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2008 Stock Incentive Plan

Our stockholders adopted our 2008 Stock Incentive Plan (2008 Plan) on December 19, 2008. The maximum number of shares of our common stock that may be granted pursuant to the 2008 Plan is currently 5,000,000. In all cases, the maximum number of shares of common stock under the 2008 Plan will be subject to adjustments for stock splits, stock dividends or other similar changes in our common stock or our capital structure. Notwithstanding the foregoing, the maximum number of shares of common stock available for grant of options intended to qualify as “incentive stock options” under the provisions of Section 422 of the Internal Revenue Code of 1986 (the Code), is 5,000,000.

Our 2008 Plan provides for the grant of stock options, restricted shares of common stock, stock appreciation rights and dividend equivalent rights, collectively referred to as “awards”. Stock options granted under the 2008 Plan may be either incentive stock options under the provisions of Section 422 of the Code, or non-qualified stock options. We may grant incentive stock options only to our employees. Awards other than incentive stock options may be granted to employees, directors and consultants.

Our board of directors or the compensation committee of the board of directors, referred to as the “Administrator”, administers our 2008 Plan, including selecting the award recipients, determining the number of shares to be subject to each award, determining the exercise or purchase price of each award and determining the vesting and exercise periods of each award.

The exercise price of all incentive stock options granted under our 2008 Plan must be at least equal to 100% of the fair market value of the shares on the date of grant. However, incentive stock options granted to an employee who owns stock possessing more than 10% of the voting power of all classes of our stock or the stock of any parent or subsidiary of us, must have an exercise price of not less than 110% of the fair market value on the grant date. The maximum term of these incentive stock options granted to employees who own stock possessing more than 10% of the voting power of all classes of our stock or the stock of any parent or subsidiary of us must not exceed five years. The maximum term of an incentive stock option granted to any other participant must not exceed ten years. The Administrator will determine the term and exercise or purchase price of all other awards granted under our 2008 Plan.

Under the 2008 Plan, incentive stock options may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the participant, only by the participant. Other awards shall be transferable:

by will and by the laws of descent and distribution; and

during the lifetime of the participant, to the extent and in the manner authorized by the Administrator by gift or pursuant to a domestic relations order to members of the participant’s immediate family.

The 2008 Plan permits the designation of beneficiaries by holders of awards, including incentive stock options. In the event of termination of a participant’s service for any reason other than disability or death, such participant may, but only during the period specified in the award agreement of not less than 30 days commencing on the date of termination (but in no event later than the expiration date of the term of such award as set forth in the award agreement), exercise the portion of the participant’s award that was vested at the date of such termination or such other portion of the participant’s award as may be determined by the Administrator. The participant’s award agreement may provide that upon the termination of the participant’s service for cause, the participant’s right to exercise the award shall terminate concurrently with the termination of the participant’s service. In the event of a participant’s change of status from employee to consultant, an employee’s incentive stock option shall convert automatically into a non-qualified stock option on the day three months and one day following such change in status. To the extent that the participant’s award was unvested at the date of termination, or if the participant does not exercise the vested portion of the

participant's award within the period specified in the award agreement of not less than 30 days commencing on the date of termination, the award shall terminate. If termination was caused by death or disability, any options which have become exercisable prior to the time of termination, will remain exercisable for twelve months from the date of termination (unless a shorter or longer period of time is determined by the Administrator).

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Following the date that the exemption from application of Section 162(m) of the Code ceases to apply to awards, the maximum number of shares with respect to which options and stock appreciation rights may be granted to any participant in any calendar year will be 2,500,000 shares of Common Stock. In connection with a participant's commencement of service with us, a participant may be granted options and stock appreciation rights for up to an additional 500,000 shares that will not count against the foregoing limitation. In addition, following the date that the exemption from application of Section 162(m) of the Code ceases to apply to awards, for awards of restricted stock and restricted shares of Common Stock that are intended to be "performance-based compensation" (within the meaning of Section 162(m)), the maximum number of shares with respect to which such awards may be granted to any participant in any calendar year will be 2,500,000 shares of common stock. The limits described in this paragraph are subject to adjustment in the event of any change in our capital structure as described below.

The terms and conditions of awards shall be determined by the Administrator, including the vesting schedule and any forfeiture provisions. Awards under the plan may vest upon the passage of time or upon the attainment of certain performance criteria. The performance criteria established by the Administrator may be based on any one of, or combination of, the following:

increase in share price;

earnings per share;

total shareholder return;

operating margin;

gross margin;

return on equity;

return on assets;

return on investment;

operating income;

net operating income;

pre-tax profit;

cash flow;

revenue;

expenses;

earnings before interest, taxes and depreciation;

economic value added; and

market share.



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Subject to any required action by our stockholders, the number of shares of common stock covered by outstanding awards, the number of shares of common stock that have been authorized for issuance under the 2008 Plan, the exercise or purchase price of each outstanding award, the maximum number of shares of common stock that may be granted subject to awards to any participant in a calendar year, and the like, shall be proportionally adjusted by the Administrator in the event of any increase or decrease in the number of issued shares of common stock resulting from certain changes in our capital structure as described in the 2008 Plan.

Effective upon the consummation of a Corporate Transaction (as defined below), all outstanding awards under the 2008 Plan will terminate unless the acquirer assumes or replaces such awards. The Administrator has the authority, exercisable either in advance of any actual or anticipated Corporate Transaction or Change in Control (as defined below) or at the time of an actual Corporate Transaction or Change in Control and exercisable at the time of the grant of an award under the 2008 Plan or any time while an award remains outstanding, to provide for the full or partial automatic vesting and exercisability of one or more outstanding unvested awards under the 2008 Plan and the release from restrictions on transfer and repurchase or forfeiture rights of such awards in connection with a Corporate Transaction or Change in Control, on such terms and conditions as the Administrator may specify. The Administrator also shall have the authority to condition any such award vesting and exercisability or release from such limitations upon the subsequent termination of the service of the grantee within a specified period following the effective date of the Corporate Transaction or Change in Control. The Administrator may provide that any awards so vested or released from such limitations in connection with a Change in Control, shall remain fully exercisable until the expiration or sooner termination of the award.

Under our 2008 Plan, a Corporate Transaction is generally defined as:

an acquisition of securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities but excluding any such transaction or series of related transactions that the Administrator determines shall not be a Corporate Transaction;

a reverse merger in which we remain the surviving entity but: (i) the shares of common stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise; or (ii) in which securities possessing more than fifty percent (50%) of the total combined voting power of our outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger;

a sale, transfer or other disposition of all or substantially all of the assets of our corporation;

a merger or consolidation in which our corporation is not the surviving entity; or

a complete liquidation or dissolution.

Under our 2008 Plan, a Change in Control is generally defined as: (i) the acquisition of more than 50% of the total combined voting power of our stock by any individual or entity which a majority of our Board of Directors (who have served on our board for at least 12 months) do not recommend our stockholders accept; (ii) or a change in the composition of our board of directors over a period of 12 months or less.

Unless terminated sooner, our 2008 Plan will automatically terminate in 2017. Our board of directors may at any time amend, suspend or terminate our 2008 Plan. To the extent necessary to comply with applicable provisions of U.S. federal securities laws, state corporate and securities laws, the Code, the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to awards granted to residents therein, we shall obtain shareholder approval of any such amendment to the 2008 Stock Plan in such a manner and to such a

degree as required.

As of July 1, 2014, we had options to purchase an aggregate of 3,964,800 shares of common stock outstanding under our 2008 Plan.

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### 1999 Stock Incentive Plan

Our Board of Directors adopted our 1999 Plan on December 6, 1999. The 1999 Plan has terminated under its own terms, and as a result, no awards may currently be granted under the 1999 Plan. However, most of the options and awards that have already been granted pursuant to the 1999 Plan remain outstanding.

The 1999 Plan permitted us to make grants of incentive stock options, non-qualified stock options and restricted stock awards. We initially reserved 450,000 shares of our common stock for the issuance of awards under the 1999 Plan, which number was subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. Generally, shares that were forfeited or cancelled from awards under the 1999 Plan also were available for future awards until the date the 1999 Plan terminated under its own terms.

The 1999 Plan could be administered by either our board of directors or a committee designated by our board of directors. Our board of directors designated our compensation committee as the committee with full power and authority to select the participants to whom awards were granted, to make any combination of awards to participants, to accelerate the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 1999 Plan. All of our directors, executive officers, employees, and certain other key persons (including consultants and advisors) were eligible to participate in the 1999 Plan.

The exercise price of incentive stock options awarded under the 1999 Plan could not be less than the fair market value of the common stock on the date of the option grant and could not be less than 110% of the fair market value of our common stock to persons owning stock representing more than 10% of the voting power of all classes of our stock. The exercise price of non-qualified stock options could not be less than 85% of the fair market value of our common stock. It is expected that the term of each option granted under the 1999 Plan will not exceed ten years (or five years, in the case of an incentive stock option granted to a 10% shareholder) from the date of grant. Our compensation committee determined at what time or times each option may be exercised (provided that in no event may it exceed ten years from the date of grant) and, subject to the provisions of the 1999 Plan, the period of time, if any, after retirement, death, disability or other termination of employment during which options could be exercised.

Restricted stock could also be granted under our 1999 Plan. Restricted stock awards issued by us were shares of common stock that vest in accordance with terms and conditions established by our compensation committee, which could impose conditions to vesting it determined to be appropriate. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture. Our compensation committee determined the number of shares of restricted stock granted to any employee. Our 1999 Plan also gave our compensation committee discretion to grant stock awards free of any restrictions.

Unless the compensation committee provided otherwise, our 1999 Plan did not generally allow for the transfer of incentive stock options and other awards and only the recipient of an award could exercise an award during his or her lifetime. Non-qualified stock options shall be transferable only to the extent provided in the award agreement, in a manner consistent with the applicable law, and by will and by the laws of descent and distribution. In the event of a change in control, any unvested outstanding options will automatically vest unless our board of directors and the board of directors of the surviving or acquiring entity shall, as to outstanding awards under the 1999 Plan, make appropriate provisions for the continuation or assumption of such awards.

As of July 1, 2014, we had options to purchase an aggregate of 262,557 shares of our common stock outstanding under our 1999 Plan.

### 401(k) Plan



We sponsor a defined contribution plan intended to qualify under Section 401 of the Code, or a 401(k) plan. Employees who are at least 21 years of age are generally eligible to participate and may enter the plan on the first day of any month. Participants may make pre-tax contributions up to the maximum limit established by the Code. Each participant is fully vested in his or her contributions and the investment earnings on those contributions. Participant contributions are held in trust as required by law. Individual participants may direct the trustee to invest their accounts in authorized investment alternatives. The plan allows for Company matching contributions, but does not require them. We have not yet made any contributions to the plan. Pre-tax contributions to the plan, and the income earned on these contributions, are generally not taxable to the participants until withdrawn.

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## 2014 Director Compensation Table

We do not have a formal compensation plan for our non-employee directors. Our informal plan prescribes that the chairman of our board of directors, who is an independent director, has, since October 1, 2011, earned \$2,500 per quarter. Our other independent directors have earned \$2,000 per quarter since that date. Beginning in July 2011, the chairman of our audit committee and each independent director who serves as a member of our audit committee have also earned \$1,000 quarterly. In addition, from time to time, our independent directors may receive non-qualified stock option, warrants or other equity-based awards. We did not pay our independent directors cash compensation during our fiscal year ended March 31, 2014.

The following table sets forth a summary of the compensation earned by our non-employee directors in our fiscal year ended March 31, 2014.

Name	Fees Earned or Paid in Cash (1) (\$)	Option and Warrant Awards (2) (\$)	Other Compensation (\$)	Total (\$)
Jon S. Saxe (3)	14,000	40,683(5)	-	54,683
Brian J. Underdown, Ph.D. (4)	12,000	32,267(5)	-	44,267

(1) The amounts shown represent fees earned for service on our board of directors and audit committee during the fiscal year which we have accrued but have not paid to the director at March 31, 2014.

(2) The amounts in this column represent the aggregate grant date fair value of warrants to purchase restricted shares of our common stock awarded to Mr. Saxe and Dr. Underdown or the effect of modifications to prior grants of options or warrants occurring during the fiscal year ended March 31, 2014, computed in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718, Compensation – Stock Compensation (ASC 718). The amounts in this column do not represent any cash payment actually received by Mr. Saxe or Dr. Underdown with respect to any of such options or warrants to purchase restricted shares of our common stock awarded to them or modified during the fiscal year ended March 31, 2014. To date, Mr. Saxe and Dr. Underdown have not exercised such options or warrants to purchase common stock, and there can be no assurance that either of them will ever realize any of the ASC 718 grant date fair value amounts presented in the Option and Warrant Awards column.

(3) Mr. Saxe has served as the chairman of our board of directors and the chairman of our audit committee throughout our fiscal year ended March 31, 2014. At March 31, 2014, Mr. Saxe holds: (i) 37,492 restricted shares of our common stock; (ii) options to purchase 264,750 restricted shares of our common stock, of which options to purchase 251,208 restricted shares are vested; and (iii) warrants to purchase 265,000 restricted shares of our common stock, of which 125,000 are exercisable.

- (4) Dr. Underdown has served as a member of our board of directors and a member of our audit committee throughout our fiscal year ended March 31, 2014. At March 31, 2014, Dr. Underdown holds: (i) options to purchase 185,000 restricted shares of our common stock, of which options to purchase 171,458 restricted shares are vested; and (ii) warrants to purchase 250,000 restricted shares of our common stock, of which 125,000 are exercisable.

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The table below provides information regarding the warrant awards and option and warrant modifications we granted to Mr. Saxe and Dr. Underdown during fiscal 2014 and the assumptions used in the Black Scholes Option Pricing Model to determine the grant date fair values of the respective awards and modifications:

	Warrant Grant 3/19/2014	Option Modification 12/20/2013	Warrant Modification 12/20/2013	Total
Saxe	\$ 18,928	\$ 15,291	\$ 6,464	\$ 40,683
Underdown	14,560	11,243	6,464	32,267
	\$ 33,488	\$ 26,534	\$ 12,928	\$ 72,950
	Before	After	Before	After
Market price per share	\$ 0.46	\$ 0.40	\$ 0.40	\$ 0.40
Exercise price per share	\$ 0.50	\$ 1.13 to \$2.10	\$ 0.50	\$ 0.50
Risk-free interest rate	1.750%	1.24% to 2.40%	1.24% to 2.40%	4.25%
Volatility	80.57%	78.9% to 97.62%	78.9% to 97.62%	76.10%
Expected term (years)	5.00	4.08 to 7.35	4.08 to 7.35	2.15
Dividend rate	0%	0%	0%	0%
Fair value per share	\$ 0.29	\$ 0.10 to \$0.27	\$ 0.21 to \$0.32	\$ 0.14
Aggregate shares	115,000	422,500	422,500	100,000

## Changes to Director Compensation for Fiscal Year Ending March 31, 2015

We have adopted a new director compensation policy for our independent directors, as independence is defined by the NASDAQ Stock Market, effective for our fiscal year beginning April 1, 2014. Under the new independent director compensation policy, our independent directors will receive a \$25,000 annual cash retainer. For service on a committee of the board, an independent director will receive an additional annual cash retainer as follows: \$7,500 for audit and compensation committee members and \$5,000 for nominating and governance committee members. In lieu of the annual cash retainer for committee participation, each independent director serving as a chair of a board committee shall receive the following annual cash retainer: \$15,000 for audit and compensation committee chairs and \$10,000 for the nominating and governance committee chairs. Each independent director will also receive an annual grant of an option to purchase 25,000 shares, which will vest monthly over a one-year period from the date of grant. The first grant of options under this policy will be made effective as soon as practicable following April 1, 2014. Future grants are expected to be made on the same date as our annual meeting. Prorated option grants will be made for partial years of service.

## Limitations of Liability and Indemnification

Our Bylaws provide that we will indemnify our directors, officers and employees to the fullest extent permitted by the Nevada Revised Statutes (NRS).

If the NRS are amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by the NRS, as so amended. Our articles of incorporation do not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, will remain available under the NRS. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our Bylaws, we are empowered to enter into indemnification agreements with our directors, officers and employees to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

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In addition to the indemnification required in our Bylaws, we have entered into indemnification agreements with each of the individuals serving on our board of directors. These agreements provide for the indemnification of our directors to the fullest extent permitted by law. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors, officers and employees. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our Bylaws may discourage shareholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and certain employees pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of July 1, 2014 and as adjusted to reflect the sale of all common stock offered by us in this Offering for:

each stockholder known by us to be the beneficial owner of more than 5% of our common stock;  
each of our directors;  
each of our named executive officers; and  
all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all of the capital stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 25,506,877 shares of capital stock outstanding at July 1, 2014. In computing the number of shares of common stock beneficially owned by a person, we deemed to be outstanding all shares of common stock subject to options or warrants held by that person or entity that are currently exercisable or that will become exercisable within 60 days of July 1, 2014 and all shares of common stock issuable pursuant to promissory notes and related accrued interest convertible into shares of common stock at July 1, 2014. In computing the percentage of shares beneficially owned before this Offering, we deemed to be outstanding all shares of common stock subject to options or warrants held by that person or entity that are currently exercisable or that will become exercisable within 60 days of July 1, 2014 and all shares of common stock issuable pursuant to promissory notes and related accrued interest convertible into shares of common stock at July 1, 2014. Unless otherwise noted below, the address of each beneficial owner listed in the table is c/o VistaGen Therapeutics, Inc., 343 Allerton Avenue, South San Francisco, California 94080.



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Name and address of beneficial owner	Number of shares beneficially owned	Percent of shares beneficially owned before Offering	Percent of shares beneficially owned after Offering
<b>Executive officers and directors</b>			
Shawn K. Singh, JD (1)	3,467,459	12.14%	___%
H. Ralph Snodgrass, PhD (2)	2,469,163	9.22%	___%
Jerrold D. Dotson (3)	314,107	1.22%	___%
Jon S. Saxe (4)	474,158	1.83%	___%
Brian J. Underdown, PhD (5)	364,166	1.41%	___%
<b>5% Stockholders</b>			
Cato BioVentures (6)	4,708,257	17.50%	___%
Platinum Long Term Growth Fund VII (7)	1,540,000	6.04%	___%
Morrison & Foerster LLP (8)	2,233,957	8.11%	___%
David Young (9)	2,104,977	7.88%	___%
University Health Network (10)	1,758,463	6.73%	___%
All executive officers and directors as a group (5 persons) (11)	7,089,053	22.91%	___%

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- (1) Includes options to purchase 1,690,833 restricted shares of common stock exercisable within 60 days of July 1, 2014; warrants to purchase 1,331,052 restricted shares of common stock exercisable within 60 days of July 1, 2014, and 33,400 restricted shares of common stock upon conversion of a currently convertible promissory note and accrued interest.
- (2) Includes options to purchase 414,695 restricted shares of common stock exercisable within 60 days of July 1, 2014 and warrants to purchase 850,000 restricted shares of common stock exercisable within 60 days of July 1, 2014.
- (3) Includes options to purchase 114,107 restricted shares of common stock exercisable within 60 days of July 1, 2014, including options to purchase 12,979 shares of common stock held by Mr. Dotson's wife, and warrants to purchase 200,000 restricted shares of common stock exercisable within 60 days of July 1, 2014.
- (4) Includes options to purchase 241,666 restricted shares of common stock exercisable within 60 days of July 1, 2014 and warrants to purchase 195,000 restricted shares of common stock exercisable within 60 days of July 1, 2014.
- (5) Includes options to purchase 176,666 restricted shares of common stock exercisable within 60 days of July 1, 2014 and warrants to purchase 187,500 restricted shares of common stock exercisable within 60 days of July 1, 2014.
- (6) Based upon information contained in Form 4 filed on January 9, 2012. Includes currently exercisable warrants to purchase 1,397,421 shares of restricted common stock. Dr. Allen E. Cato, Ph.D., M.D. is deemed to have voting and investment authority over the shares held by Cato Holding Company. The primary business address



of Cato BioVentures is 4364 South Alston Avenue, Durham, North Carolina 27713.

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- (7) Based upon information contained in Schedule 13G/A filed on February 14, 2014, we have assumed that Platinum has transferred or assigned, or agreed to transfer or assign, 15% of its holdings of our common stock and other securities as of December 31, 2013 to a third-party or multiple third-parties. The figures reported in the table above and in this note reflect the impact of Platinum's assumed transfer or assignment and are adjusted for securities sold to Platinum in transactions completed on April 1, 2014, May 14, 2014 and June 18, 2014, involving an aggregate of 750,000 restricted shares of our common stock, currently exercisable warrants to purchase 750,000 shares of our restricted common stock (subject to beneficial ownership restrictions noted below); and currently convertible promissory notes (subject to beneficial ownership restrictions noted below). The number of beneficially owned shares reported at July 1, 2014 includes 1,540,000 restricted shares of common stock owned by Platinum.

The reported number of shares beneficially owned excludes 12,750,000 restricted shares of common stock and a warrant to purchase 6,375,000 restricted shares of common stock that may currently be acquired by Platinum upon exchange of 425,000 restricted shares of our Series A Preferred. Pursuant to the October 11, 2012 Note Exchange and Purchase Agreement by and between us and Platinum, there is a limitation on exchange such that the number of shares of our common stock that may be acquired by Platinum upon exchange of the Series A Preferred is limited to the extent necessary to ensure that, following such exchange, the total number of shares of our common stock then beneficially owned by Platinum does not exceed 9.99% of the total number of our issued and outstanding shares of common stock without providing us with 61 days' prior notice thereof.

Further, the reported number of shares beneficially owned also excludes an aggregate of 12,265,775 restricted shares of our common stock that may be acquired by Platinum upon (i) conversion of various Senior Secured Convertible Promissory Notes in the aggregate face amount of \$2,994,190 and Subordinate Convertible Promissory Notes in the aggregate face amount of \$750,000 (together, the Convertible Notes) plus accrued but unpaid interest or (ii) exercise of various common stock purchase warrants to purchase an aggregate of 3,744,190 restricted shares of our common stock. Pursuant to the terms of the respective Convertible Notes and common stock purchase warrant agreements, there is a limitation on conversion of the Convertible Notes and exercise of the warrants such that the number of shares of common stock that Platinum may acquire upon such conversion or exercise is limited to the extent necessary to ensure that, following such conversion or exercise, the total number of shares of common stock then beneficially owned by Platinum does not exceed 4.99% or 9.99% of the total number of issued and outstanding shares of our common stock without providing us with 61 days' prior notice thereof.

Including the shares otherwise excluded due to the beneficial ownership restrictions noted above, Platinum beneficially owns 32,930,776 shares or 57.88% of our common stock prior to the Offering. The primary business address of Platinum Long Term Growth Fund VII is 152 West 57th Street, 54th Floor, New York, New York 10019. Mark Nordlicht has voting and investment control over the shares held by Platinum.

- (8) Includes currently exercisable warrants to purchase 2,033,957 restricted shares of common stock. The primary business address of Morrison & Foerster is 555 Market

Street, San Francisco, California 94105.

- (9) Includes currently exercisable warrants to purchase 658,728 restricted shares of common stock and 542,035 restricted shares of common stock upon conversion of currently convertible promissory notes and accrued interest. Mr. Young's primary business address is c/o Coldwell Banker Residential Brokerage, 580 El Camino Real, San Carlos, California 94070.
- (10) Includes currently exercisable warrants to purchase 620,408 restricted shares of common stock. The primary business address of University Health Network is 101 College Street, Suite 150, Toronto, Ontario Canada M5G 1L7.
- (11) Includes options to purchase an aggregate of 2,637,967 restricted shares of common stock exercisable within 60 days of July 1, 2014, warrants to purchase an aggregate of 2,763,552 restricted shares of common stock exercisable within 60 days of July 1, 2014 and 33,400 restricted shares of common stock upon conversion of a currently convertible promissory note and accrued interest.

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RELATED PARTY TRANSACTIONS

Transactions and Relationships with Certain Individuals

Sales of Securities to Cato Holding Company

Cato Holding Company (CHC), doing business as Cato BioVentures (CBV), the parent of Cato Research Ltd. (CRL), is one of our largest institutional stockholders at March 31, 2014, holding common stock and warrants to purchase common stock. Prior to the May 11, 2011 conversion of certain of VistaGen California's outstanding promissory notes and the exchange of its preferred stock into shares of common stock in connection with the Merger, CBV held various promissory notes and a majority of VistaGen California's Series B-1 Preferred Stock. Shawn Singh, our Chief Executive Officer and member of our Board of Directors, served as Managing Principal of CBV and as an officer of CRL until August 2009. In April 2011, CBV loaned us \$352,300 under the terms of a Promissory Note (2011 CHC Note). On October 10, 2012, we agreed with CHC to cancel the 2011 CHC Note and exchange it for a new unsecured promissory note in the principal amount of \$310,400 (2012 CHC Note) and a five-year warrant to purchase 250,000 restricted shares of our common stock at a price of \$1.50 per share (CHC Warrant). Additionally, on October 10, 2012, we issued to CRL: (i) an unsecured promissory note in the initial principal amount of \$1,009,000, which is payable solely in restricted shares of our common stock and which accrues interest at the rate of 7.5% per annum, compounded monthly (CRL Note), as payment in full for all contract research and development services and regulatory advice rendered by CRL to us through December 31, 2012 with respect to the preclinical and clinical development of AV-101, and (ii) a five-year warrant to purchase, at a price of \$1.00 per share, 1,009,000 restricted shares of our common stock. Total interest expense on notes payable to CHC and CRL was \$167,900 and \$101,700 for the fiscal years ended March 31, 2014 and 2013.

Contract Research and Development Agreement with Cato Research Ltd.

During fiscal year 2007, we entered into a contract research organization arrangement with CRL related to the development of AV-101, under which we incurred expenses of \$52,500 and \$703,800 for the fiscal years ended March 31, 2014 and 2013, respectively, with a substantial portion of the fiscal year 2013 expense reimbursed under the NIH grant.

Note Receivable from Shawn K. Singh, JD and Advances to us by Mr. Singh

Upon the approval of the board of directors, in December 2006, VistaGen California accepted a full-recourse promissory note in the amount of \$103,400 from Mr. Singh in payment of the exercise price for options and warrants to purchase an aggregate of 126,389 restricted shares of VistaGen California's common stock. The note accrued interest at a rate of 4.90% per annum and was due and payable no later than the earlier of (i) December 1, 2016 or (ii) ten days prior to our becoming subject to the requirements of the Exchange Act. On May 11, 2011, in connection with the Merger, the \$128,200 outstanding balance of principal and accrued interest on this note was cancelled in accordance with Mr. Singh's employment agreement and recorded as additional compensation. In accordance with his employment agreement, Mr. Singh is also entitled to receive an income tax gross-up on the compensation related to the note cancellation. At March 31, 2014 and 2013, we had accrued \$101,900 as an estimate of the gross-up amount payable to Mr. Singh, but we had not yet paid it to Mr. Singh.

Between September and December 2013, Mr. Singh provided short-term cash advances aggregating \$64,000 to meet our short-term working capital requirements. In lieu of cash repayment of the advances, in December 2013, Mr. Singh elected to invest \$50,000 of the balance due him in the 2013 Unit Private Placement. At March 31, 2014 we have partially repaid Mr. Singh the remaining balance of the advances.

Indemnification Agreements with Directors and Executive Officers

We have entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements and our Bylaws provide that we shall indemnify our directors to the fullest extent permitted by the Nevada Revised Statutes. For more information regarding these agreements, see “Executive compensation—Limitations of Liability and Indemnification.”

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LEGAL MATTERS

The Disclosure Law Group, San Diego, California, will pass upon the validity of the shares of common stock offered hereby. A partner of the Disclosure Law Group holds warrants to purchase 58,334 shares of our common stock.

EXPERTS

The financial statements as of March 31, 2014 and 2013, and for the years then ended, included in this prospectus, have been audited by OUM & Co. LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

INTEREST OF NAMED EXPERTS AND COUNSEL

No expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with this Offering was employed on a contingency basis or had, or is to receive, in connection with the Offering, a substantial interest, directly or indirectly, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents, subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

WHERE YOU CAN FIND MORE INFORMATION

We are a public company and file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's public reference room at 100 F Street, NE, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. Our SEC filings are also available, at no charge, to the public at the SEC's website at <http://www.sec.gov>.

We have filed with the SEC a Registration Statement on Form S-1 under the Securities Act with respect to the shares of common stock being offered by us under this prospectus. This prospectus is part of that registration statement. This prospectus does not contain all of the information set forth in the registration statement or the exhibits to the registration statement. For further information with respect to us and the shares we are offering pursuant to this prospectus, you should refer to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete, and you should refer to the copy of that contract or other documents filed as an exhibit to the registration statement. You may read or obtain a copy of the registration statement at the SEC's public reference facilities and Internet site referred to above.

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VISTAGEN THERAPEUTICS INC.  
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders  
VistaGen Therapeutics, Inc.  
(a development stage company)

We have audited the accompanying consolidated balance sheets of VistaGen Therapeutics, Inc. (a development stage company) as of March 31, 2014 and 2013 and the related consolidated statements of operations and comprehensive loss, cash flows, preferred stock, and stockholders' deficit for the years then ended, and for the period from May 26, 1998 (inception) through March 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of VistaGen Therapeutics, Inc. (a development stage company) at March 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for the years then ended, and for the period from May 26, 1998 (inception) through March 31, 2014, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company is a development stage company, has not yet generated sustainable revenues, has suffered recurring losses from operations and has a stockholders' deficit, all of which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ OUM & CO. LLP

San Francisco, California  
June 23, 2014



## VISTAGEN THERAPEUTICS, INC.

(a development stage company)  
CONSOLIDATED BALANCE SHEETS  
(Amounts in dollars, except share amounts)

	March 31, 2014	March 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$-	\$638,100
Prepaid expenses and other current assets	40,500	33,700
Total current assets	40,500	671,800
Property and equipment, net	176,300	180,700
Security deposits and other assets	46,900	29,000
Total assets	\$263,700	\$881,500
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$2,443,900	\$1,353,600
Accrued expenses	625,600	342,900
Advance from officer	3,600	-
Current portion of notes payable and accrued interest	1,442,300	617,200
Current portion of notes payable to related parties and accrued interest	290,400	93,000
Convertible promissory notes and accrued interest, net of discount of \$697,400 at March 31, 2014	396,000	-
Capital lease obligations	3,900	7,600
Total current liabilities	5,205,700	2,414,300
Non-current liabilities:		
Senior secured convertible promissory notes, net of discount of \$2,085,900 at March 31, 2014 and \$1,963,100 at March 31, 2013 and accrued interest	1,929,800	1,425,700
Notes payable, net of discount of \$848,100 at March 31, 2014 and \$1,142,600 at March 31, 2013 and accrued interest	1,797,600	2,091,800
Notes payable to related parties, net of discount of \$103,200 at March 31, 2014 and \$147,200 at March 31, 2013 and accrued interest	1,057,100	1,106,000
Warrant liability	2,973,900	6,394,000
Deferred rent liability	97,400	-
Capital lease obligations	2,100	6,100
Total non-current liabilities	7,857,900	11,023,600
Total liabilities	13,063,600	13,437,900
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 10,000,000 shares, including 500,000 Series A shares, authorized at March 31, 2014 and 2013; 500,000 Series A shares issued and outstanding at March 31, 2014 and 2013	500	500
Common stock, \$0.001 par value; 200,000,000 shares authorized at March 31, 2014 and 2013; 26,200,185 and 23,480,169 shares issued at March 31, 2014 and March 31, 2013, respectively	26,200	23,500
Additional paid-in capital	61,976,500	59,266,000

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Treasury stock, at cost, 2,713,308 shares of common stock held at March 31, 2014 and 2013	(3,968,100 )	(3,968,100 )
Note receivable from sale of common stock	(198,100 )	(209,100 )
Deficit accumulated during development stage	(70,636,900)	(67,669,200)
Total stockholders' deficit	(12,799,900)	(12,556,400)
Total liabilities and stockholders' deficit	\$263,700	\$881,500

See accompanying notes to consolidated financial statements.

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VISTAGEN THERAPEUTICS, INC.  
(a development stage company)  
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(Amounts in dollars, except share amounts)

	Fiscal Years Ended March 31,		May 26, 1998 (Inception) Through March 31, 2014
	2014	2013	
<b>Revenues:</b>			
Grant revenue	\$-	\$200,400	\$12,963,100
Collaboration revenue	-	-	2,283,600
Other	-	-	1,123,500
Total revenues	-	200,400	16,370,200
<b>Operating expenses:</b>			
Research and development	2,480,600	3,430,800	32,036,300
Acquired in-process research and development	-	-	7,523,200
General and administrative	2,548,300	3,562,700	33,229,400
Total operating expenses	5,028,900	6,993,500	72,788,900
Loss from operations	(5,028,900)	(6,793,100)	(56,418,700)
<b>Other expenses, net:</b>			
Interest expense, net	(1,503,000)	(920,700)	(11,865,200)
Change in warrant and put and note extension option liabilities	3,566,900	(1,635,800)	2,349,600
Loss on early extinguishment of debt	-	(3,567,800)	