VistaGen Therapeutics, Inc.
Form S-1
May 12, 2014

As filed with the Securities and Exchange Commission on May12, 2014

Registration No. 333- _____

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

FORM S-1
REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

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

Nevada	3841	20-5093315
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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
South San Francisco, CA 94080
(650) 577-3600
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications to:

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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.

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 [ ]		Smaller reporting company
Accelerated filer [ ]	Non-accelerated filer [ ] (Do not check if a smaller reporting company)	[X]

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CALCULATION OF REGISTRATION FEE

Title Of Each Class Of Securities To Be Registered	Amount To Be Registered	Proposed Maximum Aggregate Offering Price Per Share	Proposed Maximum Aggregate Offering Price (1)	Amount Of Registration Fee	
Common stock, par value $0.001 per share (2)		$	$ 10,000,000	$ 1,288.00	(1)

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933.

(2) This Registration Statement covers, under one prospectus, our direct offering of an indeterminate number of shares of our common stock that may be sold by us from time to time, for a maximum aggregate offering price of all securities not to exceed $10,000,000.

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Subject to Completion, dated _____, 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 of Common Stock

We are offering _____ shares of our common stock (the “Offering”) on a "best efforts" basis through our officers and directors, who will not receive any commissions or other remuneration for selling shares.

There is no minimum number of shares that must be sold by us for the Offering to close, and therefore we may receive no proceeds or very minimal proceeds from the Offering. The aggregate offering price of all securities sold under this Offering may not exceed $_____.

We will retain the proceeds from the sale of any of the offered shares that are sold. The Offering is being conducted on a self-underwritten, best efforts basis, which means this prospectus will permit our officers and directors to sell the shares directly to the public, with no commission or other remuneration payable to them for any shares they may sell. The Company may not sell the shares to the public until the Registration Statement of which this prospectus is a part is declared effective by the Securities and Exchange Commission (“SEC”).

We have no arrangement to place the proceeds from this Offering in an escrow, trust or similar account. Any funds raised from sales of shares to the public pursuant to this Offering will be immediately available to us for our use and retained by us regardless of whether or not there are any additional sales under this Offering. You will not have the right to withdraw your funds during the Offering. We may offer and sell these securities through the method described under “Plan of Distribution” in this prospectus.

The Offering will terminate upon the earlier to occur of: (i) the sale of all _____ shares being offered, or (ii) 365 days after the Registration Statement of which this prospectus is a part is declared effective by the SEC.

Our securities are not listed on any national securities exchange. Our common stock is quoted on the Over-the-Counter Market (OTCQB) under the symbol “VSTA”. On May 9, 2014 the closing price for our common stock was $0.40 per share.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus.

	Per Share	Total
Price to the public (1)	$_____	$_____
Proceeds, before expenses, to us	$_____	$_____

(1) Omitted in reliance upon Rule 430A under the Securities Act and may be based upon a discount to the market price of the Company's common stock at the time of pricing not later than 15 business days after the effective date of the registration statement of which this prospectus is a part.

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 _____, 2014

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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.

We own or have rights to use a number of common law trademarks and trade names that we use in connection with our business, including VistaGen Therapeutics, Inc., VistaGen, our logo, Better Cells Lead to Better Medicine, Human Clinical Trials in a Test Tube, ECG in a Test Tube, Putting Humans First, Drug Rescue Candidates, Drug Rescue Variants, CardioSafe 3D and LiverSafe 3D. Solely for convenience, the trademarks and trade names referred to in certain portions of this prospectus may have been included without the TM symbol, but any such references are not intended to indicate in any way that we will not assert to the fullest extent under applicable law our rights to use those trademarks and trade names. All other trademarks, service marks and trade names referred to in this prospectus, if any, are, to our knowledge, the property of their respective owners.

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

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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

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 medicine™ 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 for drug rescue 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 animals or 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, hepatocytes (liver cells) derived from human pluripotent stem cells, with adult functional properties, we are currently validating LiverSafe 3D, our second novel stem cell technology-based bioassay system. We believe LiverSafe 3D will enable us to assess new drug candidates for potential liver toxicity and metabolism-based safety issues resulting in adverse drug-drug interactions, early in development, before animal or human testing. Drug-related liver toxicity and adverse drug metabolism, as a group, represent one of the top-two reasons for safety-related drug failure during clinical development. We plan to use LiverSafe 3D, and the clinically predictive liver biology insight

we believe it provides, to expand the scope of our commercial opportunities related to drug rescue.

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Drug Rescue

We believe drug rescue, using our novel in vitro bioassay systems, 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 promising drug candidates have already been tested extensively and validated by a pharmaceutical or biotechnology company for their therapeutic (efficacy) and commercial potential. We refer to these promising new drug candidates that have been discovered, developed and ultimately terminated by pharmaceutical and biotechnology companies as Drug Rescue Candidates™.

Failure of promising new drug candidates due to unexpected human clinical toxicity highlights the need for new paradigms to evaluate potential toxicity early in drug development. While efforts of pharmaceutical and biotechnology companies to improve their prediction of human clinical toxicity for new drug candidates is ongoing, the existence of many Drug Rescue Candidate offers us an opportunity to use our novel drug rescue technology to take advantage of these promising Drug Rescue Candidates, each with early signs of efficacy, by eliminating the toxicity that caused them to be terminated, and bring new, safer versions back into development protected by new intellectual property. We refer to these new, safer versions of Drug Rescue Candidates we produce with our medicinal chemistry collaborator and validate internally in our bioassay systems as Drug Rescue Variants™.

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. The key commercial objective of our drug rescue model is to generate revenue from license, development and commercialization arrangements involving the new, safer and proprietary Drug Rescue Variants that we produce with our medicinal chemistry collaborator and validate internally in our bioassay systems prior to license. We anticipate that each validated lead Drug Rescue Variant will be suitable as a promising drug development program, either internally or in collaboration with a strategic partner. Through stem cell technology-based drug rescue, we intend to become a leading source of proprietary, small molecule drug candidates to the global pharmaceutical industry.

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 and 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 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 and development than was required of the pharmaceutical companies prior to their decision to terminate the Drug Rescue Candidates.

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The key elements of our current 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 preferred provider of contract medicinal chemistry and contract clinical development services, respectively;

- leverage substantial prior R&D investments made by global pharmaceutical companies and others to support the therapeutic and commercial potential of Drug Rescue Candidates, as an important criterion for selection of Drug Rescue Candidates and potential lead Drug Rescue Variants;

- use CardioSafe 3D to enhance our understanding of the cardiac liability profile of Drug Rescue Candidates, important biological insight not available when the Drug Rescue Candidates were originally discovered and developed by pharmaceutical companies;

- leverage our knowledgebase about each Drug Rescue Candidate's specific chemistry to design and produce a portfolio of novel potential lead Drug Rescue Variants for each Drug Rescue Candidate;

- 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

- license each validated lead Drug Rescue Variant to a global pharmaceutical company in a revenue-generating agreement providing for the full 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

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 many of the high costs and risks typically inherent in the labor-intensive early-stage drug discovery screening necessary to identify a lead compound that has a desired therapeutic profile. 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 currently available to us in the public domain by entering into contractual arrangements with third-parties.

Strategic Licensing of Drug Rescue Variants

We believe many pharmaceutical companies are experiencing, and will continue to experience, critical R&D productivity issues, as measured by their lack of, or very low number of, FDA-approved products each year during the past decade. For example, in 2013, the U.S. pharmaceutical industry invested over $51 billion in R&D and the Center for Drug Evaluation and Research (CDER) of the FDA approved a total of only thirty-nine novel drugs, known as

New Molecular Entities (NMEs). In 2013, CDER approved only twenty-seven NMEs, thirteen of which NME approvals (48%) were received by only five pharmaceutical companies, including Bayer (2), GlaxoSmithKline (4), Johnson & Johnson (3), Roche (2) and Takeda (2). Despite remarkable levels of R&D investment by the global pharmaceutical industry as a whole, since 2003, the FDA has only approved an average of approximately twenty-six NMEs per year. In addition, we believe many pharmaceutical companies with established products that are no longer patent protected are also experiencing substantial market pressure from generic competition.

As a result of R&D productivity issues, diminishing product pipelines and generic competition, we believe there is and will continue to be a critical need among pharmaceutical companies to license the new, 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.

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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 license that Drug Rescue Variant to a pharmaceutical company, including the company that developed the Drug Rescue Candidate, or further develop it on our own. If we decide to 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.

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 and help slow rapidly rising healthcare costs in the U.S. 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 and biologics with regenerative and therapeutic potential. Our regenerative medicine focus will be based on our expertise in human biology and 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. Our objective will be to explore regenerative medicine opportunities through pilot nonclinical proof-of-concept studies, after which we intend to assess any potential opportunities for further development and commercialization of therapeutically and commercially promising regenerative medicine programs, 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, 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 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 and depression. 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 completed to date will support development of AV-101 for multiple indications, including epilepsy and depression. Upon completion of this offering, we intend to pursue potential opportunities for further development and commercialization of AV-101 for neuropathic pain, epilepsy and depression, either on our own or with a strategic partner. In the event that we successfully complete a strategic partnering arrangement for AV-101, we plan to use the net proceeds from such an arrangement to expand our drug rescue and regenerative medicine programs.

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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.

- 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 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. 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 by VistaGen Therapeutics, Inc.	_____ shares
Common stock to be outstanding after this Offering	_____ shares
Use of proceeds	We intend to use the net proceeds from this Offering for funding our operations, approximately as follows: $_____ for research and product development expenses related to our stem cell technology-based Human Clinical Trials in a Test Tube platform, including Drug Rescue Variants, novel human cell-based assay systems for drug discovery, and pilot nonclinical regenerative medicine studies; $_____ for general and administrative expenses, including audit, legal and other professional services related to being public company; $_____ for property, plant and equipment expenses; and the remaining proceeds for working capital and other general corporate purposes. We may also acquire or invest in complementary businesses or other assets; however, we currently have no agreements or commitments to complete any such transaction. See “Use of Proceeds” on page 44.
Dividend policy	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.
OTCQB symbol	VSTA
Risk factors	See “Risk factors” beginning on page 9 of this prospectus for a discussion of factors you should carefully consider before investing in our securities.

The number of shares of common stock to be outstanding after this Offering is based on 24,236,877 shares outstanding as of April 30, 2014, and does not include, as of that date:

- 4,227,357 shares issuable upon the exercise of outstanding options;
- 735,200 shares of our common stock reserved for issuance in connection with future awards under our stock 2008 Stock Incentive Plan;
- 17,845,633 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 to be issued upon the exchange of our Series A Preferred; and

- 80,000 shares of common stock and warrants issued upon the purchase of units consisting of shares of common stock, promissory notes and common stock purchase warrants issued in a private placement after April 30, 2014

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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, 2012 and 2013 and the balance sheet data as of March 31, 2012 and 2013 have been derived from our audited financial statements and notes thereto, which are included elsewhere in this prospectus. The unaudited summary statements of operations data for the nine months ended December 31, 2012 and 2013 and the unaudited balance sheet data as of December 31, 2013 have been derived from our unaudited financial statements included elsewhere in this prospectus. We have prepared the unaudited financial information on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements. 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.

(Dollars in thousands, except share and per share data)	Fiscal Year Ended March 31,		Nine Months Ended December 31,	
	2013	2012	2013	2012
Revenues:				
Grant revenue	$ 200	$ 1,342	$ -	$ 200
Total revenues	200	1,342	-	200
Operating expenses:				
Research and development	3,431	5,389	1,916	3,092
General and administrative	3,562	4,997	2,048	2,430
Total operating expenses	6,993	10,386	3,964	5,522
Loss from operations	(6,793)	(9,044)	(3,964)	(5,322)
Other expenses, net:				
Interest expense, net	(921)	(1,893)	(1,000)	(612)
Change in warrant and other derivative liabilities	(1,636)	(78)	3,824	358
Loss on early extinguishment of debt	(3,568)	(1,193)	-	(3,537)
Other income	35	-	-	-
Loss before income taxes	(12,883)	(12,208)	(1,140)	(9,113)
Income taxes	(4)	(2)	(3)	(4)
Net loss	(12,887)	(12,210)	(1,143)	(9,117)
Deemed dividend on Series A Preferred Stock	(10,193)	-	-	(10,193)
Net loss attributable to common stockholders	$ (23,080)	$ (12,210)	$ (1,143)	$ (19,310)
Net loss attributable to common stockholders, basic and diluted	$ (1.27)	$ (0.83)	$ (0.05)	$ (1.11)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders	18,108,444	14,736,651	21,554,929	17,411,993
Pro-forma net loss attributable to common stockholders, basic and diluted (1)	$ _____	$ _____	$ _____	$ _____

Weighted average shares used in computing pro-forma basic and diluted net loss attributable to common stockholders	_____	_____	_____	_____

(1) The number of weighted-average common shares used in computing pro forma net loss per share attributable to common stockholders in the table above gives effect to the issuance of _____ shares of common stock pursuant to this Offering on a retroactive basis for each of the periods presented.

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(dollars in thousands) Balance sheet data:	March 31, 2013	March 31, 2012	December 31, 2013	Pro forma as adjusted(1)
Cash and cash equivalents	$ 638	$ 81	$ 21	$ _____
Total current assets	672	238	91	_____
Total assets	882	342	329	_____
Total current liabilities	2,414	3,183	3,712	_____
Long-term debt, less current portion	4,624	2,798	5,470	_____
Accumulated deficit	(67,669)	(54,783)	(68,812)	_____
Stockholders' deficit	(12,556)	(5,706)	(11,670)	_____

(1) The pro forma as adjusted balance sheet data reflects estimated net proceeds of $_____ received pursuant to the sale of _____ shares of our common stock at an assumed public offering price of $____ per share, inclusive of estimated Offering expenses, as of December 31, 2013.

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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, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment.

Risks Related to Our Business and Strategy

We are a development stage biotechnology company with no approved products, which makes it difficult to assess our future viability.

We are a development stage biotechnology company. Since inception, 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;
- 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.

If we are unsuccessful in accomplishing these fundamental objectives, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

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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 or 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

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, which may never occur. 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 or produce suitable lead Drug Rescue Variants for license to and preclinical and clinical development by pharmaceutical companies and others, we may not be able to obtain sufficient revenues in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. 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. 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 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 assay 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 license or sell 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 license them to strategic partners, the resources such partners choose to dedicate to development and commercialization of any Drug Rescue Variants licensed from us.

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

Our proprietary internal studies conducted to validate the utility of CardioSafe 3D for drug rescue, including our ability to use it 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 acquire from them certain Drug Rescue Candidates which might be of interest to us. Even if such results can be replicated by external peer reviewers or other third-parties, they may nevertheless conclude that their current screening models are better than our CardioSafe 3D and that a license to the Drug Rescue Candidate we seek from them is not warranted. Our drug rescue business model is predicated on our ability to identify and, if information is not otherwise available in the public domain, obtain licenses from third-parties to Drug Rescue Candidates of interest to us. If third-party licenses are required, and if we cannot obtain such licenses to on reasonable terms, or at all, our business may be adversely affected.

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 direct liver toxicity and drug metabolism. Furthermore, we may never be able to do so, which could adversely affect our business and the potential applications of our Human Clinical Trials in a Test Tube platform for 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 products.

The success of our drug rescue business is highly dependent, in the first instance, upon CardioSafe 3D, and, in the second instance, when fully 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 fully-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 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 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 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, 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 adverse effect on our potential 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 independently or in collaboration, will compete with products from other companies in the biotechnology and pharmaceutical industries.

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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;
- 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, 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.

Some of our most important ongoing and planned research and development programs involve the use 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.

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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 pilot 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 April 30, 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 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 formulating 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.

If our employees commit fraud or other misconduct, including noncompliance with regulatory standards and requirements and insider trading, our business may experience serious adverse consequences.

We are exposed to the risk of employee fraud or other misconduct, including scientific misconduct. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and

the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering.

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Despite the adoption of an Insider Trading Policy, we may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

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.

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.

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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.

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. The failure of any collaborator to conduct, successfully and diligently, their collaborative activities relating to the product candidate we license or sell to them would have a material adverse effect on us. Additionally, to the extent that we are unable to license or sell our Drug Rescue Variants to pharmaceutical companies or others, we would require substantial additional capital to undertake development and commercialization activities for any such product candidate on our own, and that substantial additional capital may not be available to us on a timely basis, on reasonable terms, or at all.

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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:

- 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.

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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.

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.

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.

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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 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.

Our human cell-based 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 we intend to rely on such third-party manufacturers 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 plan 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 have limited staffing. 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 manufactures with whom we work will need to increase their scale of production or we will need to secure alternate suppliers.

If, in the future, we are unable to enter into licensing or collaboration agreements for the sales, marketing and distribution of our Drug Rescue Variants and other product candidates, such as AV-101, we may not be successful in commercializing our Drug Rescue Variants and other product candidates.

We currently have a relatively small number of employees and 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.

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Our business is subject to the risks of earthquakes, fire, floods and other natural catastrophic events, and to interruption by man-made problems such as computer viruses or terrorism.

Our corporate headquarters are located in the San Francisco Bay Area, a region known for seismic activity. A significant natural disaster, such as an earthquake, fire or a flood, could harm our business. In addition, our servers are vulnerable to computer viruses, break-ins and similar disruptions from unauthorized tampering with our computer systems. In addition, acts of terrorism or war could cause disruptions in our business or the economy as a whole.

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.

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Our compliance with the Sarbanes-Oxley Act of 2002 and SEC rules concerning internal controls is costly, difficult and time-consuming.

Prior to May 2011, we did not operate as a publicly-traded company. Given our limited size and personnel resources, it is costly, difficult and time consuming for us to maintain the internal controls and reporting procedures of publicly traded companies required by the Sarbanes-Oxley Act of 2002. If we are unable to comply with the Sarbanes-Oxley Act's internal controls and disclosure requirements, we may not be able to obtain the independent registered public accounting firm attestations that the Sarbanes-Oxley Act of 2002 requires certain publicly-traded companies to obtain. If it is determined that we have a material weakness in our internal control over financial reporting, or if our independent registered accounting firm is unable to provide an unqualified attestation report on our internal controls when such a report is required, we could incur additional costs and suffer adverse publicity and other consequences of any such determination, investors could lose confidence in our financial information and the price of our common stock could decline.

We are a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements and relief from certain other significant obligations that are applicable to smaller reporting companies will make our common stock less attractive to investors

We are a "smaller reporting company," as defined in the Exchange Act and, as such, we are exempted from various reporting requirements that are applicable to larger public companies, including, but not limited to, being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, more extensive disclosure obligations regarding executive compensation in our periodic reports and proxy statements, the requirements to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. Our classification as a "smaller reporting company" is determined on September 30 of each year, based on whether our public float (the product of the number of outstanding shares of our common stock held by non-affiliate (less than 10% ownership) stockholders multiplied by the closing market price of our common stock) on that day is less than $75 million. We intend to take advantage of these reporting exemptions until we no longer qualify as a "smaller reporting company." Subsequent to the completion of this Offering and, in the event we experience an increase in the market price for our stock, we may no longer be classified as a "smaller reporting company." We cannot predict whether investors find our common stock less attractive because we are currently relying on these exemptions. If some investors find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Our management is currently required to assess the effectiveness of our controls and we are required to disclose changes made in our internal control over financial reporting on a quarterly basis. As a "smaller reporting company," however, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot continue to favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls whenever required in the future, investors could lose confidence in our financial information and the price of our common stock could decline. Additionally, should we cease to be a "smaller reporting company", we will incur additional expense and management effort to facilitate the required attestation of the effectiveness of our internal control over financial reporting by our independent registered public accounting firm.

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

We are currently dependent on CardioSafe 3D and medicinal chemistry to produce lead product candidates, and we cannot provide any assurance that we will produce any product candidates that will be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the development of CardioSafe 3D and AV-101, which has successfully completed Phase 1 clinical development. Our future success depends heavily on our ability to successfully produce and, either on our own or in collaboration with others, develop, obtain regulatory approval for, and commercialize Drug Rescue Variants and AV-101, which may never occur. We currently generate no revenues, and we may never be able to develop or commercialize a marketable drug.

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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.

We have not previously submitted a biologics license application, or BLA, or 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.

We or our potential collaborator may also seek regulatory approval to commercialize our product candidates in the United States, the European Union and potentially in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Developing and obtaining FDA approval to develop, market and sell new Drug Rescue Variants in the U.S. is complex, expensive, time-consuming and uncertain.

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, there can be no assurance that the current regulatory framework will not change through regulatory, legislative or judicial actions or that additional regulations will not arise during development that may affect approval, delay the submission or review of an application, if required, or require additional expenditures by us or our prospective collaborators.

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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.

Our or our collaborator's future clinical trials can 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.

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In the event we or our collaborators are able to conduct a pivotal clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. For any such pivotal 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 possibly overall survival or complete response rate, the FDA may refuse to approve a BLA or NDA based on such pivotal trial. The FDA may require additional clinical trials as a condition for approving our product candidates.

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.

As noted, a company seeking FDA approval to market a new drug candidate must file an NDA; a company seeking FDA approval to market a new biological candidate must file a BLA. In addition to reports of the nonclinical and human clinical trials conducted under the IND application, the NDA and BLA include evidence of the product's safety, purity, potency and efficacy, as well as manufacturing, product identification and other information. Submission of an NDA or BLA does not assure FDA approval for marketing. The application review process generally takes at least one to three years to complete, although reviews of drugs or biological products for life-threatening diseases may be accelerated or expedited. However, the process may take substantially longer.

The FDA requires at least one and generally two properly conducted, adequate and well-controlled clinical studies demonstrating efficacy with sufficient levels of statistical assurance. However, additional information may be required. Notwithstanding the submission of such data, the FDA ultimately may decide that the NDA or BLA, as the case may be, does not satisfy the regulatory criteria for approval and deny the application. The FDA may impose post-approval obligations, such as additional clinical tests following NDA or BLA approval to confirm safety and efficacy (Phase IV human clinical trials). The FDA may, in some circumstances, also impose restrictions on the use of the biological product that may be difficult and expensive to administer. Further, the FDA requires reporting of certain safety and other information that becomes known to a manufacturer of an approved biological product. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market.

Prior to approving an application, the FDA will inspect the prospective manufacturer to ensure that the manufacturer conforms to the FDA's current good manufacturing practice (cGMP) regulations that applicable to new biological candidates. To comply with the cGMP regulations, manufacturers must expend time, money and effort in product recordkeeping and quality control to assure that the product meets applicable specifications and other requirements. The FDA periodically inspects manufacturing facilities in the U.S. and abroad to assure compliance with applicable cGMP requirements. Our failure to comply with the FDA's cGMP regulations or other FDA regulatory requirements could have a significant adverse effect on us.

After a product is approved for a given indication in an NDA or BLA, subsequent new indications or dosage levels for the same product are reviewed by the FDA via the filing and approval of an NDA or BLA supplement. The NDA or BLA supplement is more focused than the NDA or BLA and deals primarily with safety and effectiveness data related to the new indication or dosage. Applicants are required to comply with certain post-approval obligations, such as compliance with cGMPs. Product approvals may be withdrawn by the FDA if compliance with regulatory

requirements is not maintained or if problems occur after the product reaches the market.

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We have limited experience as a corporation developing new drug candidates, including Drug Rescue Variants, biological candidates or regenerative medicine product candidates, including conducting clinical trials and other areas required for the successful development and commercialization of therapeutic products.

We and 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. Such 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. As a company, we have limited experience developing new drug candidates, including Drug Rescue Variants, biological candidates or regenerative medicine products, including conducting clinical trials and in other areas required for the successful development and commercialization of therapeutic products. Such trials will require additional financial and management resources, third-party collaborators with the requisite clinical experience or reliance on third party clinical investigators, contract research organizations and independent consultants. Relying on third parties may force us to encounter delays that are outside of our control, which could materially harm our business.

We also do not currently have marketing and distribution capabilities for product candidates. Developing an internal sales and distribution capability would be an expensive and time-consuming process. To market and distribute any new drug candidate, including any Drug Rescue Variants, biological candidate or regenerative medicine product, we plan to enter into strategic partnering arrangements for marketing and distribution. However, these third-party collaborators may not be capable of successfully selling any of our new product candidates.

Entry into clinical trials with one or more new drug candidates, including Drug Rescue Variants, may not result in any commercially viable products.

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;

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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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.

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, our Drug Rescue Variants or other products may not be successful commercially, and 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.

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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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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, including net losses of $12.2 million and $12.9 million during fiscal years ending March 31, 2012 and 2013, respectively. We incurred net losses of $9.1 million and $1.1 million during the nine months ended December 31, 2012 and 2013, respectively. As of December 31, 2013, we had an accumulated deficit of $68.8 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, following this Offering, we expect that our general and administrative expenses will increase due to additional operational and reporting costs associated with achieving our goal of obtaining a listing on a national

securities exchange. The net losses we incur may fluctuate from quarter to quarter.

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We anticipate that our business will generate operating losses until we successfully implement our drug rescue strategy and generate significant revenue to support our level of operating expenses. Because of the numerous risks and uncertainties associated with our drug rescue efforts and future strategic partnering and product development arrangements, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability. With the net proceeds from this Offering, we believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operations and our capital expenditures for at least the next 24 months. If our cash is insufficient to meet future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our current stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all.

If we do not successfully develop, license, sell or obtain regulatory approval for our future product candidates and effectively manufacture, market and sell, or collaborate to accomplish such activities, for 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.

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 believe that 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 obtain approval from the FDA or other regulatory authorities and we successfully commercialize one or more of our compounds. As the outcome of our product candidate development activities and our 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. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to 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;
- 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;

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- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- 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, any of which could harm our operating results.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. 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 independent auditors have expressed substantial doubt about our ability to continue as a going concern.

We believe that the net proceeds from this Offering will be sufficient to meet our anticipated cash requirements for at least the next 24 months. Our consolidated financial statements for the year ended March 31, 2013 included in this prospectus have been prepared assuming that we will continue to operate as a going concern. However, due to our continuing operating losses and our accumulated deficit, the report of our independent registered public accounting firm on our consolidated financial statements for the fiscal year ended March 31, 2013, includes an explanatory paragraph discussing conditions that raise a substantial doubt about our ability to continue as a going concern.

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 or after this Offering, 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. If we are unable to maintain these licenses, 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, 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. 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. 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 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.

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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.

If we seek to leverage prior discovery and development of Drug Rescue Candidates under 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 generate 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 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.

We could be unsuccessful in obtaining adequate patent protection for one or more of our product candidates.

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 patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. 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 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.

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.

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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 U.S. Patent and Trademark Office, 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.

Claims that our Human Clinical Trials in a Test Tube platform, our product candidates 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.

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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.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products.

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.

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.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

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. Accordingly, the market price of our common stock may decline.

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Key aspects of our Human Clinical Trials in a Test Tube platform are protected by intellectual property exclusively licensed from academic institutions. If the licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position and market share will be harmed.

We are a party to several license agreements under which certain aspects of our business depend on patents and/or patent applications owned by other institutions. We are likely to enter into additional license agreements as part of the development of our business in the future. Our licensors may not successfully prosecute certain patent applications under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. In addition, in spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to obtain regulatory approval and to market products covered by these license agreements. Our licensors may also terminate the license agreements if we fail to meet specified milestones. If these in-licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive business position and our business prospects.

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. Nevertheless, 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;

- 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 U.S. Patent and Trademark Office, 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.

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.

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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.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

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 predict which, if any, of such pending applications will issue as patents or the claims that might be allowed. No consistent policy regarding the breadth of claims allowed in life sciences patents has emerged to date in the United States. The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to prevent the infringement of our patents. Proceedings to enforce our intellectual property rights could result in substantial cost and divert our efforts and attention from other aspects of our business and we may not prevail. Changes in either the patent laws or in interpretations of patent laws in the United States or in other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

Certain of our technology may not be eligible for patent protection, which leaves us vulnerable to theft of the technology we protect under trade secret law. We take steps to protect such intellectual property and proprietary technology, by limiting access to the materials embodying such intellectual property and by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, collaborators and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure or other breaches of the

agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we cannot ensure that the steps we have taken to prevent such disclosure are, or will be, adequate. In addition, courts outside the United States may be less willing or unwilling to protect trade secrets. Further, others may independently discover or invent trade secrets and proprietary information similar to ours, and in such cases we could not assert any trade secret rights against such party.

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We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others' proprietary rights or to defend against third party claims of intellectual property infringement, which in each case could require us to spend significant time and money and could prevent us from selling our products or adversely impact our stock price.

Litigation or other proceedings may be necessary for us to enforce our patent and proprietary rights and/or to determine the scope, coverage and validity of others' proprietary rights. To determine the priority of inventions, which is determinative of patent rights, we may have to initiate and participate in interference proceedings declared by the U.S. Patent and Trademark Office that could result in substantial legal fees and could substantially affect the scope of our patent protection. Also, our intellectual property may be subject to significant administrative and litigation proceedings such as invalidity, unenforceability, re-examination or opposition proceedings against our patents. We cannot be certain that we do not and will not infringe on the intellectual property rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or on otherwise favorable terms. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our profitability. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. In the event that we are unsuccessful in enforcing our intellectual property rights or other proprietary rights of others, our business would be negatively impacted and the price of our common stock could decline.

Our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in the stem cell market, and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization.

In addition, our competitors and others may have patents or may in the future obtain patents that broadly apply to the manufacture of human cells and their uses and claim that the manufacture or use of our products infringes these patents. As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us.

Patent infringement suits can be expensive, lengthy and disruptive to business operations. We could incur substantial costs and divert the attention of our management and technical personnel in prosecuting or defending against any claims, and these claims may harm our reputation. We cannot be certain that we will have the required resources to pursue litigation or otherwise to protect our proprietary rights or that we will prevail in any suit. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us, including treble damages and attorneys' fees and costs in the event that we are found to be a willful infringer of third party patents.

In the event of a successful claim of infringement against us, we may be required to obtain one or more licenses from third parties, which we may not be able to obtain at a reasonable cost or on otherwise favorable terms, if at all. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any

required licenses on favorable terms could prevent us from commercializing our products, and the risk of a prohibition on the sale of any of our products could adversely affect our ability to grow and gain market acceptance for our products.

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Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our suppliers, distributors, customers and other entities with whom we do business may require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine that it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition.

We may be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.

Our business may bring us into conflict with our consultants, contractors, employees, investors, licensees, licensors, service providers, suppliers or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve such conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. Any such litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities, or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

Much of the information and know-how that is critical to our business is not patentable and we may not be able to prevent others from obtaining this information and establishing competitive enterprises.

We rely, in part, on trade secrets to protect our proprietary stem cell technologies, especially in circumstances in which we believe patent protection may not be appropriate or available. We attempt to protect our proprietary technologies in part by confidentiality agreements with our advisors, collaborators, consultants, contractors and employees. We cannot assure you that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors, any of which would harm our business significantly.

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 anticipate hiring additional highly skilled scientific and technical employees following the completion of this Offering, 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.

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Risks Related to Our Common Stock and this Offering

We do not know whether 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.

Prior to this Offering, there has been a limited public market for shares of our common stock on the OTC Markets (OTCQB), formerly the OTC Bulletin Board or OTCBB. We do not yet meet the initial listing standards of the New York Stock Exchange, the NASDAQ Global 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 OTC markets, 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 the 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 Global Market, or other similar national securities exchanges, or how liquid that market might become. 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 following this Offering 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;
- 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.

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The stock market in general, and 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 the 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. You should also be aware that price volatility is likely to be worse if the trading volume of our common stock remains low and limited.

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 Offering, 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 shares issued upon the exchange of our Series A Preferred and exercise of outstanding options and warrants, in the public market after this Offering, or the possibility of these 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 April 30, 2014, we will have _____ shares of common stock outstanding, assuming no conversion of convertible promissory notes for common stock, no exchange of Series A Preferred for common stock and no exercise of outstanding options or warrants. 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. All other outstanding shares of common stock will be restricted securities eligible for sale in the public market under Rule 144 of the Securities Act, 6,103,025 of which restricted shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act. In addition, 22,072,990 shares of common stock that are subject to outstanding options and warrants as of April 30, 2014 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act as described in the “Shares Eligible for Future Sale” section of this prospectus.

Our principal institutional stockholders will continue to have substantial control over us after this Offering 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 own a significant percentage of our outstanding common stock or other securities convertible or exercisable into our common stock. Accordingly, these stockholders will 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, see “Principal stockholders.”

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.

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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 and warrants to acquire common stock at prices below the public offering price. To the extent outstanding options and warrants are ultimately exercised, 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, 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.”

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 has authorized the issuance of 500,000 shares of Series A Preferred, all of which shares are currently outstanding. 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.

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 broad discretion in the use of the net proceeds from this Offering and may not use them effectively.

We will have broad discretion in the application of the net proceeds from this Offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We intend to use the net proceeds from this Offering for funding our operations; research and product development activities; for property, plant and equipment; and for working capital and other general corporate purposes. We may also use a portion of our net proceeds to acquire or invest in complementary businesses or other assets; however, we currently have no agreements or commitments to complete any such transaction. We have not allocated these net proceeds for any specific purposes. We might not be able to yield a significant return, if any, on any investment of these net proceeds. You will not have the opportunity to influence our management’s decisions on how to use the net proceeds from this Offering, and our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

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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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 id 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.

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.

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USE OF PROCEEDS

The principal purposes of this Offering are to obtain additional working capital and improve the public market for our common stock. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds of this Offering. However, assuming total net proceeds of $_____ from this Offering, we intend to use the net proceeds from this Offering for funding our operations, approximately as follows: (1) $_____ for research and development expenses related to our stem cell technology-based Human Clinical Trials in a Test Tube platform, including Drug Rescue Variants, novel human cell-based assay systems for drug discovery, and pilot nonclinical regenerative medicine studies; (2) $_____ for general and administrative expenses, including audit, legal and other professional services related to being a public company; (3) $_____ for property, plant and equipment expenses; and (4) the remaining proceeds for working capital and other general corporate purposes. We may also acquire or invest in complementary businesses, technologies or other assets; however, we currently have no agreements or commitments to complete any such transaction.

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.

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DIVIDEND POLICY

We have never declared or paid and do not anticipate declaring or paying any cash dividends on our common stock in the near future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable law, and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

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CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2013 which is derived from our unaudited 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 December 31, 2013 (dollars in thousands, except per share amounts)		Actual		Pro forma
Cash and cash equivalents	$	21	$	_____
Long-term debt, excluding current portion		5,470		_____
Stockholders' equity:				
Series A preferred stock, $0.001 par value, 10,000,000 shares, including 500,000 Series A shares authorized, 500,000 Series A shares issued and outstanding, actual; 15,000,000 shares authorized, issued and outstanding, pro forma and pro forma as adjusted		1		_____
Common stock, $0.001 par value, 200,000,000 shares authorized; 25,295,185 shares issued, 22,581,877 outstanding, actual; _____ shares issued and _____ shares outstanding, proforma		25		_____
Additional paid-in capital		61,282		_____
Treasury stock, at cost, 2,713,308 shares		(3,968)		_____
Note receivable from sale of common stock		(198)		_____
Accumulated deficit		(68,812)		_____
Total stockholders' equity		(11,670)		_____
Total capitalization	$	(6,200)	$	_____

Common stock outstanding in the table above excludes the following shares as of December 31, 2013:

· 4,705,270 shares of common stock issuable upon the exercise of outstanding options

· 15,710,885 shares of our common stock issuable upon the exercise of outstanding warrants;

· 412,701 shares of common stock reserved for issuance under our 2008 Equity Incentive Plan;

· 8,980,076 shares of our common stock issuable upon conversion of outstanding convertible notes and related accrued interest into common stock;

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

· 7,500,000 shares of our common stock issuable upon the exercise of warrants to be issued upon the exchange of our Series A Preferred

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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 December 31, 2013, 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.

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, our pro forma as adjusted net tangible book value as of December 31, 2013, 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.

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

Assumed public offering price per share		$____
Pro forma net tangible book value per share as of December 31, 2013	$____	
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 December 31, 2013, 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		
	Number	Percent	Amount (in thousands)	Percent	Average price per share
Existing stockholders	_____	__%	$ _____	__%	$ $____
New investors	_____	__%	$ _____	__%	$ $____
Total	_____	___%	$ _____	___%	$ $____

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The outstanding share information set forth above is as of December 31, 2013 and excludes:

- 4,705,270 shares of common stock issuable upon the exercise of outstanding options;
- 15,710,885 shares of our common stock issuable upon the exercise of outstanding warrants;
- 412,701 shares of common stock reserved for issuance under our 2008 Equity Incentive Plan;
- 8,980,076 shares of our common stock issuable upon conversion of outstanding convertible notes and related accrued interest into common stock;
- 15,000,000 shares of our common stock issuable upon conversion of our Series A Preferred; and
- 7,500,000 shares of our common stock issuable upon the exercise of warrants to be issued upon the conversion of our Series A Preferred.

To the extent that any outstanding Series A Preferred are exchanged for common stock and/or any outstanding options or warrants are exercised, new investors will experience further dilution.

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SELECTED FINANCIAL DATA

We have derived the selected statement of operations data for the years ended March 31, 2012 and 2013, and the selected balance sheet data as of March 31, 2012 and 2013 from our audited consolidated financial statements included elsewhere in this prospectus. The unaudited condensed consolidated statements of operations data for the nine months ended December 31, 2012 and 2013 and the unaudited condensed consolidated balance sheet data as of December 31, 2013 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. We have prepared the unaudited condensed consolidated financial information on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements. 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. The following selected financial data should be read in conjunction with “Management’s discussion and analysis of financial condition and results of operations” and our financial statements and related notes included elsewhere in this prospectus.

(Dollars in thousands, except share and per share data)	Fiscal Year Ended March 31,		Nine Months Ended December 31,	
	2013	2012	2013	2012
Revenues:				