UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2020
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____ .

Commission File Number: 001-37761

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**20-5093315**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

343 Allerton Avenue
South San Francisco, CA 94080
(Address of principal executive offices including zip code)

(650) 577-3600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VTGN	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-Accelerated filer	[ ]	Smaller reporting company	[X]
		Emerging growth company	[ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 13, 2020, 73,998,057 shares of the registrant's common stock, $0.001 par value, were issued and outstanding.

VistaGen Therapeutics, Inc.
Quarterly Report on Form 10-Q
for the Quarter Ended June 30, 2020

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in Dollars, except share amounts)

	June 30, 2020 (Unaudited)	March 31, 2020 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,545,900	$ 1,355,100
Prepaid expenses and other current assets	633,000	225,100
Total current assets	2,178,900	1,580,200
Property and equipment, net	184,200	209,600
Right of use asset - operating lease	3,492,100	3,579,600
Deferred offering costs	263,900	355,100
Security deposits and other assets	47,800	47,800
Total assets	$ 6,166,900	$ 5,772,300
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,307,300	$ 1,836,600
Accrued expenses	607,800	561,500
Current notes payable, including accrued interest	428,900	56,500
Operating lease obligation - current portion	325,700	313,400
Financing lease obligation - current portion	3,400	3,300
Total current liabilities	2,673,100	2,771,300
Non-current liabilities:		
Non-current portion of notes payable	124,700	-
Accrued dividends on Series B Preferred Stock	5,347,600	5,011,800
Operating lease obligation - non-current portion	3,631,100	3,715,600
Financing lease obligation - non-current portion	2,100	3,000
Total non-current liabilities	9,105,500	8,730,400
Total liabilities	11,778,600	11,501,700
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2020 and March 31, 2020:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at June 30, 2020 and March 31, 2020	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2020 and March 31, 2020; 1,160,240 shares issued and outstanding at June 30, 2020 and March 31, 2020	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at June 30, 2020 and March 31, 2020; 2,318,012 shares issued and outstanding at June 30, 2020 and March 31, 2020	2,300	2,300
Common stock, $0.001 par value; 175,000,000 shares authorized at June 30, 2020 and March 31, 2020; 55,937,472 and 49,348,707 shares issued and outstanding at June 30, 2020 and March 31, 2020, respectively		
Additional paid-in capital	203,330,700	200,092,800
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2020 and March 31, 2020	(3,968,100)	(3,968,100)
Accumulated deficit	(205,034,200)	(201,907,400)
Total stockholders' deficit	(5,611,700)	(5,729,400)
Total liabilities and stockholders' deficit	$ 6,166,900	$ 5,772,300

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(Amounts in dollars, except share amounts)

	Three Months Ended June 30,	
	2020	**2019**
Operating expenses:		
Research and development	$ 1,731,200	$ 4,313,900
General and administrative	1,390,600	1,910,100
Total operating expenses	3,121,800	6,224,000
Loss from operations	(3,121,800)	(6,224,000)
Other income (expenses), net:		
Interest income (expense), net	(3,200)	16,500
Other income	600	-
Loss before income taxes	(3,124,400)	(6,207,500)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	$ (3,126,800)	$ (6,209,900)
Accrued dividends on Series B Preferred stock	(335,800)	(302,500)
Net loss attributable to common stockholders	$ (3,462,600)	$ (6,512,400)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.07)	$ (0.15)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	51,321,355	42,622,965

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(Amounts in Dollars)

	Three Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (3,126,800)	$ (6,209,900)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	25,400	26,200
Stock-based compensation	674,600	1,063,000
Amortization of fair value of common stock issued for services	-	69,100
Amortization of fair value of warrants issued for services	-	10,300
Changes in operating assets and liabilities:		
Receivable from supplier	-	300,000
Prepaid expenses and other current assets	39,200	(80,900)
Right of use asset - operating lease	87,500	81,700
Operating lease liability	(72,200)	(61,100)
Accounts payable and accrued expenses	(434,400)	40,200
Net cash used in operating activities	(2,806,700)	(4,761,400)
Cash flows from property and investing activities:		
Net cash used in investing activities	-	-
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	62,600	-
Expense related to registration of shares underlying outstanding warrants	(29,400)	-
Net proceeds from sale of common stock under equity line	2,790,600	-
Proceeds from issuance of note under Payroll Protection Plan	224,400	-
Repayment of capital lease obligations	(800)	(700)
Repayment of notes payable	(49,900)	(41,100)
Net cash provided by (used in) financing activities	2,997,500	(41,800)
Net increase (decrease) in cash and cash equivalents	190,800	(4,803,200)
Cash and cash equivalents at beginning of fiscal year	1,355,100	13,100,300
Cash and cash equivalents at end of fiscal year	$ 1,545,900	$ 8,297,100
Supplemental disclosure of noncash activities:		
Insurance premiums settled by issuing note payable	$ 322,200	$ 230,200
Accrued dividends on Series B Preferred	$ 335,800	$ 320,600

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE THREE MONTHS ENDED JUNE 30, 2019 AND 2020
(Unaudited)
(Amounts in Dollars, except share amounts)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in	Treasury	Accumulated	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balances at March 31, 2019	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**42,758,630**	**$ 42,800**	**$192,129,900**	**($3,968,100)**	**$(181,133,400)**	**$ 7,075,200**
Accrued dividends on Series B Preferred stock	-	-	-	-	-	-	-	-	(302,500)	-	-	(302,500)
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,063,000	-	-	1,063,000
Net loss for the quarter ended June 30, 2019	-	-	-	-	-	-	-	-	-	-	(6,209,900)	(6,209,900)
Balances at June 30, 2019	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**42,758,630**	**$ 42,800**	**$192,890,400**	**($3,968,100)**	**$(187,343,300)**	**$ 1,625,800**
Balances at March 31, 2020	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**49,348,707**	**$ 49,300**	**$200,092,800**	**($3,968,100)**	**$(201,907,400)**	**$ (5,729,400)**
Proceeds from sale of units of common stock and warrants for cash in private placement	-	-	-	-	-	-	125,000	200	49,800	-	-	50,000
Net proceeds from sale of common stock under equity line	-	-	-	-	-	-	6,201,995	6,200	2,741,300	-	-	2,747,500
Issuance of common stock at fair value for professional services	-	-	-	-	-	-	233,645	200	124,800	-	-	125,000
Sale of common stock pursuant to 2019 Employee Stock Purchase Plan	-	-	-	-	-	-	28,125	-	12,600	-	-	12,600
Expenses related to S-3 registration												

statement for shares underlying outstanding warrants	-	-	-	-	-	-	-	-	(29,400)	-	-	(29,400)
Accrued dividends on Series B Preferred stock							-	-	(335,800)	-	-	(335,800)
Stock-based compensation expense	-	-	-	-	-	-	-	-	674,600	-	-	674,600
Net loss for the quarter ended June 30, 2020	-	-	-	-	-	-	-	-	-	-	(3,126,800)	(3,126,800)
Balances at June 30, 2020	**500,000**	**$ 500**	**1,160,240**	**$ 1,200**	**2,318,012**	**$ 2,300**	**55,937,472**	**$ 55,900**	**$203,330,700**	**$(3,968,100)**	**$(205,034,200)**	**$ (5,611,700)**

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Description of Business

VistaGen Therapeutics. Inc., a Nevada corporation (which may be referred to as *VistaGen*, the *Company*, *we*, *our*, or *us*), is a biopharmaceutical company committed to developing new generation therapies for anxiety, depression and certain additional central nervous system (*CNS*) disorders for which we believe current treatment options are inadequate, resulting in high unmet need in multiple CNS markets worldwide. Our pipeline includes three clinical-stage CNS product candidates, PH94B, PH10 and AV-101, each with a differentiated mechanism of action, an exceptional safety profile in all clinical studies to date, and therapeutic potential in multiple CNS indications. We are currently preparing PH94B for Phase 3 clinical development for the acute treatment of anxiety in adult patients with social anxiety disorder (*SAD*). We are also preparing PH94B for an exploratory Phase 2A open-label clinical study in adult patients experiencing adjustment disorder with anxiety (*AjDA*), including, but not limited to, AjDA as a result of the diverse impact of the COVID-19 pandemic (e.g., anxiety regarding health and safety, economic loss, unemployment, social isolation, remote education and work, etc.), as well as recent social unrest. PH10 has completed successful exploratory Phase 2A clinical development as a new generation treatment for major depressive disorder (*MDD*). We are currently preparing PH10 for Phase 2B clinical development as a potential stand-alone treatment for MDD that is fundamentally different from all current MDD therapies. In several clinical studies, we have established that AV-101 is orally available and has an excellent safety profile. Based on successful preclinical studies involving AV-101 alone and in combination with probenecid, we are currently assessing additional preclinical data and potential Phase 1B development of AV-101, in combination with probenecid, for treatment of several CNS indications involving abnormal function of the NMDAR (*N-methyl-D-aspartate receptor*). Additionally, our subsidiary, VistaStem Therapeutics (*VistaStem*), has pluripotent stem cell technology focused on assessing and developing potential small molecule new chemical entities *(NCEs*) for our CNS pipeline, or for out-licensing, by utilizing *CardioSafe* 3D™, VistaStem's customized human heart cell-based cardiac bioassay system. Our goal is to become a fully integrated biopharmaceutical company that develops and commercializes innovative medicine for large and growing neuropsychiatry and neurology markets worldwide where we believe current treatments are inadequate to meet the needs of millions of patients.

Our Product Candidates

PH94B is a novel, first-in-class neuroactive nasal spray with therapeutic potential in a wide range of indications involving anxiety or phobia. Self-administered in microgram-level doses, PH94B does not require systemic uptake and distribution to produce its rapid-onset anti-anxiety effects. We are initially developing PH94B as a potential rapid-onset (within 15 minutes), non-sedating, non-addictive new generation acute treatment of anxiety in adult patients with SAD, and as an acute treatment for adult patients with AjDA. With its rapid-onset pharmacology, lack of systemic exposure and excellent safety profile, we believe PH94B also has potential as a novel treatment for postpartum anxiety (*PPA*), post-traumatic stress disorder (*PTSD*), preoperative anxiety (*POA*), panic disorder and other anxiety-related disorders. The FDA has granted Fast Track designation for development of PH94B as a potential acute treatment of anxiety in adults with SAD.

PH10 is an odorless, fast-acting synthetic neurosteroid delivered intranasally that has therapeutic potential in a wide range of neuropsychiatric indications involving depression. Self-administered in microgram-level doses, PH10 does not require systemic uptake and distribution to produce its rapid-onset antidepressant effects. We are initially developing PH10 as a potential rapid-onset, non-sedating, non-addictive new generation stand-alone treatment of MDD. With its rapid-onset pharmacology, lack of systemic exposure, and exceptional safety profile in all studies to date, we believe PH10 also has potential as a novel treatment for postpartum depression (*PPD*), treatment-resistant depression (*TRD*) and suicidal ideation (*SI*).

AV-101 (4-Cl-KYN) is a novel, oral prodrug that targets the NMDAR, an ionotropic glutamate receptor in the brain. Abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101's active metabolite, 7-chloro-kynurenic acid (*7-Cl-KYNA*), is a potent and selective full antagonist of the glycine coagonist site of the NMDAR that inhibits the function of the NMDAR, but does not block the NMDAR receptor like ketamine and other NMDAR antagonists. We have demonstrated in clinical trials that AV-101 is orally-available, well-tolerated and does not cause dissociative or hallucinogenic psychological side effects or safety concerns similar to those that may be caused by other NMDAR antagonists. With its exceptionally few side effects and excellent safety profile, we believe AV-101 has potential to be an oral, new generation treatment for multiple CNS indications involving abnormal NMDAR function and where current treatments are inadequate to meet high unmet patient needs. The FDA has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain (*NP*). We are currently assessing AV-101's potential in combination with probenecid, to treat both MDD and NP, as well as dyskinesia associated with levodopa therapy for Parkinson's disease, epilepsy and suicidal ideation.

VistaStem is applying pluripotent stem cell (*hPSC*) technology and CardioSafe 3D, our customized cardiac bioassay system, to discover and develop, novel small molecule NCEs for our CNS pipeline or for out-licensing. To advance potential cell therapy (*CT*) and regenerative medicine (*RM*) applications of VistaStem's hPSC technologies related to heart cells, in 2016, we licensed to BlueRock Therapeutics LP, a next generation CT/RM company formed jointly by Bayer AG and Versant Ventures, rights to develop and commercialize certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease. As a result of its acquisition of BlueRock Therapeutics in 2019, Bayer AG now holds rights to develop and commercialize VistaStem's hPSC technologies relating to the production of heart cells for the treatment of heart disease (the *Bayer Agreement*), which is described more completely in Note 11, *Sublicensing and Collaboration Agreements*.

Our product candidates are protected through a combination of patents, trade secrets, and proprietary know-how. If approved, they may also be eligible for periods of regulatory exclusivity. Our intellectual property portfolio includes issued U.S. and foreign patents, as well as U.S. and foreign patent applications.

Subsidiaries

As noted above, VistaStem, a California corporation, is our wholly-owned subsidiary. Our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q (*Report*) also include the accounts of VistaStem and VistaStem's two wholly-owned inactive subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation, and VistaStem Canada, Inc., a corporation organized under the laws of Ontario, Canada.

Note 2. Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (*U.S. GAAP*) for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required for complete consolidated financial statements. In the opinion of management, the accompanying unaudited Condensed Consolidated Financial Statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly our interim financial information. The accompanying Condensed Consolidated Balance Sheet at March 31, 2020 has been derived from our audited consolidated financial statements at that date but does not include all disclosures required by U.S. GAAP. The operating results for the three months ended June 30, 2020 are not necessarily indicative of the operating results to be expected for our fiscal year ending March 31, 2021, or for any other future interim or other period.

The accompanying unaudited Condensed Consolidated Financial Statements and notes to the Condensed Consolidated Financial Statements contained in this Report should be read in conjunction with our audited Consolidated Financial Statements for our fiscal year ended March 31, 2020 contained in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (*SEC*) on June 29, 2020.

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared assuming we will continue as a going concern. As a clinical-stage biopharmaceutical company having not yet developed commercial products or achieved sustainable revenues, we have experienced recurring losses and negative cash flows from operations resulting in a deficit of approximately $205.0 million accumulated from inception (May 1998) through June 30, 2020. We expect losses and negative cash flows from operations to continue for the foreseeable future as we engage in further development of PH94B, PH10 and AV-101, execute our drug rescue programs and pursue potential drug development and regenerative medicine opportunities.

Since our inception in May 1998 through June 30, 2020, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity and debt securities for cash proceeds of approximately $86.1 million, as well as from an aggregate of approximately $17.7 million of government research grant awards (excluding the fair market value of government sponsored and funded clinical trials), strategic collaboration payments, intellectual property licensing and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $38.2 million in noncash acquisitions of product licenses and in settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

Recent Developments

At June 30, 2020, we had cash and cash equivalents of approximately $1.5 million. As more completely described in Note 8, *Capital Stock*, on March 24, 2020, we entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund (*Lincoln Park*) pursuant to which Lincoln Park committed to purchase up to $10,250,000 of our common stock at market-based prices over a period of 24 months (the *LPC Agreement*). To satisfy our obligations under the registration rights agreement, we filed a Registration Statement on Form S-1 (the *LPC Registration Statement*) with the Securities and Exchange Commission (the *SEC*) on March 31, 2020, which the SEC declared effective on April 14, 2020 (Registration No. 333-237514). Subsequent to the effectiveness of the LPC Registration Statement, through June 30, 2020, we sold 6,201,995 registered shares of our common stock to Lincoln Park and received gross cash proceeds of $2,840,200. Refer to Note 12, *Subsequent Events*, for dislosure of additional sales of our common stock under the LPC Agreement subsequent to June 30, 2020.

As more completely described in Note 11, *Sublicensing and Collaboration Agreements*, and in Note 12, *Subsequent Events*, in June 2020, we entered into a strategic licensing and collaboration agreement for the clinical development and commercialization of PH94B for acute treatment of anxiety in adults with SAD and other potential anxiety-related disorders, with EverInsight Therapeutics Inc., a biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products for patients in Greater China and other parts of Asia (the *EverInsight Agreement*). Under the terms of the EverInsight Agreement, EverInsight agreed to make a non-dilutive upfront license payment of $5.0 million to us. Upon successful development and commercialization of PH94B, we are also eligible to receive up to $172 million in additional development and commercial milestone payments, in addition to royalties on commercial sales. In August 2020, we received the $5.0 million non-dilutive upfront license payment from EverInsight, which resulted in net cash proceeds to us of approximately $4.655 million after the sublicense payment we agreed to make to Pherin Pharmaceuticals, Inc. (*Pherin*) pursuant to our PH94B license from Pherin, and payment for consulting services related to the EverInsight Agreement.

As described more completely in Note 12, *Subsequent Events*, on August 2, 2020, we entered into an underwriting agreement (the *Underwriting Agreement*) pursuant to which we sold to the Underwriter, in an underwritten public offering (the *Public Offering*), an aggregate of 15,625,000 shares (the *Shares*) of our common stock for a public offering price of $0.80 per Share, resulting in gross proceeds to us of $12,500,000. The Public Offering closed on August 5, 2020. Under the terms of the Underwriting Agreement, we granted to the Underwriter a 45-day over-allotment option (the *Over-Allotment Option*) to purchase up to an additional 2,343,750 Shares (the *Option Shares*) at a public offering price of $0.80 per share. On August 5, 2020, the Underwriter exercised the Over-Allotment Option with respect to an aggregate of 2,243,250 Option Shares (the *Exercised Option Shares*). We completed the sale of the Exercised Option Shares on August 7, 2020, which resulted in additional gross proceeds to us of $1,794,600. Net proceeds to us from the sale of the Shares and the Exercised Option Shares, after deducting underwriting discounts and commissions and offering expenses payable by us, were approximately $12.9 million.

Going Concern

Although the transactions described above have generated approximately $20.0 million in net cash procceds for us between April 1, 2020 and the date of this Report, we believe it is possible that our cash position at June 30, 2020, together with such net proceeds will not be sufficient to fund our planned operations for the twelve months following the issuance of these financial statements, which raises substantial doubt that we can continue as a going concern. During the next twelve months, subject to securing appropriate and adequate additional financing, we plan to prepare for and launch (i) a pivotal Phase 3 clinical trial of PH94B for acute treatment of anxiety in adult patients with SAD, (ii) a small exploratory open-label Phase 2A study of PH94B for acute treatment of adult patients with AjDA, and (iii) several nonclinical studies involving PH94B, PH10 and AV-101. When necessary and advantageous, we plan to raise additional capital, through the sale of our equity securities in one or more (i) private placements to accredited investors, (ii) public offerings and/or (iii) in strategic licensing and development collaborations involving one or more of our drug candidates in markets outside the United States, similar to the Everinsight Agreement. Subject to certain restrictions, our Registration Statement on Form S-3 (Registration No. 333-234025) (the *S-3 Registration Statement*), which became effective on October 7, 2019, remains available for future sales of our equity securities in one or more public offerings from time to time. While we may make additional sales of our equity securities under the S-3 Registration Statement, we do not have an obligation to do so.

As we have been in the past, we expect that, when and as necessary, we will be successful in raising additional capital from the sale of our equity securities either in one or more public offerings or in one or more private placement transactions with individual accredited investors and institutions. In addition to the potential sale of our equity securities, we may also seek to enter research, development and/or commercialization collaborations similar to the EverInsight Agreement and the Bayer Agreement that could generate revenue or provide funding, including non-dilutive funding, for development of one or more of our CNS product candidate programs. We may also seek additional government grant awards or agreements similar to our prior agreement with the U.S. National Institutes of Health (*NIH*), Baylor University and the U.S. Department of Veterans Affairs in connection with certain government-sponsored studies of AV-101. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. We may also pursue intellectual property arrangements similar to the EverInsight Agreement and the Bayer Agreement with other parties. Although we may seek additional collaborations that could generate revenue and/or provide non-dilutive funding for development of our product candidates, as well as new government grant awards and/or agreements, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

Our future working capital requirements will depend on many factors, including, without limitation, potential impacts related to the current COVID-19 pndemic, the scope and nature of opportunities related to our success and the success of certain other companies in nonclinical and clinical trials, including our development and commercialization of our current product candidates and various applications of our stem cell technology platform, the availability of, and our ability to obtain, government grant awards and agreements, and our ability to enter into collaborations on terms acceptable to us. To further advance the clinical development of PH94B, PH10, and AV-101 and, to a lesser extent, our stem cell technology platform, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including our employee headcount and related expenses, as well as costs relating to regulatory consulting, contract manufacturing, research and development, investor and public relations, business development, legal, intellectual property acquisition and protection, public company compliance and other professional services and operating costs.

Notwithstanding the foregoing, there can be no assurance that our current strategic collaborations under the EverInsight Agreement and the Bayer Agreement, will generate revenue from future potential milestone payments, or that future financings or government or other strategic collaborations will be available to us in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2021 or thereafter, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. As noted above, these Condensed Consolidated Financial Statements do not include any adjustments that might result from the negative outcome of this uncertainty.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include those relating to revenue recognition, share-based compensation, right-of-use assets and lease liabilities and assumptions that have been used historically to value warrants and warrant modifications.

Revenue Recognition

We generate revenue from collaborative research and development arrangements, licensing and technology transfer agreements, including strategic licenses or sublicenses, and government grants. We expect that our primary source of revenue beginning in the second fiscal quarter of our current fiscal year will be from the EverInsight Agreement involving clinical development and commercialization of PH94B for acute treatment of anxiety in adults with SAD, and potentially other anxiety-related disorders, in Greater China, South Korea, and Southeast Asia, which is described in more detail in Note 11, *Sublicensing and Collaboration Agreements.* The terms of the EverInsight Agreement include a $5.0 million non-refundable upfront license fee, potential payments based upon achievement of certain development and commercial milestones, and royalties on product sales. We also have the Bayer Agreement, pursuant to which we recorded sublicense revenue in the third quarter of our fiscal year ended March 31, 2017, also described in Note 11, *Sublicensing and Collaborative Agreements*, as a potential revenue generating arrangement.

Under Accounting Standards Codification (*ASC*) Topic 606, *Revenue from Contracts with Customers (Topic 606)*, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to a customer.

Performance Obligations

We assess whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires judgments about the individual promised goods or services and whether such components are separable from the other aspects of the contractual relationship. In assessing whether a promised good or service is distinct in the evaluation of a collaboration arrangement subject to Topic 606, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace.

Collaboration arrangements can have several promised goods or services including a license for our intellectual property, product supply and development and regulatory services. When the customer could not obtain the intended benefit of the contract from a promised good or service without one or more other promises in the contract, the promise is determined to be not distinct in the context of the contract and is combined with other promises until the combined promises are distinct to identify performance obligations. We have determined that the Everinsight Agreement includes a single combined performance obligation that includes both the license to intellectual property and development and regulatory services.

Arrangements can include promises for optional additional items, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future supply of product for either clinical development or commercial supply and optional research and development services at the customer’s or the Company’s discretion are generally considered as options. We assess whether these options provide a material right to the customer and if so, such material rights are accounted for as separate performance obligations. When the customer exercises an option, any additional payments related to the option are recorded in revenue when the customer obtains control of the goods or services.

Transaction Price

Arrangements may have both fixed and variable consideration. For collaboration agreements, the non-refundable upfront fees and product supply selling prices are considered fixed, while milestone payments are considered variable consideration when determining the transaction price. At the inception of each arrangement, we evaluate whether the development milestones are considered probable of being achieved and estimate an amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as approvals from regulators, are generally not considered probable of being achieved until such approvals are received.

For sales-based royalties, including commercial milestone payments based on the level of sales, for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of when (a) the related sales occur, or (b) the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

In determining the transaction price, we adjust consideration for the effects of the time value of money if the timing of payments provides us with a significant benefit of financing. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensee and the transfer of the promised goods or services to the licensee will be one year or less.

Allocation of Consideration

As part of the accounting for collaboration arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The transaction price is allocated to the identified performance obligations in proportion to their stand-alone selling prices (*SSP*) on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and satisfaction of the performance obligations. In developing the SSP for a performance obligation, we consider applicable market conditions and relevant Company-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. We validate the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations. Since the EverInsight Agreement includes a single combined performance obligation that is not distinct, there is no allocation of consideration.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under collaboration arrangements and the period over which we expect to complete our performance obligations under the arrangement. The performance period or measure of progress is estimated at the inception of the arrangement and re-evaluated in each reporting period. This re-evaluation may shorten or lengthen the period over which revenue is recognized. Changes to these estimates are recorded on a cumulative catch up basis. Revenue is recognized for products at a point in time and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time using an output or input method. For performance obligations that are a combination of licenses to intellectual property and interdependent services, the nature of the combined performance obligation is considered when determining the method and measure of progress that best represents the satisfaction of the performance obligation. For the single combined performance obligation of the EverInsight Agreement, the measure of progress is stand-ready straight-line over the period in which we expect to perform the services related to the license of PH94B.

We have recorded no receivables, contract assets, or contract liabilities as of June 30, 2020 related to the EverInsight Agreement, as there are no rights and obligations as of that date. In subsequent periods, the difference between revenue recognized to-date and the consideration invoiced to-date will be recognized as either a contract asset/unbilled revenue (revenue earned exceeds invoices) or a contract liability/deferred revenue (invoices exceed revenue earned).

Contract Costs

Subsequent to June 30, 2020, we expect to make cash payments aggregating $345,000 for sublicense fees which we are obligated to make pursuant to our PH94B license from Pherin, and fees for consulting services exclusively related to the EverInsight Agreement. Additionally, on June 24, 2020, we issued 233,645 unregistered shares of our common stock, valued at $125,000, as partial compensation for consulting services exclusively related to the EverInsight Agreement. These sublicense fees and consulting payments were incurred solely as a result of obtaining the EverInsight Agreement, and will, accordingly, be capitalized as contract acquisition costs. Capitalized contract acquisition costs are amortized over the period in which we expect to satisfy the performance obligations under the arrangement and will be included in general and administrative expenses. At June 30, 2020, the $125,000 fair value of the common stock issued has been recorded as a prepaid asset. In subsequent periods, the aggregate costs of $470,000 incurred to obtain the EverInsight Agreement will be capitalized as contract acquisition costs and amortized as indicated. In the quarter ended June 30, 2020, no amounts were amortized to expense, as services have not yet commenced under the arrangement.

Research and Development Expenses

Research and development expenses are composed of both internal and external costs. Internal costs include salaries and employment-related expenses, including stock-based compensation expense, of scientific personnel and direct project costs. External research and development expenses consist primarily of costs associated with clinical and non-clinical development of PH94B, PH10, AV-101, and stem cell research and development costs, and costs related to the application and prosecution of patents related to those product candidates and, to a lesser extent, our stem cell technology platform. All such costs are charged to expense as incurred. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by contract research organizations (*CRO*s) and clinical trial sites. Progress payments are generally made to contract research and development organizations, clinical sites, investigators and other professional service providers. We analyze the progress of clinical trials, including levels of subject enrollment, invoices received and contracted costs, when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the clinical trial accrual in any reporting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to research and development expense in the period in which the facts that give rise to the revision become known. Costs incurred in obtaining product or technology licenses are charged immediately to research and development expense if the product or technology licensed has not achieved regulatory approval or reached technical feasibility and has no alternative future uses, as was the case with our acquisition of the exclusive worldwide licenses for PH94B and PH10 from Pherin during our fiscal year ended March 31, 2019.

Stock-Based Compensation

We recognize compensation cost for all stock-based awards to employees and non-employee consultants based on the grant date fair value of the award. We record non-cash, stock-based compensation expense over the period during which the employee or other grantee is required to perform services in exchange for the award, which generally represents the scheduled vesting period. We have not granted restricted stock awards to employees nor do we have any awards with market or performance conditions. Non-cash expense attributable to compensatory grants of shares of our common stock to non-employees is determined by the quoted market price of the stock on the date of grant and is either recognized as fully-earned at the time of the grant or amortized ratably over the term of the related service agreement, depending on the terms of the specific agreement.

The table below summarizes stock-based compensation expense included in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended June 30, 2020.

	Three Months Ended June 30,	
	2020	**2019**
Research and development expense	$ 226,600	$ 390,600
General and administrative expense	448,000	672,400
Total stock-based compensation expense	$ 674,600	$ 1,063,000

Expense amounts reported above include $2,500 and $1,500 in research and development expense and general and administrative expense, respectively, attributable to our 2019 Employee Stock Purchase Plan for the quarter ended June 30, 2020.

During the quarter ended June 30, 2020, we granted from our 2019 Omnibus Equity Incentive Plan (the *2019 Plan*) options to purchase an aggregate of 1,945,000 shares of our common stock at exercise prices at or above the closing market price of our common stock on the date of grant to the independent members of our Board, our officers and employees and certain consultants. The options vested 25% upon grant with the remaining shares vesting ratably over two years for independent directors, officers and employees, and over one or two years for consultants. We valued the options granted during the quarter ended June 30, 2020 using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	Weighted Average	Range
Market price per share at grant date	$ 0.41	$ 0.40 to 0.54
Exercise price per share	$ 0.41	$ 0.40 to 0.55
Risk-free interest rate	0.39%	0.35% to 0.44%
Expected term in years	5.36	5.20 to 5.94
Volatility	84.10%	82.93% to 85.85%
Dividend rate	0.0%	0.0%
Shares	1,945,000	
Fair Value per share	**$ 0.28**	

At June 30, 2020, there were stock options outstanding under our 2016 Equity Incentive Plan (the *2016 Plan*) and our 2019 Plan to purchase 11,948,088 shares of our common stock at a weighted average exercise price of $1.21 per share. At that date, there were also 4,785,162 shares of our common stock available for future issuance under the 2019 Plan. There are no additional shares available for issuance under our 2016 Plan.

Leases, Right-of-Use Assets and Lease Liabilities

On April 1, 2019, we adopted Financial Accounting Standards Board (*FASB*) Accounting Standards Update (*ASU*) No. 2016-02, *Leases*, which replaced the existing guidance in Accounting Standards Codification (*ASC*) 840, "Leases", and its subsequent amendments including ASU No. 2018-11, *Leases (Topic 842):* Targeted Improvements (*ASC 842*) using the modified transition method.

We determine whether an arrangement is an operating or financing lease at contract inception. Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. In determining the present value of the lease payments, we use the interest rate implicit in the lease when it is readily determinable and we use our estimated incremental borrowing rate based upon information available at the commencement date when the implicit rate is not readily determinable.

The lease payments used to determine our operating lease assets include lease incentives and stated rent increases and may include escalation or other clauses linked to rates of inflation or other factors when determinable and are recognized in our operating lease assets in our condensed consolidated balance sheets.

Our operating leases are reflected in right of use asset – operating leases, other current liabilities and non-current operating lease liability in our condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Short-term leases, defined as leases that have a lease term of 12 months or less at the commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease.

Our accounting for financing leases, previously referred to as "capital leases" under earlier guidance, remained substantially unchanged with our adoption of ASC 842. Financing leases are included in property and equipment, net and as current and non-current financing lease liabilities in our condensed consolidated balance sheets. Refer to Note 10, *Commitments and Contingencies*, for additional information regarding ASC 842 and its impact on our condensed consolidated financial statements.

Comprehensive Loss

We have no components of other comprehensive loss other than net loss, and accordingly our comprehensive loss is equivalent to our net loss for the periods presented.

Loss per Common Share

Basic net loss attributable to common stockholders per share of common stock excludes the effect of dilution and is computed by dividing net loss increased by the accrual of dividends on outstanding shares of our Series B 10% Convertible Preferred Stock (*Series B Preferred*), by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue shares of common stock were exercised or converted into shares of common stock. In calculating diluted net loss attributable to common stockholders per share, we have generally not increased the denominator to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method because the result is antidilutive.

As a result of our net loss for all periods presented, potentially dilutive securities were excluded from the computation of diluted net loss per share, as their effect would be antidilutive. Potentially dilutive securities excluded in determining diluted net loss attributable to common stockholders per common share are as follows:

	At June 30, 2020	At March 31, 2020
Series A Preferred stock issued and outstanding [1]	750,000	750,000
Series B Preferred stock issued and outstanding [2]	1,160,240	1,160,240
Series C Preferred stock issued and outstanding [3]	2,318,012	2,318,012
Outstanding options under the Company's Amended and Restated 2016 (formerly 2008) Stock Incentive Plan and 2019 Omnibus Equity Incentive Plan	11,948,088	10,003,088
Outstanding warrants to purchase common stock	26,589,834	26,555,281
Total	42,766,174	40,786,621

[1] Assumes exchange under the terms of the October 11, 2012 Note Exchange and Purchase Agreement, as amended

[2] Assumes exchange under the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series B 10% Convertible Preferred Stock, effective May 5, 2015; excludes shares of unegistered common stock issuable in payment of dividends on Series B Preferred upon conversion

[3] Assumes exchange under the terms of the Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock, effective January 25, 2016

Fair Value Measurements

We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. We carried no assets or liabilities that are measured on a recurring basis at fair value at June 30, 2020 or March 31, 2020.

Recent Accounting Pronouncements

Other than as described in our Form 10-K for our fiscal year ended March 31, 2020, we do not expect that accounting standards that have been issued or proposed by the Financial Accounting Standards Board *(FASB*) or other standards-setting bodies that do not require adoption until a future date will have a material impact on our consolidated financial statements upon adoption.

Note 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are composed of the following at June 30, 2020 and March 31, 2020:

	June 30, 2020	March 31, 2020
Clinical and nonclinical materials and contract services	$ 115,200	$ 115,200
Fair value of securities issued for professional services	125,000	-
Insurance	391,200	107,200
All other	1,600	2,700
	$ 633,000	$ 225,100

Note 5. Property and Equipment

Property and equipment is composed of the following at June 30, 2020 and March 31, 2020:

	June 30, 2020	March 31, 2020
Laboratory equipment	$ 892,500	$ 892,500
Tenant improvements	214,400	214,400
Computers and network equipment	54,600	54,600
Office furniture and equipment	84,600	84,600
	1,246,100	1,246,100
Accumulated depreciation and amortization	(1,061,900)	(1,036,500)
Property and equipment, net	$ 184,200	$ 209,600

Included in amounts reported above for office furniture and equipment is the right-of-use asset related to a financing lease of certain office equipment. Amounts associated with assets subject to the financing lease at June 30, 2020 and March 31, 2020 are as follows:

	June 30, 2020	March 31, 2020
Office equipment subject to financing lease	$ 14,700	$ 14,700
Accumulated depreciation	(10,100)	(9,400)
Net book value of ofice equipment subject to financing lease	$ 4,600	$ 5,300

Note 6. Accrued Expenses

Accrued expenses are composed of the following at June 30, 2020 and March 31, 2020:

	June 30, 2020	March 31, 2020
Accrued expenses for clinical and nonclinical materials, development and contract services	$ 397,100	$ 462,300
Accrued professional services	194,600	76,500
All other	16,100	22,700
	$ 607,800	$ 561,500

Note 7. Notes Payable

The following table summarizes our unsecured promissory notes at June 30, 2020 and March 31, 2020:

	June 30, 2020			March 31, 2020		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
7.30% and 6.30% Notes payable to insurance premium financing company (current)	$ 328,800	$ -	$ 328,800	$ 56,500	$ -	$ 56,500
1% Note payable under Paycheck Protection Program	224,400	400	224,800	-	-	-
less: current portion	(99,700)	(400)	(100,100)	-	-	-
Non-current portion	$ 124,700	$ -	$ 124,700	$ -	$ -	$ -
Total current notes payable	$ 428,500	$ 400	$ 428,900	$ 56,500	$ -	$ 56,500

In May 2020, we executed a 6.30% promissory note in the principal amount of $322,200 in connection with certain insurance policy premiums. The note is payable in monthly installments of $33,200, including principal and interest, through March 2021, and had an outstanding principal balance of $290,800 at June 30, 2020. In February 2020, we executed a 7.30% promissory note in the principal amount of $62,600 in connection with other insurance policy premiums. That note is payable in monthly installments of $6,500 including principal and interest, through December 2020 and had an outstanding principal balance of $38,000 at June 30, 2020.

In April 2020, we entered into a note payable agreement (the *PPP Loan Agreement*) with Silicon Valley Bank as lender (the *Lender*), pursuant to which we received net proceeds of $224,400 from a potentially forgivable loan from the U.S. Small Business Administration (*SBA*) pursuant to the Paycheck Protection Program (*PPP*) enacted by Congress under the Coronavirus Aid, Relief, and Economic Security Act (the *CARES Act*) administered by the SBA (the *PPP Loan*). The PPP Loan matures on April 22, 2022. Under the CARES Act and the PPP Loan Agreement, all payments of both principal and interest are deferred until at least October 22, 2020, after which time we will be required to make monthly principal payments of approximately $12,500 until maturity, unless the loan is forgiven prior to maturity. The PPP Loan will accrue interest at a rate of 1.00% per annum, and interest will continue to accrue throughout the period the PPP Loan is outstanding, or until it is forgiven. The CARES Act (including subsequent guidance issued by SBA and U.S. Department of the Treasury related thereto) provides that all or a portion of the PPP Loan may be forgiven upon our request to the Lender, subject to requirements in the PPP Loan Agreement and the CARES Act. While we currently believe that the use of the PPP Loan proceeds will meet the conditions for forgiveness under the PPP, there can be no assurance that we will obtain full or partial forgiveness of the loan.

Note 8. Capital Stock

Common Stock Purchase Agreement with Lincoln Park Capital Fund

On March 24, 2020, we entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund (*LPC*) pursuant to which LPC committed to purchase up to $10,250,000 of our common stock at market-based prices over a period of 24 months (the *LPC Agreement*). On March 24, 2020, we sold 500,000 unregistered shares of our common stock (the *Initial Purchase Shares*) to LPC under the purchase agreement at a price of $0.50 per share for gross cash proceeds of $250,000 (the *Initial Purchase*) and we also issued 750,000 unregistered shares of our common stock to LPC under the terms of the LPC Agreement for its purchase commitments under the LPC Agreement (the *Commitment Shares*). To satisfy our obligations under the registration rights agreement associated with the LPC Agreement, we filed a Registration Statement on Form S-1 (the *LPC Registration Statement*) with the SEC on March 31, 2020 (Registration No. 333-237514), which the SEC declared effective on April 14, 2020 (the *Commencement Date*). The LPC Registration Statement included registration of the Initial Purchase Shares and the Commitment Shares. The fair value of the Commitment Shares, $284,400, determined based on the quoted closing market price of our common stock on March 24, 2020, is a component of deferred offering costs attributable to this offering, which costs are amortized ratably to additional paid-in capital as we sell shares of our common stock to LPC under the LPC Agreement. Subsequent to the Commencement Date and through June 30, 2020, we sold an additional 6,201,995 registered shares of our common stock to LPC and received aggregate gross cash proceeds of $2,840,200. At June 30, 2020, there were approximately 2.1 million registered shares of our common stock remaining available for sale under the LPC Agreement.

On any business day during the term of the LPC Agreement, we have the right, in our sole discretion, to direct LPC to purchase up to 100,000 shares on such business day (the "*Regular Purchase*") (subject to adjustment under certain circumstances as provided in the LPC Agreement). The purchase price per share for each such Regular Purchase will be based on prevailing market prices of our common stock immediately preceding the time of sale as computed under the LPC Agreement. In each case, LPC's maximum commitment in any single Regular Purchase may not exceed $1,000,000. In addition to Regular Purchases, provided that we present LPC with a purchase notice for the full amount allowed for a Regular Purchase, we may also direct LPC to make accelerated purchases and additional accelerated purchases as described in the LPC Agreement. Although LPC has no right to require us to sell any shares of our common stock to LPC, LPC is obligated to make purchases as we direct, subject to certain conditions. In all instances, we may not sell shares of our common stock to LPC under the LPC Agreement if such sales would result in LPC beneficially owning more than 9.99% of our common stock. There are no upper limits on the price per share that LPC must pay for shares of our common stock. See Note 12, *Subsequent Events*, for disclosure regarding sales of our common stock under the LPC Agreement after June 30, 2020.

Sale of Common Stock and Warrants in the Spring 2020 Private Placement

In April 2020, in a self-directed private placement, we sold to an accredited investor units to purchase an aggregate of 125,000 unregistered shares of our common stock and four-year warrants to purchase 125,000 shares of our common stock at an exercise price of $0.50 per share and we received cash proceeds of $50,000 (the *Spring 2020 Private Placement*).

Registration Statement for shares underlying warrants issued in Private Placements

On May 1, 2020, we filed a registration statement on Form S-3 (Registration No. 333-237968) to register approximately 12.1 million shares of common stock underlying outstanding warrants that we had issued in earlier private placement offerings, including the Spring 2020 Private Placement, as well as common stock underlying warrants that had been previously issued to various consultants as full or partial compensation for their services. Included in the registration statement were shares of our common stock underlying approximately 5.8 million outstanding warrants to purchase shares of our common stock that had been modified in December 2019 to temporarily reduce, for a period of two years or, if sooner, until the expiration of the warrant, the exercise price of such warrants to $0.50 per share, in order to more closely align the exercise price of the warrants with the trading price of our common stock at that time (the *Winter 2019 Warrant Modification*). We also registered approximately 0.8 million shares of unregistered outstanding common stock held by former holders of warrants who had exercised such warrants subsequent to the Winter 2019 Warrant Modification. Further, we registered the 125,000 shares of common stock issued in the Spring 2020 Private Placement. The SEC declared the registration statement effective on May 13, 2020 (the *Warrant Registration Statement*). As a result of the effectiveness of this registration statement, the shares of common stock underlying essentially all of our outstanding warrants have been registered.

Warrants Outstanding

The following table summarizes warrants outstanding and exercisable as of June 30, 2020 subsequent to the issuance in the Spring 2020 Private Placement described above. The weighted average exercise price of outstanding and exercisable warrants at June 30, 2020 is $1.64 per share and $1.80 per share, respectively.

Exercise Price per Share	Expiration Date	Warrants Outstanding at June 30, 2020	Warrants Exercisable at June 30, 2020
$ 0.50	3/25/2021 to 4/30/2024	8,151,312	8,026,312
$ 0.73	7/25/2025	3,870,077	-
$ 0.805	12/31/2022	80,431	80,431
$ 1.50	12/13/2022	9,596,200	9,596,200
$ 1.82	3/7/2023	1,388,931	1,388,931
$ 3.51	12/31/2021	50,000	50,000
$ 5.30	5/16/2021	2,705,883	2,705,883
$ 7.00	9/2/2020 to 3/3/2023	747,000	747,000
		26,589,834	22,594,757

At June 30, 2020, with the effectiveness of the Warrant Registration Statement in May 2020, the shares of common stock underlying essentially all of the outstanding warrants except those having an exercise price of $7.00 per share have been registered for resale by the warrant holders. The warrants exercisable at $0.73 per share become exercisable on July 25, 2020. Additionally, no outstanding warrant is subject to any down round anti-dilution protection features and all of the outstanding warrants are exercisable by the holders only by payment in cash of the stated exercise price per share.

Note 9. Related Party Transactions

Contract Research and Development Agreement with Cato Research Ltd.

Cato Holding Company (*CHC*), doing business as Cato BioVentures (*CBV*), was the parent of Cato Research Ltd. (*CRL*), now known as Cato Research LLC. CRL is a contract research, development and regulatory services organization (*CRO*) that we have in the past, and continue to engage for a wide range of material aspects related to the nonclinical and clinical development, manufacturing and regulatory affairs associated with our efforts to develop and commercialize PH94B, PH10, AV-101. In October 2018, CHC completed the sale of CRL to an independent third party. As a result of this transaction, CHC and/or CBV is no longer affiliated with or has any control over CRL. Prior to the sale of CRL, CBV held shares of our common stock and at June 30 2020, CBV held approximately 1.7% of our outstanding common stock.

In July 2017, we entered into a Master Services Agreement (*MSA*) with CRL, which replaced a substantially similar May 2007 master services agreement, pursuant to which CRL may assist us in the evaluation, development, commercialization and marketing of our potential product candidates, and provide regulatory and strategic consulting services as requested from time to time. Specific projects or services are and will be delineated in individual work orders negotiated from time-to-time under the MSA. Under the terms of work orders issued pursuant to the July 2017 MSA, we incurred expenses of $124,800 and $1,405,100 during the quarters ended June 30, 2020 and 2019, respectively. At June 30, 2020 and March 31, 2020, we had recorded accounts payable and accrued expenses related to CRL aggregating $422,800 and $578,800, respectively. We anticipate periodic expenses for CRO services from CRL related to nonclinical and clinical development of, and regulatory affairs related to PH94B, PH10, AV-101 and other potential product candidates will remain significant in future periods.

License and Option Agreements with Pherin Pharmaceuticals, Inc.

During our fiscal year ended March 31, 2019, we issued an aggregate of 2,556,361 shares of our unregistered common stock having an issue-date fair market value of $4,250,000 to Pherin to acquire exclusive worldwide licenses to develop and commercialize PH94B and PH10. We recorded the acquisition of the licenses as research and development expense during our fiscal year ended March 31, 2019. During the quarters ended June 30, 2020 and 2019, we recorded $10,000 and $30,000, respectively, as research and development expense for monthly support payments to Pherin under the terms of the PH94B and PH10 license agreements. Our liability for such monthly support payments terminated in April 2020 under the terms of the PH10 license agreement. We recorded no amounts payable to Pherin at June 30, 2020 or March 31, 2020. At June 30,2020, Pherin held approximately 2.4% of our outstanding common stock.

Consulting Agreement

During the quarters ended June 30, 2020 and 2019, we engaged a consulting firm headed by one of the independent members of our Board to provide various market research studies, competitive analyses, and commercial advisory projects for certain of our CNS pipeline candidates pursuant to which we recorded research and development expense of $15,000 and $27,700 for the quarters ended June 30, 2020 and 2019, respectively. We recorded accounts payable and accrued expenses of $15,000 at June 30, 2020 and no amounts payable at March 31, 2020 related to these projects and services.

Note 10. Commitments and Contingencies

Operating Leases

We lease our headquarters office and laboratory space in South San Francisco, California under the terms of a lease that expires on July 31, 2022 and that provides an option to renew for an additional five years at then-current market rates. Consistent with the guidance in Accounting Standards Codification Topic 842, Leases (*ASC 842*), beginning April 1, 2019, we recorded this lease in our Condensed Consolidated Balance Sheet as an operating lease. For the purpose of determining the right-of-use asset and associated lease liability, we determined that the renewal of this lease is reasonably probable. The lease of our South San Francisco facilities does not include any restrictions or covenants requiring special treatment under ASC 842.

The following table summarizes the presentation of the operating lease in our Condensed Consolidated Balance Sheet at June 30, 2020 and March 31, 2020:

	As of June 30, 2020	As of March 31, 2020
Assets		
Right of use asset – operating lease	$ 3,492,100	$ 3,579,600
Liabilities		
Current operating lease obligation	$ 325,700	$ 313,400
Non-current operating lease obligation	3,631,100	3,715,600
Total operating lease liability	$ 3,956,800	$ 4,029,000

The following table summarizes the effect of operating lease costs in the Company's condensed consolidated statements of operations for the three months ended June 30, 2020 and 2019:

	For the Three Months Ended June 30, 2020	For the Three Months Ended June 30, 2019
Operating lease cost	$ 212,800	$ 208,800

The minimum (base rental) lease payments related to our South San Francisco operating lease are expected to be as follows:

Fiscal Years Ending March 31,	
2021 (remaining nine months)	$ 488,000
2022	668,400
2023	726,000
2024	766,000
2025	789,000
Thereafter	1,931,400
Total lease expense	5,368,800
Less imputed interest	(1,412,000)
Present value of operating lease liabilities	$ 3,956,800

The remaining lease term, including the assumed five-year extension at the expiration of the current lease period, and the discount rate assumption for our South San Francisco operating lease is as follows:

	As of June 30, 2020
Assumed remaining lease term in years	7.08
Assumed discount rate	8.54%

The interest rate implicit in lease contracts is typically not readily determinable and, as such, we used our estimated incremental borrowing rate based on information available at the adoption of ASC 842, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Supplemental disclosure of cash flow information related to our operating lease included in cash flows used by operating activities in the condensed consolidated statements of cash flows is as follows:

	For the Three Months Ended June 30, 2020	For the Three Months Ended June 30, 2019
Cash paid for amounts included in the measurement of lease liabilities	$ 197,500	$ 188,200

During the three months ended June 30, 2020, we recorded no new right of use assets arising from new lease liabilities.

We also lease a small office in the San Francisco Bay Area under a month-to-month arrangement at insignificant cost and have made an accounting policy election not to apply the ASC 842 operating lease recognition requirements to such short-term lease. We recognize the lease payments for this lease in general and administrative expense over the lease term. We recorded rent expense of $3,500 and $3,400 for the three months ended June 30, 2020 and 2019, respectively, attributable to this lease.

Note 11. Sublicensing and Collaborative Agreements

PH94B Sublicense Agreement with EverInsight

On June 24, 2020, we entered into a license and collaboration agreement (the *EverInsight Agreement*) with EverInsight Therapeutics Inc., a company incorporated under the laws of the British Virgin Islands (*EverInsight*), pursuant to which we granted EverInsight an exclusive license to develop and commercialize PH94B, our neurosteroid drug candidate for multiple anxiety-related disorders, in Greater China (which includes Mainland China, Hong Kong, Macau and Taiwan), South Korea and Southeast Asia (which includes Indonesia, Malaysia, Philippines, Thailand and Vietnam) (collectively, the *Territory*). We retain exclusive development and commercialization rights for PH94B in the rest of the world.

Under the terms of the EverInsight Agreement, EverInsight is be responsible for all costs related to developing, obtaining regulatory approval of, and commercializing PH94B for treatment of SAD, and potentially other anxiety-related indications, in the Territory. A joint development committee has been established between us and EverInsight to coordinate and review the development and commercialization plans with respect to PH94B in the Territory.

We are responsible to pursue clinical development and regulatory submissions of PH94B for acute treatment of anxiety in adults with SAD, and potentially other anxiety-related indications, in the United States on a ‘‘best efforts’’ basis, with no guarantee of success. EverInsight has the option to participate in the global Phase 3 clinical trials of PH94B and will assume all direct costs and expenses of conducting such clinical trial in the Territory and a portion of the indirect costs of the global trial. We will transfer all development data (nonclinical and clinical data) and our regulatory documentation related to PH94B throughout the term as it is developed or generated or otherwise comes into our control. We will grant to EverInsight a Right of Reference to all of our regulatory documentation and our development data.

Under the terms of the EverInsight Agreement, EverInsight agreed to pay us a non-refundable upfront license payment of $5.0 million within 30 business days of the effective date of the agreement. Refer to Note 12, *Subsequent Events*, for disclosure regarding receipt of this payment in August 2020. Additionally, upon successful development and commercializatipn of PH94B in the Territory, we are eligible to receive milestone payments of up to $172.0 million. Further, we are eligible to receive royalty payments on a country-by-country basis on net sales for the later of ten years or the expiration of market or regulatory exclusivity in the jurisdiction, except that payments will be reduced on a country-by-country basis in the event that there is no market exclusivity in the period. Royalty payments may also be reduced if there is generic competitive product in the period.

We have determined that we have one combined performance obligation for the license to develop and commercialize PH94B in the Territory and related development and regulatory services. In addition, EverInsight has an option that will create manufacturing obligations for us during development upon exercise by EverInsight. These option for manufacturing services was evaluated and determined not to include a material right.

Development and commercialization milestones were not considered probable at inception and are therefore were excluded from the initial transaction price. The royalties were excluded from the initial transaction price because they relate to a license of intellectual property and are subject to the royalty constraint.

We recognize revenue as the combined performance obligation is satisfied over time using an output method. The measure of progress is stand-ready straight-line over the period in which we expect to perform the services related to the license of PH94B. As of June 30, 2020, no revenue related to this agreement has been recognized. As of June 30, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligation is $5.0 million and will be recognized as revenue as the services are completed, which is expected to occur over approximately the next four years beginning in the quarter ending September 30, 2020.

Unless earlier terminated due to certain material breaches of the contract, or otherwise, the License Agreement will expire on a jurisdiction-by-jurisdiction basis until the latest to occur of expiration of the last valid claim under a licensed patent of PH94B in such jurisdiction, the expiration of regulatory exclusivity in such jurisdiction or ten years after the first commercial sale of PH94B in such jurisdiction.

BlueRock Therapeutics Sublicense Agreement

In December 2016, we entered into an Exclusive License and Sublicense Agreement with BlueRock Therapeutics, LP, a next generation regenerative medicine company established in December 2016 by Bayer AG and Versant Ventures (*BlueRock Therapeutics*), pursuant to which BlueRock Therapeutics received exclusive rights to utilize certain technologies exclusively licensed by us from University Health Network (*UHN*) for the production of cardiac stem cells for the treatment of heart disease. As a result of its acquisition of BlueRock Therapeutics in 2019, Bayer AG now holds the rights to develop and commercialize our hPSC technologies relating to the production of heart cells for the treatment of heart disease (the *Bayer Agreement*). We retained rights to cardiac stem cell technology licensed from UHN related to small molecule, protein and antibody drug discovery, drug rescue and drug development, including small molecules with cardiac regenerative potential, as well as small molecule, protein and antibody testing involving cardiac cells. To date, we have recognized $1.25 million in sublicense revenue, in our fiscal year ended March 31, 2017, under the Bayer Agreement.

Note 12. Subsequent Events

We have evaluated subsequent events through the date of this Report and have identified the following matters requiring disclosure:

Registered Public Offering of Common Stock

On August 2, 2020, we entered into an underwriting agreement (the *Underwriting Agreement*) with Maxim Group, LLC as representative of the underwriters named therein (the *Underwriter*), pursuant to which we sold to the Underwriter, in an underwritten public offering (the *Public Offering*), an aggregate of 15,625,000 shares (the *Shares*) of our common stock for a public offering price of $0.80 per Share, resulting in gross proceeds to us of $12,500,000. The Public Offering closed on August 5, 2020 at which time we sold the Shares to the Underwriter. Under the terms of the Underwriting Agreement, we granted to the Underwriter a 45-day over-allotment option (the *Over-Allotment Option*) to purchase up to an additional 2,343,750 Shares (the *Option Shares*) at a public offering price of $0.80 per share. On August 5, 2020, the Underwriter elected to exercise the Over-Allotment Option with respect to an aggregate of 2,243,250 Option Shares (the *Exercised Option Shares*). We completed the sale of the Exercised Option Shares on August 7, 2020 and received additional gross proceeds of $1,794,600. After deducting underwriting discounts and commissions and offering expenses payable by us, we received net proceeds of approximately $12.9 million from the sale of the Shares and the Exercised Option Shares.

Receipt of $5,000,000 Upfront License Payment from EverInsight

On August 3, 2020, we received the $5,000,000 non-dilutive upfront license fee payment from EverInsight, which resulted in net cash proceeds to us of approximately $4.655 million after the sublicense payment we agreed to make to Pherin pursuant to our PH94B license from Pherin, and payment for consulting services related to the EverInsight Agreement.

Exercise of Warrants

During July 2020, holders of warrants to purchase an aggregate of 228,000 shares of our common stock exercised such warrants, and we received aggregate cash proceeds of $114,000. We issued 228,000 registered shares of our common stock upon these exercises pursuant to the effectiveness of the Warrant Registration Statement.

Sales of Common Stock under the LPC Agreement

During July 2020, we sold an additional 100,000 registered shares of our common stock to LPC under the terms of the LPC Agreement and received cash proceeds of $51,000.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (Report) includes forward-looking statements. All statements contained in this Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Our business is subject to significant risks including, but not limited to, our ability to obtain substantial additional financing, the results of our research and development efforts, the results of nonclinical and clinical testing, the effect of regulation by the U.S. Food and Drug Administration (FDA) and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, the effect of our accounting policies, and other risks as detailed in the section entitled "Risk Factors" in this Report. Further, even if our product candidates appear promising at various stages of development, our share price may decrease such that we are unable to raise additional capital without significant dilution or other terms that may be unacceptable to our management, Board of Directors (Board) and stockholders.

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 or Board 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 Report 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 Report 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.

Business Overview

VistaGen Therapeutics, Inc., a Nevada corporation (which may be referred to as *VistaGen*, the *Company*, *we*, *our*, or *us*), is a biopharmaceutical company committed to developing differentiated new generation medications for anxiety, depression and other central nervous system (*CNS*) disorders. Our pipeline includes three clinical-stage CNS drug candidates, each with a differentiated mechanism of action, an exceptional safety profile in all clinical studies to date, and therapeutic potential in multiple CNS markets. We aim to become a fully-integrated biopharmaceutical company that develops and commercializes innovative CNS therapies for large and growing mental health and neurology markets where we believe current treatments are inadequate to meet the needs of millions of patients and their caregivers worldwide.

PH94B Neuroactive Nasal Spray for Anxiety-related Disorders

PH94B neuroactive nasal spray is a rapid-onset synthetic neurosteroid with therapeutic potential in a wide range of neuropsychiatric indications involving anxiety or phobia. Conveniently self-administered in microgram-level doses without systemic exposure, we are initially developing PH94B as a potential fast-acting, non-sedating, non-addictive new generation acute treatment of anxiety in adults with social anxiety disorder (*SAD*). SAD affects over 20 million Americans and, according to the National Institutes of Health (*NIH*), is the third most common psychiatric condition after depression and substance abuse. A person with SAD feels symptoms of anxiety or fear in certain social situations, such as meeting new people, dating, being on a job interview, answering a question in class, or having to talk to a cashier in a store. Doing everyday things in front of people - such as eating or drinking in front of others or using a public restroom - also causes anxiety or fear. A person with SAD may also feel symptoms of fear and anxiety in performance situations, such as giving a lecture, a speech or a presentation to classmates at school or colleagues at work, as well as playing in a sports game, or dancing or playing a musical instrument on stage. A person with SAD is afraid that he or she will be humiliated, judged, and rejected. The fear and anxiety that people with SAD have in social and performance situations is so strong that they feel they are beyond their ability to control. As a result, SAD gets in the way of going to work, attending school, or doing everyday things in situations with potential for interpersonal interaction. People with SAD may worry about these and other things for weeks before they happen. Sometimes, they end up staying away from places or events where they think they might have to do something that will embarrass or humiliate them. Without treatment, SAD can last for many years or a lifetime and prevent a person from reaching his or her full potential.

Only three drugs, all oral antidepressants (*ADs*), are approved by the U.S Food and Drug Administration (*FDA*) specifically for treatment of SAD. These FDA-approved ADs have slow onset of therapeutic effect (often taking many weeks to months), require chronic administration and often cause significant side effects beginning soon after administration. Slow onset of effect, chronic administration and significant side effects may make the FDA-approved ADs inadequate or inappropriate treatment alternatives for many individuals affected by SAD episodically. Our PH94B is fundamentally different from all current anti-anxiety drugs, including all ADs approved by the FDA for treatment of SAD.

Intranasal self-administration of a microgram level dose (3.2 mcg) of PH94B engages specific nasal chemosensory neurons (*NCNs*). NCNs activate olfactory bulb neurons (*OBNs*) on the base of the brain. OBNs send neural connections to neurons in the central limbic amygdala, the brain center where fear and anxiety are regulated. Neurons in the limbic amygdala modulate inhibitory/excitatory neurotransmitters, resulting in rapid-onset anti-anxiety effects, without requiring systemic uptake and distribution to produce such rapid-onset effects. In all clinical studies to date, PH94B has not shown psychological side effects (such as dissociation or hallucinations), detectable systemic exposure, sedation or other side effects and safety concerns that may be caused by the current ADs approved by the FDA for treatment of SAD, as well as by benzodiazepines and beta blockers, which are not approved by the FDA to treat SAD but which are be prescribed by psychiatrists and physicians for treatment of SAD on an off-label basis.

In a peer-reviewed, published double-blind, placebo-controlled Phase 2 clinical trial, PH94B neuroactive nasal spray was highly significantly more effective than placebo in reducing both public-speaking (performance) anxiety (p=0.002) and social interaction anxiety (p=0.009) in laboratory-simulated challenges of SAD patients within 15 minutes of self-administration of a non-systemic 1.6 microgram dose of PH94B. Based on its novel mechanism of pharmacological action, rapid-onset of therapeutic effects and exceptional safety and tolerability profile in clinical trials to date, we are preparing for Phase 3 clinical development of PH94B for acute treatment of anxiety in adults with SAD. Our goal is to develop and commercialize PH94B as the first FDA-approved, rapid-onset, acute treatment of anxiety in adults with SAD, for acute use on demand much like a rescue inhaler is used on demand before an asthma attack or a migraine drug is used before a migraine episode. We believe additional potential anxiety-related neuropsychiatric indications for PH94B include general anxiety disorder, postpartum anxiety, perioperative and pre-testing (e.g., pre-MRI) anxiety, panic disorder, post-traumatic stress disorder and specific social phobias. The FDA has granted Fast Track designation for development of PH94B for acute treatment of anxiety in adults with SAD, which we believe is the FDA's first such designation for a drug candidate for SAD.

In addition to development of PH94B as a potential treatment for SAD, we are currently planning for exploratory open-label Phase 2A clinical development of PH94B for acute treatment of adjustment disorder with anxiety (*AjDA*), an emotional or behavioral reaction considered excessive or out of proportion to a stressful event or major life change, occurring within three months of the stressor, and/or significantly impairing a person's social, occupational and/or other important areas of functioning. Given the diverse impact of the COVID-19 pandemic, including, among other things, fear and axiety about health and safety, economic loss, unemployment, social isolation, disruption of established education and work practices, we submitted our preliminary protocol for the study to the FDA through the FDA's Coronavirus Treatment Acceleration Program (*CTAP*). As a result of that submission, we are currently in discussions wih the FDA's Division of Psychiatric Products to determine the appropriate next steps for the study, including the study protocol. We are planning to conduct the proposed Phase 2A study in New York City and enroll approximately 25 to 30 subjects suffering from AjDA-provoking stressors, including, but not limited to, stressors related to the diverse impact of the COVID-19 pandemic and recent social unrest in the U.S.

PH10 Neuroactive Nasal Spray for Depression and Suicidal Ideation

PH10 neuroactive nasal spray is an odorless, fast-acting synthetic neurosteroid drug candidate with therapeutic potential in a wide range of neuropsychiatric indications involving depression and suicidal ideation. Conveniently self-administered in microgram-level doses without systemic exposure, we are initially developing PH94B as a potential rapid-onset, treatment of major depressive disorder (*MDD*).

Depression is a serious medical illness and a global public health concern that can occur at any time over a person's life. While most people will experience depressed mood at some point during their lifetime, MDD is different. MDD is the chronic, pervasive feeling of utter unhappiness and suffering, which impairs daily functioning. Symptoms of MDD include diminished pleasure or loss of interest in activities, changes in appetite that result in weight changes, insomnia or oversleeping, psychomotor agitation, loss of energy or increased fatigue, feelings of worthlessness or inappropriate guilt, difficulty thinking, concentrating or making decisions, and thoughts of death or suicide and attempts at suicide. Current FDA-approved medications available in the multi-billion-dollar global AD market often fall far short of satisfying the unmet medical needs of millions suffering from the debilitating effects of depression.

While current FDA-approved ADs are widely used, about two-thirds of patients with MDD do not respond to their initial AD treatment. Inadequate response to current ADs is among the key reasons MDD is one of the leading public health concerns in the United States, creating a significant unmet medical need for new agents with fundamentally different mechanisms of action and side effect and safety profiles.

PH10 is a new generation antidepressant with a mechanism of action that is fundamentally different from all current ADs. After self-administration, a non-systemic microgram-level dose of PH10 binds to nasal chemosensory receptors that, in turn, activate key neural circuits in the brain that can lead to rapid-onset antidepressant effects, but without the psychological side effects (such as dissociation and hallucinations) or safety concerns that maybe be caused by ketamine-based therapy (*KBT*), including intravenous ketamine or esketamine nasal spray, or the significant side effects of current ADs. In an exploratory 30-patient Phase 2A clinical trial, PH10, self-administered at a dose of 6.4 micrograms, was well-tolerated and demonstrated significant (p=0.022) rapid-onset antidepressant effects, which were sustained over an 8-week period, as measured by the Hamilton Depression Rating Scale (*HAM-D*), without side effects or safety concerns that may be caused by KBT. Based on positive results from this exploratory Phase 2A study, we are preparing for Phase 2B clinical development of PH10 in MDD, which preparation includes two additional preclinical toxicology studies required by the FDA to support our new Investigational New Drug (*IND*) application for proposed Phase 2B clinical development of PH10 in the U.S. With its exceptional safety profile during clinical development to date, we believe PH10, has potential for multiple applications in global depression markets, including first as a stand-alone therapy for MDD, and eventually also an add-on therapy to augment current FDA-approved ADs for patients with MDD who have an inadequate response to standard ADs, and to prevent relapse following successful treatment with KBT.

AV-101, an Oral NMDA Receptor Antagonist

AV-101 (4-Cl-KYN) targets the NMDAR (N-methyl-D-aspartate receptor), an ionotropic glutamate receptor in the brain. Abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-chloro-kynurenic acid (7-Cl-KYNA), which is a potent and selective full antagonist of the glycine co-agonist site of the NMDAR that inhibits the function of the NMDAR. Unlike ketamine and many other NMDAR antagonists, 7-Cl-KYNA is not an ion channel blocker. In all studies to date, AV-101 has exhibited no dissociative or hallucinogenic psychological side effects or safety concerns similar to those that may be caused by amantadine and KBT. With its exceptionally few side effects and excellent safety profile in all studies to date, AV-101 has potential to be a new, differentiated oral treatment for multiple large-market CNS indications where we believe current treatments are inadequate to meet high unmet patient needs. The FDA has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain.

In late-2019, we completed a Phase 2 clinical trial of AV-101 as a potential adjunctive treatment, together with a standard FDA-approved oral AD (either a selective serotonin reuptake inhibitor (*SSRI*) or a serotonin norepinephrine reuptake inhibitor (*SNRI*)), in MDD patients who had an inadequate response to a stable dose of a standard AD (the *Elevate Study*). Topline results of the Elevate Study (n=199) indicated that the AV-101 treatment arm (1440 mg) did not differentiate from placebo on the primary endpoint (change in the Montgomery-Åsberg Depression Rating Scale (*MADRS-10*) total score compared to baseline), potentially due to sub-therapeutic levels of 7-Cl-KYNA in the brain. As in prior clinical studies, AV-101 was well tolerated, with no psychotomimetic side effects or drug-related serious adverse events.

Recent discoveries from successful AV-101 preclinical studies suggest that there is a substantially increased brain concentration of AV-101 and its active metabolite, 7-Cl-KYNA, when AV-101 is given together with probenecid, a safe and well-known oral anion transport inhibitor approved by the FDA for treatment of gout. These surprising effects were first revealed as to AV-101 and 7-Cl-KYNA in our recent preclinical studies, although the effects are consistent with well-documented clinical studies of probenecid increasing the therapeutic benefits of several classes of FDA-approved drugs that are unrelated to AV-101 and 7-Cl-KYNA, including certain antibacterial, anticancer and antiviral drugs. When probenecid was administered adjunctively with AV-101 in an animal model, substantially increased brain concentrations of both AV-101 and of 7-Cl-KYNA were discovered. We also recently identified that some of the same kidney transporters that reduce drug concentrations in the blood, by excretion in the urine, are also found in the blood brain barrier and function to reduce 7-Cl-KYNA levels in the brain by pumping it out of the brain and back into the blood. In the recent preclinical studies with AV-101 and probenecid, we discovered that blocking those transporters in the blood brain barrier with probenecid resulted, as noted above, in a substantially increased brain concentration of 7-Cl-KYNA. This 7-Cl-KYNA efflux-blocking effect of probenecid, with the resulting increased brain levels and duration of 7-Cl-KYNA, suggests the potential impact of AV-101 with probenecid could result in far more profound therapeutic benefits for patients with MDD and other NMDAR-focused CNS disorders than demonstrated in the Elevate Study. Some of the new discoveries from our recent AV-101 preclinical studies with adjunctive probenecid were presented by a collaborator of VistaGen at the British Pharmacological Society's Pharmacology 2019 annual conference in Edinburgh, UK in December 2019.

In addition, a Phase 1B target engagement study completed after the Elevate Study by the Baylor College of Medicine (*Baylor*) with financial support from the U.S. Department of Veterans Affairs (*VA*), involved 10 healthy volunteer U.S. military Veterans who received single doses of AV-101 (720 mg or 1440 mg) or placebo, in a double-blind, randomized, cross-over controlled trial. The primary goal of the study was to identify and define a dose-response relationship between AV-101 and multiple electrophysiological (*EEG*) biomarkers related to NMDAR function, as well as blood biomarkers associated with suicidality (the *Baylor Study*). The findings from the Baylor Study suggest that, in healthy Veterans, the higher dose of AV-101 (1440 mg) was associated with dose-related increase in the 40 Hz Auditory Steady State Response (*ASSR*), a robust measure of the integrity of inhibitory interneuron synchronization that is associated with NMDAR inhibition. Findings from the Baylor Study were presented at the 58th Annual Meeting of the American College of Neuropsychopharmacology (*ACNP*) in Orlando, Florida in December 2019.

The successful Baylor Study and the recent discoveries in our preclinical studies involving AV-101 and adjunctive probenecid suggest that it may be possible to increase therapeutic concentrations and duration of 7-Cl-KYNA in the brain, and thus increase NMDAR antagonism in MDD patients with an inadequate response to standard ADs when AV-101 and probenecid are combined. During 2020, we plan to complete preclinical assessment of of AV-101 with adjunctive probenecid and evaluate its potential for future clinical development and commercialization for treatment of CNS indications involving abnormal function of the NMDAR.

VistaStem Therapeutics – Stem Cell Technology for Drug Rescue and Regenerative Medicine

In addition to our current CNS drug candidates, we have stem cell technology-based, pipeline-enabling capabilities through our wholly-owned subsidiary, VistaStem Therapeutics (*VistaStem*). VistaStem is focused on applying human pluripotent stem cell (*hPSC*) technologies, including our customized cardiac bioassay system, *CardioSafe* 3D, to discover and develop small molecule New Chemical Entities (*NCEs*) for our CNS pipeline or out-licensing. In addition, VistaStem's stem cell technologies involving hPSC-derived blood, cartilage, heart and liver cells have multiple potential applications in the cell therapy (*CT*) and regenerative medicine (*RM*) fields.

To advance potential CT and RM applications of VistaStem's hPSC technologies related to heart cells, in 2016, we licensed to BlueRock Therapeutics LP, a next generation CT/RM company formed jointly by Bayer AG and Versant Ventures, rights to develop and commercialize certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease. As a result of its acquisition of BlueRock Therapeutics in 2019, Bayer AG now holds rights to develop and commercialize VistaStem's hPSC technologies relating to the production of heart cells for the treatment of heart disease (the *Bayer Agreement*). In a manner similar to the Bayer Agreement, we may pursue additional collaborations involving rights to develop and commercialize VistaStem's hPSC technologies for production of blood, cartilage, and/or liver cells for CT and RM applications, including, among other indications, treatment of arthritis, cancer and liver disease.

Subsidiaries

As noted above, VistaStem, a California corporation, is our wholly-owned subsidiary. Our Condensed Consolidated Financial Statements in this Report also include the accounts of VistaStem and VistaStem's two wholly-owned inactive subsidiaries, Artemis Neuroscience, Inc., a Maryland corporation, and VistaStem Canada, Inc., a corporation organized under the laws of Ontario, Canada.

Financial Operations Overview and Results of Operations

Our critical accounting policies and estimates and recent accounting pronouncements are disclosed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020, as filed with the SEC on June 29, 2020, and in Note 3 to the accompanying unaudited Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Report.

Summary

Net Loss

We have not yet achieved recurring revenue-generating status from any of our product candidates or technologies. Since inception, we have devoted substantial time and effort to developing AV-101 for multiple CNS indications, including manufacturing research, process development and production of AV-101 drug substance and finished drug product, preclinical efficacy and safety studies, and clinical efficacy and safety studies in CNS indications. In addition, since acquiring our exclusive worldwide licenses to PH 94B and PH10 in 2018, we have devoted substantial resources focused on development and commercialization of PH94B and PH10, for which we are actively pursuing initiatives to advance manufacturing research, process development and production programs for drug substance and finished drug product, additional preclinical safety studies, and clinical efficacy and safety studies in multiple neuropsychiatry indications. Also, from-time-to-time, we have devoted resources to VistaStem's stem cell technology research and development, bioassay development and small molecule drug rescue initiatives, as well as creating, protecting and patenting intellectual property (*IP*) related to our product candidates and stem cell technologies, with the corollary initiatives of recruiting and retaining personnel and raising working capital. As of June 30, 2020, we had an accumulated deficit of approximately $205.0 million. Our net loss for the three months ended June 30, 2020 and 2019 was approximately $3.1 million and $6.2 million, respectively. We expect losses to continue for the foreseeable future, primarily as we engage in further development of PH94B, PH10 and AV-101, and pursue potential drug rescue, drug development and CT and RM opportunities.

Summary of the Three Months Ended June 30, 2020

During the three months ended June 30, 2020, we continued to advance our manufacturing, preclinical and clinical development, and regulatory initiatives necessary to develop and commercialize our Phase 3 clinical development of PH94B for acute treatment of anxiety in adults with SAD and acute treatment of, PH10 for MDD and AV-101 for NMDAR-focused indications. In addition, we continued to expand the regulatory and intellectual property foundation to support broad clinical development and, ultimately, commercialization of our product candidates in the U.S. and foreign markets, and on a limited basis, advance drug rescue applications of our stem cell technology to further expand our CNS pipeline.

Throughout the quarter ended June 30, 2020 and through the date of this Report, a new strain of coronavirus (*COVID-19*) has spread to many countries in the world and the outbreak has been declared a pandemic by the World Health Organization. The U.S. Secretary of Health and Human Services has also declared a public health emergency in the U.S. in response to the outbreak. Our operations and those of our contract research organizations (*CROs*) and contract development and manufacturing organizations (*CDMOs*) have been impacted by shelter-in-place orders, social distancing measures, travel bans and restrictions, and certain business and government closures or reductions in service. Our headquarters operations have been significantly curtailed as our employees have been working remotely throughout this period. Since the beginning of the COVID-19 pandemic, we have experienced delays in the delivery of supplies of active pharmaceutical product (*API*) required to continue development of PH94B and PH10. Future unexpected delays may result in a significant, material delay or disruption to our current clinical development plans, programs, and our operations.

During the quarter ended June 30, 2020, we completed a successful and positive meeting with the FDA regarding Phase 3 clinical development of PH94B for the acute treatment of anxiety in adult patients with SAD, reaching consensus with the FDA on key aspects of a unique initial pivotal Phase 3 clinical trial of PH94B involving a single-event, laboratory-simulated public speaking challenge in adult patients with SAD. We agreed with the FDA that our initial pivotal Phase 3 study of PH94B will be a randomized, double-blind, placebo-controlled, parallel comparison study conducted at approximately 12 to 15 sites in North America. Dr. Michael Liebowitz, Professor of Clinical Psychiatry at Columbia University, director of the Medical Research Network in New York City, and creator of the Liebowitz Social Anxiety Scale (LSAS), is expected to be the Principal Investigator of the study. Target enrollment for the study (completed patients) is approximately 182 adult patients with SAD. As in the highly statistically significant (p=0.002) Phase 2 study of PH94B in SAD, our initial pivotal Phase 3 study will involve a single laboratory-simulated, anxiety-provoking public speaking challenge. Also, as in the Phase 2 study, the Subjective Units of Distress Scale (*SUDS*) will be used to assess the primary efficacy endpoint of our Phase 3 study.

In June 2020, we entered into a strategic licensing and collaboration agreement for the clinical development and commercialization of PH94B with EverInsight Therapeutics Inc., a biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products for patients in Greater China and other parts of Asia (the *EverInsight Agreement*). Under the terms of the EverInsight Agreement, EverInsight will be responsible for clinical development, regulatory submissions and commercialization of PH94B for treatment of SAD, and potentially other anxiety-related indications, in key markets in Asia, including markets in Greater China, South Korea and Southeast Asia (collectively, the *Territory*). Under the terms of the EverInsight greement, in August 2020, we received a non-dilutive upfront license fee payment of $5.0 million from EverInsight. Upon successful development and commercialization of PH94B in the Territory, we are eligible to receive up to $172 million in additional development and commercial milestone payments. After payment of sublicense fees to Pherin pursuant to our PH94B license from Pherin, and payment of consulting fees related to consummation of the EverInsight Agreement, we received net cash proceeds of approximately $4.655 million.

To satisfy our obligations under the common stock purchase and registration rights agreements that we entered with Lincoln Park Capital Fund (*LPC*) in March 2020, we filed a Registration Statement on Form S-1 (the *LPC Registration Statement*) with the SEC on March 31, 2020 (Registration No. 333-237514), which the SEC declared effective on April 14, 2020 (the *Commencement Date*). Subsequent to the Commencement Date and through June 30, 2020, we sold an additional 6,201,995 registered shares of our common stock to LPC and received aggregate cash proceeds to us of $2,840,200. Since June 30, 2020 and through the date of this Report, we have sold an additional 100,000 shares of our common stock to LPC and received $51,000 in cash proceeds.

Subsequent to the end of the quarter, on August 2, 2020, we entered into an underwriting agreement (the *Underwriting Agreement*) with Maxim Group, LLC as representative of the underwriters named therein (the *Underwriter*), pursuant to which we sold to the Underwriter, in an underwritten public offering (the *Public Offering*), an aggregate of 15,625,000 shares (the *Shares*) of our common stock for a public offering price of $0.80 per Share, resulting in gross proceeds to us of $12,500,000. The Public Offering closed on August 5, 2020, at which time we sold the Shares to the Underwriter. Under the terms of the Underwriting Agreement, we granted to the Underwriter a 45-day over-allotment option (the *Over-Allotment Option*) to purchase up to an additional 2,343,750 Shares (the *Option Shares*) at a public offering price of $0.80 per share. On August 5, 2020, the Underwriter exercised the Over-Allotment Option with respect to an aggregate of 2,243,250 Option Shares. The sale of the exercised Option Shares was completed on August 7, 2020 and resulted in additional gross proceeds to us of $1,794,600. Net proceeds to us from the sale of the Shares and the exercised Option Shares, after deducting underwriting discounts and commissions and offering expenses payable by us, is approximately $12.9 million.

As a matter of course, we continue to minimize, to the greatest extent possible, cash commitments and expenditures for both internal and external research and development and general and administrative services. To further advance the nonclinical and clinical development of PH94B, PH10, AV-101 and our stem cell technology platform, as well as support our operating activities, we continue to carefully manage our routine operating costs, including our internal employee related expenses, as well as external costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and internal costs.

Results of Operations

Comparison of Three Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the three months ended June 30, 2020 and 2019 (amounts in thousands).

	Three Months Ended June 30,	
	2020	**2019**
Operating expenses:		
Research and development	$ 1,731	$ 4,314
General and administrative	1,391	1,910
Total operating expenses	3,122	6,224
Loss from operations	(3,122)	(6,224)
Interest income (expense), net	(3)	16
Other income	1	-
Loss before income taxes	(3,124)	(6,208)
Income taxes	(3)	(2)
Net loss	(3,127)	(6,210)
Accrued dividends on Series B Preferred Stock	(336)	(302)
Net loss attributable to common stockholders	$ (3,463)	$ (6,512)

Revenue

We reported no revenue for either quarter ended June 30, 2020 or 2019. As described more completely in Note 11, *Sublicensing and Collaboration Agreements*, to our Condensed Consolidated Financial Statements in Part I of this Report, on June 24, 2020 we entered into the EverInsight Agreement, pursuant to which we received an non-dilutive upfront license fee payment of $5.0 million on August 3, 2020. We expect to recognize revenue pursuant to this payment in future periods beginning with the quarter ending September 30, 2020. While we may potentially receive additional cash payments and royalties in the future under the EverInsight Agreement or the 2016 Bayer Agreement (also described in Note 11, *Sublicensing and Collaborative Agreements*, to our Condensed Consolidated Financial Statements in Part I of this Report) in the event certain performance-based milestones and commercial sales are achieved, there can be no assurance that the EverInsight Agreement or the Bayer Agreement will provide additional revenue beyond that noted or cash payments to us in the near term, or at all.

Research and Development Expense

Research and development expense decreased from $4.3 million to $1.7 million for the quarters ended June 30, 2020 and 2019, respectively, primarily due to the completion of the Elevate Study in the fourth calendar quarter of 2019. Expenses related to the Elevate Study and other AV-101 related nonclinical activities decreased by $2.5 million in the quarter ended June 30, 2020 compared to expense in the quarter ended June 30, 2019. Noncash research and development expenses, primarily stock-based compensation and depreciation in both periods, accounted for approximately $249,000 and $416,000 in the quarters ended June 30, 2020 and 2019, respectively. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2020	**2019**
Salaries and benefits	$ 348	$ 340
Stock-based compensation	227	391
Consulting and other professional services	93	136
Technology licenses and royalties	108	167
Project-related research, licenses and supplies:		
Elevate study and other AV-101 expenses	165	2,666
PH94B and PH10 project expenses	635	424
Stem cell and all other	5	42
	805	3,132
Rent	138	136
Depreciation	12	12
Total Research and Development Expense	$ 1,731	$ 4,314

Salaries and benefits expense is essentially unchanged between periods, reflecting no changes in compensation levels for our Chief Medical Officer (*CMO*), Chief Scientific Officer (*CSO*), or members of our scientific staff between the periods. The change reflects the return from leave of absence of one member of our scientific staff during the quarter ended June 30, 2019 and modest increases in the cost of Company-provided benefits beginning in mid-2019.

Stock-based compensation expense reflects the amortization of option grants made to our CMO, CSO, members of our scientific staff and certain clinical and scientific consultants since June 2016, all earlier outstanding grants having become fully vested and amortized. Grants awarded after June 30, 2019, including those granted during the quarter ended June 30, 2020, account for approximately $101,000 of expense in the quarter ended June 30, 2020, offset by the expense reduction of approximately $199,000 attributable to certain options granted between June 2016 and February 2018 that became fully vested and amortized during the quarter ended June 30, 2020 or earlier. Stock compensation expense is further reduced in the quarter ended June 30, 2020 by approximately $58,000 due to the absence of the impact of immediate vesting attributable to certain options granted in May 2019. Expense attributable to recent option grants is generally being amortized over two-year to three-year vesting periods, with essentially all of the grants made since May 2019, including those made in the quarter ended June 30, 2020, being immediately vested and expensed upon grant, in accordance with the terms of the respective grants.

Consulting and other professional services reflects fees incurred, generally on an as-needed basis, for project-based scientific, nonclinical and clinical development and regulatory advisory and analytical services rendered to us by third parties, including by members of our Scientific Advisory Board and CNS Clinical and Regulatory Advisory Board, especially in support of our PH94B and PH10 development initiatives.

Technology license and royalties expense reflects both recurring annual license fees, as well as legal counsel and other costs related to patent prosecution and protection pursuant to our stem cell technology license agreements, our AV-101 patents, or patents that we have elected to pursue for commercial purposes. These costs do not occur ratably throughout the year or between years. In both periods, this expense includes legal counsel and other costs we have incurred to advance various patent applications in the U.S. and numerous foreign countries, primarily with respect to AV-101 and our stem cell technology platform, but also nominally with respect to our PH94B and PH10 intellectual property portfolios.

AV-101 project expense for the quarter ended June 30, 2019 reflects the costs of conducting the Elevate Study in MDD, including various CROs, investigator and clinical site costs, and CRO support services for AV-101 projects for indications other than MDD, as well as expense incurred to manufacture additional quantities of AV-101 for use in potential future clinical development of AV-101 in a number of potential CNS indications. AV-101 project expense for the quarter ended June 30, 2020 primarily reflects the cost of certain preclinical studies related to the use of AV-101 with adjunctive probenecid and certain AV-101 manufacturing stability studies.

PH94B and PH10 project expenses for the quarters ended June 30, 2020 and 2019 primarily reflect manufacturing and regulatory initiatives necessary to facilitate Phase 3 clinical development of PH94B for acute treatment of anxiety in patients with SAD and Phase 2B development of PH10 for MDD. Manufacturing, formulation and analysis of sufficient quantities of API and drug product are currently the critical path items for advancing the clinical development of both of these product candidates and production and analytical processes for both have been delayed by issues related to the ongoing COVID-19 pandemic.

Stem cell and other project related expenses reflects costs associated with drug rescue applications of our stem cell technology in both years. These expenses are typically incurred by our in-house scientific personnel. As a result of shelter-in-place and remote working requirements related to the ongoing COVID-19 pandemic, such expenses have been reduced to an insignificant level in the quarter ended June 30, 2020.

Rent expense for both periods presented reflects our implementation of ASC 842 effective April 1, 2019 and the requirement to recognize, as an operating lease related to our South San Francisco office and laboratory facility, a right-of-use asset and a lease liability, both of which must be amortized over the expected lease term. The underlying lease reflects commercial property rents prevalent in the South San Francisco real estate market at the time of our November 2016 lease amendment extending the lease of our headquarters facilities in South San Francisco by five years from July 31, 2017 to July 31, 2022. In implementing ASC 842, we also projected that we would exercise a five-year option to extend our tenancy under the lease when it expires in 2022, which extension would be subject to projected market rent conditions at that time. We allocate total rent expense for our South San Francisco facility between research and development expense and general and administrative expense based generally on square footage dedicated to each function. Refer to Note 10, *Commitments and Contingencies*, in the accompanying Condensed Consolidated Financial Statements in Part I of this Report for additional information. Following our implementation of ASC 842, changes in rent expense between periods are primarily related to changes in such items as common area maintenance fees, taxes and insurance which are generally assessed to us by our landlord.

General and Administrative Expense

General and administrative expense decreased to approximately $1.4 million from approximately $1.9 million for the quarters ended June 30, 2020 and 2019, respectively. Noncash general and administrative expense, $466,000 in the quarter ended June 30, 2020, decreased from $772,000 in the quarter ended June 30, 2019 primarily due to decreases in stock-based compensation and the noncash components of investor and public relations expense attributable to the amortization of the fair value of common stock or warrants granted to service providers. The following table indicates the primary components of general and administrative expense for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2020	**2019**
Salaries and benefits	$ 348	$ 344
Stock-based compensation	448	672
Board fees	46	46
Legal, accounting and other professional fees	195	279
Investor and public relations	112	304
Insurance	102	82
Travel expenses	4	30
Rent and utilities	90	90
All other expenses	46	63
	$ 1,391	$ 1,910

Salaries and benefits expense is essentially unchanged between periods, reflecting no changes in compensation levels for our Chief Executive Officer (*CEO*), Chief Financial Officer (*CFO*), Vice President-Corporate Development (*VP Corporate Development*) and a non-officer member of our administrative staff and modest increases in the cost of Coimpany-provided benefits beginning in mid-2019.

Stock-based compensation expense reflects the amortization of option grants made to our CEO, CFO, VP Corporate Development, administrative staff, independent members of our Board and certain consultants since June 2016, all earlier grants having become fully vested and amortized. Grants awarded after June 30, 2019, including those granted during the quarter ended June 30, 2020, account for approximately $229,000 of expense in the quarter ended June 30, 2020, offset by the expense reduction of approximately $333,000 attributable to certain options granted between June 2016 and February 2018 that became fully vested and amortized during the quarter ended June 30, 2020 or earlier. Stock compensation expense is further reduced in the quarter ended June 30, 2020 by approximately $98,000 due to the absence of the impact of immediate vesting attributable to certain options granted in May 2019. Expense attributable to recent option grants is generally being amortized over two-year to three-year vesting periods, with essentially all of the grants made since May 2019, including those made in the quarter ended June 30, 2020, being immediately vested and expensed upon grant, in accordance with the terms of the respective grants.

Board fees represents fees paid as consideration for Board and Board Committee services to the independent members of our Board.

Legal, accounting and other professional fees for the quarters ended June 30, 2020 and 2019 includes expense related to routine legal fees as well as the accounting expense related to the annual audit of our prior year financial statments. In 2019, we also incurred $30,000 attributable to services provided by an international business development consultant.

Investor and public relations expense includes the fees of our various external service providers for a broad spectrum of investor relations, public relations and social media services, and well as market awareness and strategic advisory and support functions and initiatives that, in 2019, included numerous in-person meetings in multiple U.S. and certain foreign markets and other communication activities focused on expanding global market awareness of the Company, our CNS product candidate pipeline and technologies and our research and development programs, including among registered investment professionals and investment advisors, individual and institutional investors, and prospective strategic collaborators for development and commercialization of our product candidates in major pharmaceutical markets worldwide. During the quarter ended June 30, 2020, we curtailed the number of external service providers engaged in these activities compared to the prior year. Further, in the quarter ended June 30, 2019, in addition to cash fees and expenses we incurred for such activities, we recognized approximately $79,400 of noncash expense attributable to the amortization of the fair value of stock and warrants granted in previous periods to various corporate development, investor relations, and market awareness service providers. No such noncash expense ws incurred in the quarter ended June 30, 2020.

The increase in insurance expense is primarily attributable to the market-rate increase in the premium for our directors and officers liability insurance upon renewal of our policy in May 2020.

In the quarter ended June 30, 2019, travel expense reflects costs associated with in-person management presentations and meetings held in multiple U.S. markets and certain international markets with existing and potential individual and institutional investors, investment professionals and advisors, media, and securities analysts, as well as various investor relations, market awareness and corporate development and partnering initiatives and in monitoring the progress of our Elevate Study. As a result of shelter-in-place and travel restrictions associated with the ongoing COVID-19 pandemic, such meetings have occurred remotely and there has generally been no in-person business travel by our executives.

Rent expense for both periods presented reflects our implementation of ASC 842 effective April 1, 2019 and the requirement to recognize, as an operating lease related to our South San Francisco office and laboratory facility, a right-of-use asset and a lease liability, both of which must be amortized over the expected lease term. The underlying lease reflects commercial property rents prevalent in the South San Francisco real estate market at the time of our November 2016 lease amendment extending the lease of our headquarters facilities in South San Francisco by five years from July 31, 2017 to July 31, 2022. In implementing ASC 842, we also projected that we would exercise a five-year option to extend our tenancy under the lease when it expires in 2022, which extension would be subject to projected market rent conditions at that time. We allocate total rent expense for our South San Francisco facility between research and development expense and general and administrative expense based generally on square footage dedicated to each function. Refer to Note 10, *Commitments and Contingencies*, in the accompanying Condensed Consolidated Financial Statements in Part I of this Report for additional information. Following our implementation of ASC 842, changes in rent expense between periods are primarily related to changes in such items as common area maintenance fees, taxes and insurance which are generally assessed to us by our landlord.

Interest and Other Expenses

Interest expense totaled $3,200 for the quarter ended June 30, 2020 compared to interest income, net of interest expense of $16,500 for the quarter ended June 30, 2019. The following table indicates the primary components of interest income and expense for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2020	**2019**
Interest income	$ -	$ 19
Interest expense on financing lease, insurance premium financing notes and Payroll Protection Program loan	(3)	(3)
Interest income (expense), net	$ (3)	$ 16

Following the completion of our underwritten public offering in February 2019, which generated $11.5 million in gross proceeds to us, during the quarter ended June 30, 2019, we deposited a portion of the proceeds in interest-bearing cash equivalent accounts and earned interest income. As a result of the decline in market interest rates in 2020 compared to 2019 and a reduction in the amount of cash deposited in such accounts, we earned no interest in the quarter ended June 30, 2020. Interest expense in both periods relates to interest paid on insurance premium financing notes and on our financing lease of office equipment subject to ASC 842, and in 2020, interest accrued on our Payroll Protection Program loan.

We recognized $335,800 and $302,500 for the quarters ended June 30, 2020 and 2019, respectively, representing the 10% cumulative dividend accrued on outstanding shares of our Series B 10% Convertible Preferred Stock (*Series B Preferred*) as an additional deduction in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss included in Part I of this Report. There have been no conversions of outstanding shares of Series B Preferred stock into shares of our common stock since August 2016.

Liquidity and Capital Resources

Since our inception in May 1998 through June 30, 2020, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity and debt securities for cash proceeds of approximately $86.1 million, as well as from an aggregate of approximately $17.7 million of government research grant awards (excluding the fair market value of government sponsored and funded clinical trials), strategic collaboration payments, intellectual property licensing and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $38.2 million in noncash acquisitions of product licenses and in settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services.

Recent Developments

At June 30, 2020, we had cash and cash equivalents of approximately $1.5 million. As more completely described in Note 8, *Capital Stock* and Note 12, *Subsequent Events*, to our Condensed Consolidated Financial Statements in Part I of this Report, on March 24, 2020, we entered into a purchase agreement and a registration rights agreement with LPC pursuant to which LPC committed to purchase up to $10,250,000 of our common stock at market-based prices over a period of 24 months (the *LPC Agreement*). To satisfy our obligations under the LPC Agreement, we filed the LPC Registration Statement with the SEC on March 31, 2020, which the SEC declared effective on April 14, 2020 (Registration No. 333-237514). Subsequent to the effectiveness of the LPC Registration Statement and through the date of this Report, we sold 6,301,995 registered shares of our common stock to Lincoln Park and received gross cash proceeds of $2,891,200.

As more completely described in Note 11, *Sublicensing and Collaboration Agreements*, and in Note 12, *Subsequent Events*, to our Condensed Consolidated Financial Statements in Part I of this Report, on June 24, 2020, we entered into a strategic licensing and collaboration agreement for the clinical development and commercialization of PH94B with EverInsight Therapeutics Inc., a biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products for patients in Greater China and other parts of Asia (the *EverInsight Agreement*). Under the terms of the EverInsight Agreement, EverInsight agreed to make a non-dilutive upfront license fee payment of $5.0 million to us, and we are eligible to receive up to $172 million of additional milestone payments upon successful achievement of specific development and commercial milestones in the future, in addition to royalties. We received net cash proceeds of approximately $4.655 million in August 2020, after a required sublicense payment to Pherin Pharmaceuticals, Inc. (*Pherin*) pursuant to our PH94B license from Pherin and consulting payments related to consummation of the EverInsight Agreement.

As described more completely in Note 12, *Subsequent Events*, to our Condensed Consolidated Financial Statements in Part I of this Report, on August 2, 2020, we entered into an underwriting agreement (the *Underwriting Agreement*) pursuant to which we sold to the Underwriter, in an underwritten public offering (the *Public Offering*), an aggregate of 15,625,000 shares (the *Shares*) of our common stock for a public offering price of $0.80 per Share, resulting in gross proceeds to us of $12,500,000. The Public Offering closed on August 5, 2020. Under the terms of the Underwriting Agreement, we granted to the Underwriter a 45-day over-allotment option (the *Over-Allotment Option*) to purchase up to an additional 2,343,750 Shares (the *Option Shares*) at a public offering price of $0.80 per share. On August 5, 2020, the Underwriter exercised the Over-Allotment Option with respect to an aggregate of 2,243,250 Option Shares (the *Exercised Option Shares*). We completed the sale of the Exercised Option Shares on August 7, 2020, which resulted in additional gross proceeds to us of $1,794,600. Net proceeds to us from the sale of the Shares and the Exercised Option Shares, after deducting underwriting discounts and commissions and offering expenses payable by us, is approximately $12.9 million.

Going Concern

Although the transactions described above have generated approximately $20.0 million in net cash procceds to us between April 1, 2020 and the date of this Report, we believe it is possible that our cash position at June 30, 2020, together with such net proceeds, will not be sufficient to fund our planned operations for the twelve months following the issuance of these financial statements, which raises substantial doubt that we can continue as a going concern. During the next twelve months, subject to securing appropriate and adequate additional financing, we plan to prepare for and launch (i) a pivotal Phase 3 clinical trial of PH94B for acute treatment of anxiety in adult patients with SAD, (ii) a small exploratory open-label Phase 2A study of PH94B for acute treatment of adult patients with AjDA and (iii) several nonclinical studies involving PH94B, PH10 and AV-101. When necessary and advantageous, we plan to raise additional capital, through the sale of our equity securities in one or more (i) private placements to accredited investors, (ii) public offerings and/or (iii) in strategic licensing and development collaborations involving one or more of our drug candidates in markets outside the United States, similar to the Everinsight Agreement. Subject to certain restrictions, our Registration Statement on Form S-3 (Registration No. 333-234025) (the *S-3 Registration Statement*), which became effective on October 7, 2019, remains available for future sales of our equity securities in one or more public offerings from time to time. While we may make additional sales of our equity securities under the S-3 Registration Statement, we do not have an obligation to do so.

As we have been in the past, we expect that, when and as necessary, we will be successful in raising additional capital from the sale of our equity securities either in one or more public offerings or in one or more private placement transactions with individual accredited investors and institutions. In addition to the potential sale of our equity securities, we may also seek to enter research, development and/or commercialization collaborations that could generate revenue or provide funding, including non-dilutive funding, for development of one or more of our CNS product candidates. We may also seek additional government grant awards or agreements similar to our relationships with the NIH, Baylor and the VA in connection with certain government-sponsored studies. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. We may also pursue intellectual property arrangements similar to the EverInsight Agreement and the Bayer Agreement (described more completely in Note 11, *Sublicensing and Collaboration Agreements* to our Condensed Consolidated Financial Statements in Part I of this Report) with other parties. Although we may seek additional collaborations that could generate revenue and/or provide non-dilutive funding for development of our product candidates, as well as new government grant awards and/or agreements, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of opportunities related to our success and the success of certain other companies in clinical trials, including our development and commercialization of our current product candidates and various applications of our stem cell technology platform, the availability of, and our ability to obtain, government grant awards and agreements, and our ability to enter into collaborations on terms acceptable to us. To further advance the clinical development of PH94B, PH10, and AV-101 and, to a lesser extent, our stem cell technology platform, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including our employee headcount and related expenses, as well as costs relating to regulatory consulting, contract research and development, investor and public relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and operating costs.

Notwithstanding the foregoing, there can be no assurance that our current strategic collaborations under the EverInsight Agreement and the Bayer Agreement will generate additional revenue from future potential milestone payments, or that future financings or government or other strategic collaborations will be available to us in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2020 or thereafter, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. As noted above, these Condensed Consolidated Financial Statements do not include any adjustments that might result from the negative outcome of this uncertainty.

Cash and Cash Equivalents

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

	Three Months Ended June 30,	
	2020	**2019**
Net cash used in operating activities	$ (2,807)	$ (4,761)
Net cash used in investing activities	-	-
Net cash provided by (used in) financing activities	2,998	(42)
Net increase (decrease) in cash and cash equivalents	191	(4,803)
Cash and cash equivalents at beginning of period	1,355	13,100
Cash and cash equivalents at end of period	$ 1,546	$ 8,297

The decrease in cash used in operations results primarily from the completion of the Elevate Study, which commenced at the end of the first calendar quarter of 2018 and was completed during the fourth calendar quarter of 2019, partially offset by nonclinical development and manufacturing advancements related to PH94B and PH10 during our current fiscal year. We used no cash for investing activities in either year presented. Cash provided by financing activities in the quarter ended June 30, 2020 primarily reflects the cash proceeds to us from sales of our common stock pursuant to the LPC Agreement and from the Spring 2020 Private Placement, net of routine insurance premium financing note and financing lease payments. Cash used in financing activities in the three months ended June 30, 2019 primarily reflects routine insurance premium financing note and financing lease payments.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Recent Accounting Pronouncements

For information relating to recent accounting pronouncements and the expected impact of such pronouncements on our condensed consolidated financial statements, see Note 3 of the Notes to Condensed Consolidated Financial Statements included In Part I of this Report.

Item 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Report were effective.

Internal Control over Financial Reporting

In our Annual Report on Form 10-K for our fiscal year ended March 31, 2020 filed with the Securities and Exchange Commission on June 29, 2020, we identified two material weaknesses in our internal control over financial reporting relating to (i) segregation of duties and (ii) the functionality of our accounting software. Management does not believe that these weaknesses have resulted in any deficient financial reporting and believes that current resources would be more appropriately applied elsewhere and when resources permit, they will alleviate such material weaknesses through various steps, which may include the addition of qualified financial personnel and/or the acquisition and implementation of alternative accounting software. Accordingly, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this Report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Investing in our securities 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 Quarterly Report on Form 10-Q (Report) and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for our fiscal year ended March 31, 2020 before investing in our securities. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and/or operating results. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

The COVID-19 pandemic has, and continues to have an impact on our business, and may have several adverse effects on our business.

In recent months, a new strain of coronavirus (*COVID-19*) has spread to many countries in the world and the outbreak has been declared a pandemic by the World Health Organization. The U.S. Secretary of Health and Human Services has also declared a public health emergency in the U.S. in response to the outbreak. Considerable uncertainty still surrounds the COVID-19 virus and its potential effects, and the extent of and effectiveness of responses taken on international, national and local levels. Measures taken to limit the impact of COVID-19, including shelter-in-place orders, social distancing measures, travel bans and restrictions, and business and government shutdowns have already resulted in significant negative economic impacts on a global basis.

As the coronavirus pandemic continues to rapidly evolve, we cannot at this time accurately predict the effects of these conditions on our operations. Uncertainties remain as to the ultimate geographic spread of the virus, the severity of the disease, the duration of the outbreak, and the length and scope of the travel restrictions and business closures imposed by the governments of impacted countries. The continued outbreak of COVID-19, or another infectious disease with similar characteristics, may lead to the implementation of further responses, including additional travel restrictions, government-imposed quarantines or stay-at-home orders, and other public health safety measures, which may result in further disruptions to our business and operations. The global COVID-19 pandemic has had an impact on our business, and a continuing outbreak or future outbreaks may have several adverse effects on our business, results of operations and financial condition.

- ***Delayed product development:*** We have, and may continue to face delays and other disruptions to our ongoing clinical development programs for PH94B, PH10 and AV-101 due to the ongoing COVID-19 pandemic. In addition, regulatory oversight and actions regarding our products may be disrupted or delayed in regions impacted by COVID-19, including the U.S. and elsewhere, which may impact review and approval timelines for our product candidates in various stages of development. Although we remain focused on advancing our clinical development programs for our current product candidates, our research and development efforts may be impacted if our employees, our contract research organizations (*CROs*) or our third-party contract development and manufacturing organizations (*CDMOs*) have reductions in force or are advised to continue to work remotely as part of social distancing measures or other protective measures necessitated by the COVID-19 pandemic.

- ***Negative impacts on our suppliers, manufacturers and employees***: COVID-19 or similar infectious diseases has impacted and may in the future impact the health of our employees, contractors, suppliers, CROs or CDMOs, or reduce the availability of our workforce or the workforce of one or more of the companies with which we do business, divert our attention toward succession planning, or create disruptions in our supply or distribution networks. Since the beginning of the COVID-19 pandemic, we have experienced delays of the delivery of supplies of active pharmaceutical ingredient (*API* or *drug substance*) and formulated drug product required to advance development of PH94B and PH10. Although our supply of raw materials and API remains sufficiently operational, we may experience adverse effects of such events in the future, which may result in a significant, material delay of or disruption to our clinical development programs, and our operations. Additionally, having shifted to remote working arrangements, we also face a heightened risk of cybersecurity attacks or data security incidents and are more dependent on internet and telecommunications access and capabilities.

The ongoing COVID-19 pandemic has also created significant disruption to and volatility in national, regional and local economies and markets. Uncertainties related to, and perceived or experienced negative effects from, COVID-19 may cause significant volatility or decline in the trading price of our securities, capital market conditions and general economic environment. Our future results of operations and liquidity could be adversely impacted by supply chain disruptions and operational challenges faced by our CROs, CDMOs and other contractors. Continued outbreaks of COVID-19 or a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in a further economic downturn or a global recession. Such events may limit or restrict our ability to access capital on favorable terms, or at all, lead to consolidation that negatively impacts our business, weaken demand, increase competition, cause us to reduce our capital spend further, or otherwise disrupt our business or make it more difficult to implement our strategic plans.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend heavily on the success of one or more of our current drug candidates and we cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize any of our product candidates.

We currently have no drug products for sale and may never be able to develop and commercialize marketable drug products. Our business currently depends heavily on the successful development, manufacturing, regulatory approval and commercialization of one or more of our current CNS drug candidates, as well as, but to a more limited extent, our ability to acquire, license or produce, develop and commercialize additional product candidates. Each of our current CNS drug candidates will require substantial additional nonclinical and clinical development, manufacturing and regulatory approval before any of them may be commercialized, and there can be no assurance that any of them will ever achieve regulatory approval. Any new chemical entity (*NCE*) we may produce through drug rescue activities will require substantial nonclinical development, all phases of clinical development, manufacturing and regulatory approval before it may be commercialized. The nonclinical and clinical development of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through numerous nonclinical and clinical studies that the product candidate is safe and effective for use in each target indication. Research and development of product candidates in the pharmaceutical industry is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of nonclinical or clinical studies. This process takes many years and may also include post-marketing studies, surveillance obligations and drug safety programs, which would require the expenditure of substantial resources beyond the proceeds we have raised to date. Of the large number of drug candidates in development in the U.S., only a small percentage will successfully complete the required FDA regulatory approval process and will be commercialized. Accordingly, we cannot assure you that any of our current drug candidates or any future product candidates will be successfully developed or commercialized in the U.S. or any market outside the U.S.

We are not permitted to market our product candidates in the U.S. until we receive approval of a New Drug Application (*NDA*) from the FDA, or in any foreign countries until we receive the requisite approval from such countries. Obtaining FDA approval of a NDA is a complex, lengthy, expensive and uncertain process. The FDA may refuse to permit the filing of our NDA, delay, limit or deny approval of a NDA for many reasons, including, among others:

- if we submit a NDA and it is reviewed by a FDA advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional nonclinical or clinical studies, limitations on approved labeling or distribution and use restrictions;

- a FDA advisory committee may recommend, or the FDA may require, a Risk Evaluation and Mitigation Strategies (*REMS*) safety program as a condition of approval or post-approval;

- a FDA advisory committee or the FDA or applicable regulatory agency may determine that there is insufficient evidence of overall effectiveness or safety in a NDA and require additional clinical studies;

- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party contract manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices (*cGMPs*); or

- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully commercialize any current or future drug product candidate we may develop. Any such setback in our pursuit of regulatory approval for any product candidate would have a material adverse effect on our business and prospects.

In addition, we anticipate that certain of our product candidates, including PH94B and PH10, will be subject to regulation as combination products, which means that they are composed of both a drug product and device product. Although we do not contemplate doing so, if marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. Our product candidates that are considered to be drug-device combination products will require review and coordination by FDA's drug and device centers prior to approval, which may delay approval. A combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the Federal Food, Drug and Cosmetic Act of 1938. In reviewing the NDA application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. Under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System (*QS*) regulations applicable to medical devices. Problems associated with the device component of the combination product candidate may delay or prevent approval.

We have been granted Fast Track designation from the FDA for development of PH94B for the treatment of social anxiety disorder (SAD) and AV-101 for the adjunctive treatment of major depressive disorder (MDD) and for the treatment of neuropathc pain (NP). However, these designations may not actually lead to faster development or regulatory review or approval processes for PH94B or AV-101. Further, there is no guarantee the FDA will grant Fast Track designation for PH94B or AV-101 as a treatment option for other CNS indications or for any of our other product candidates in the future.

The Fast Track designation is a program offered by the FDA, pursuant to certain mandates under the FDA Modernization Act of 1997, designed to facilitate drug development and to expedite the review of new drugs that are intended to treat serious or life-threatening conditions. Compounds selected must demonstrate the potential to address unmet medical needs. The FDA's Fast Track designation allows for close and frequent interaction with the FDA. A designated Fast Track drug may also be considered for priority review with a shortened review time, rolling submission, and accelerated approval if applicable. The designation does not, however, guarantee FDA approval or expedited approval of any application for the product candidate.

In December 2017, the FDA granted Fast Track designation for development of AV-101 for the adjunctive (add-on) treatment of MDD in patients with an inadequate response to current antidepressants. In September 2018, the FDA granted Fast Track designation for development of AV-101 for the treatment of NP. In December 2019, the FDA granted Fast Track designation for development of PH94B for the treatment of SAD. However, these FDA Fast Track designations may not lead to a faster development or regulatory review or approval process for PH94B or AV-101 and the FDA may withdraw Fast Track designation of PH94B or AV-101 for if it believes that the respective designation is no longer supported by data from our clinical development programs.

In addition, we may apply for Fast Track designation for PH94B, PH10 and AV-101 as a treatment option for other CNS indications,. The FDA has broad discretion whether or not to grant a Fast Track designation, and even if we believe PH94B, PH10, AV-101 or other product candidates may be eligible for this designation, we cannot be sure that the review or approval will compare to conventional FDA procedures.

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 PH94B, PH10, AV-101 and/or our other future product candidates, if any, including positive results, may not be predictive of the results of later-stage clinical trials. PH94B, PH10, AV-101 or any other future product candidates in later stages of clinical development may fail to show the desired safety and efficacy results despite having progressed through nonclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in later-stage 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.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA approval. With respect to our current product candidates, if one or more of the future Phase 3 clinical trials of PH94B for acute treatment of anxiety in adults with SAD, any future clinical study of AV-101 or a future Phase 2 clinical trial of PH10 for MDD fail(s) to produce positive results, the development timeline and regulatory approval and commercialization prospects for PH94B, PH10 or AV-101 and, correspondingly, our business and financial prospects, could be materially adversely affected.

This drug candidate development risk is heightened by any changes in planned timing or nature of clinical trials compared to completed clinical trials. As product candidates are developed through preclinical to early- and late-stage clinical trials towards regulatory 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 have been affected by supply chain disruptions experienced by certain of our CDMOs as a result of the ongoing COVID-19 pandemic. In addition, clinical development of our products may be further affected if we or any of our collaborators 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 nonclinical or clinical studies of our product candidates.

If serious adverse events or other undesirable side effects or safety concerns attributable to future clinical trials of our product candidates, it may adversely affect or delay our clinical development and commercialization of PH94B, PH10 or AV-101.

Undesirable side effects or safety concerns caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval. Although no treatment-related serious adverse events (*SAEs*) were observed in any clinical trials of our product candidates to date, if treatment-related SAEs or other undesirable side effects or safety concerns, or unexpected characteristics attributable to PH94B, PH10 and/or AV-101 are observed in any furture clinical trials, including investigator-sponsored clinical trials, it may adversely affect or delay our clinical development and commercialization of the effected product candidate, and the occurrence of these events could have a material adverse effect on our business and financial prospects. Results of our future clinical trials could reveal a high and unacceptable severity and prevalence of adverse side effects. In such an event, our trials could be suspended or terminated and the FDA or other regulatory agency could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects or safety concerns caused by these product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend, or limit approvals of such product and require us to take them off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS or REMS-like plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product;
- we may be required to conduct additional post-marketing studies or surveillance;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and
- our products may become less competitive or our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

Failures or delays in the commencement or completion of our planned clinical trials and nonclinical studies of PH94B, PH10, AV-101 or other our product candidates could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

We will need to complete at least two pivotal Phase 3 clinical studies of PH94B, additional toxicology and other standard nonclinical and clinical safety studies, as well as certain standard smaller clinical studies prior to our submission of an NDA for regulatory approval of PH94B as acute treatment of anxiety in adults with SAD or any other CNS indication. For PH10, we will need to complete at least one additional Phase 2 clinical study, two pivotal Phase 3 clinical trials, additional toxicology and other standard nonclinical and clinical safety studies, as well as certain standard smaller clinical studies prior to the submission of an NDA for regulatory approval of PH10 as a stand-alone rapid-onset treatment for MDD, or any other CNS indication. For AV-101, for treatment of any CNS indication, we will need to complete at least one Phase 1B clinical study, two Phase 2 clinical studies, two pivotal Phase 3 clinical trials, additional toxicology and other standard nonclinical and clinical safety studies, as well as certain standard smaller clinical studies prior to the submission of an NDA for regulatory approval. Successful completion of our nonclinical and clinical trials is a prerequisite to submitting an NDA and, consequently, the ultimate approval required before commercial marketing of any product candidate we may develop. We do not know whether any of our future-planned nonclinical and clinical trials of PH94B, PH10, AV-101 or any other product candidate will be completed on schedule, if at all, as the commencement and completion of nonclinical and clinical trials can be delayed or prevented for a number of reasons, including, among others:

- delays due to events resulting from the ongoing COVID-19 pandemic;
- the regulatory authority may deny permission to proceed with planned clinical trials or any other clinical trials we may initiate, or may place a planned or ongoing clinical trial on hold;
- delays in filing or receiving approvals from regulatory authorities of additional INDs that may be required;
- negative or ambiguous results from nonclinical or clinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, investigators and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, investigators and clinical trial sites;
- delays in the manufacturing of, or insufficient supply of product candidates necessary to conduct nonclinical or clinical trials, including delays in the manufacturing of sufficient supply of drug substance or finished drug product;
- inability to manufacture or obtain clinical supplies of a product candidate meeting required quality standards;
- difficulties obtaining Institutional Review Board (*IRB*) approval to conduct a clinical trial at a prospective clinical site or sites;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the proximity of patients to clinical trial sites;
- eligibility criteria for a clinical trial, the nature of a clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- severe or unexpected adverse drug-related side effects experienced by patients in a clinical trial;
- delays in validating any endpoints utilized in a clinical trial;
- the regulatory authority may disagree with our clinical trial design and our interpretation of data from prior nonclinical studies or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- reports from nonclinical or clinical testing of other CNS indications or therapies that raise safety or efficacy concerns; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest.

Clinical trials may also be delayed or terminated prior to completion as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the regulatory authority, the IRBs at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board (*DSMB*), overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or approved clinical protocols;
- inspection of the clinical trial operations or trial sites by the regulatory authority that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, including any that could be identified in nonclinical carcinogenicity studies, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials that may lead to regulatory actions; and
- lack of adequate funding to continue nonclinical or clinical studies.

Changes in regulatory requirements, regulatory guidance or unanticipated events during our nonclinical studies and clinical trials of PH94B, PH10, AV-101 or other product candidates may occur, which may result in changes to nonclinical studies and clinical trial protocols or additional nonclinical studies and clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, guidance or unanticipated events during our nonclinical studies and clinical trials of PH94B, PH10, AV-101 or other product candidates may force us to amend nonclinical studies and clinical trial protocols or the regulatory authority may impose additional nonclinical studies and clinical trial requirements. Amendments or changes to our clinical trial protocols would require resubmission to the regulatory authority and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of clinical trials. Similarly, amendments to our nonclinical studies may adversely impact the cost, timing, or successful completion of those nonclinical studies. If we experience delays completing, or if we terminate, any of our nonclinical studies or clinical trials, or if we are required to conduct additional nonclinical studies or clinical trials, the commercial prospects for PH94B, PH10, AV-101 or other product candidates may be harmed and our ability to generate product revenue will be delayed.

We rely, and expect that we will continue to rely, on third parties to conduct our nonclinical and clinical trials of our current product candidates and will continue to do so for any other future product candidates. If these third parties do not successfully carry out their contractual duties and/or meet expected deadlines, completion of our nonclinical or clinical trials and development of PH94B, PH10, AV-101 or other future product candidates may be delayed and we may not be able to obtain regulatory approval for or commercialize PH94B, PH10, AV-101 or other future product candidates and our business could be substantially harmed.

By strategic design, we do not have the extensive internal staff resources to independently conduct nonclinical and clinical trials of our product candidates completely on our own. We rely on our network of strategic relationships with various academic research centers, medical institutions, nonclinical and clinical investigators, contract laboratories, CROs and other third parties to assist us to conduct and complete nonclinical and clinical trials of our product candidates. We enter into agreements with third-party CROs to provide monitors for and to manage data for our clinical trials, as well as provide other services necessary to prepare for, conduct and complete clinical trials. We rely heavily on these and other third-parties for execution of nonclinical and clinical trials for our product candidates and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these nonclinical and clinical trials and the management of data developed through nonclinical and clinical trials than would be the case if we were relying entirely upon our own internal staff resources. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. CROs and other outside parties may:

- experience disruptions to their operations, such as reduced staffing and supply chain disruptions, as a result of the ongoing COVID-19 pandemic;
- have staffing difficulties and/or undertake obligations beyond their anticipated capabilities and resources;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our nonclinical and clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted and completed in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards, and our reliance on CROs, or independent investigators does not relieve us of our regulatory responsibilities. We and our CROs, and any investigator in an investigator-sponsored study are required to comply with regulations and guidelines, including current Good Clinical Practice regulations (*cGCPs*) for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, any of our CROs or any of our third-party collaborators fail to comply with applicable cGCPs, the clinical data generated in clinical trials involving our product candidates may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced under cGMPs and will require a large number of test patients. Our failure or the failure of our CROs or other third-party collaborators to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we design our clinical trials for our product candidates, our clinical development strategy involves having CROs and other third-party investigators and medical institutions conduct clinical trials of our product candidates. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, although CROs, or independent investigators or medical institutions, as the case may be, may not perform all of their obligations under arrangements with us or in compliance with applicable regulatory requirements, under certain circumstances, we may be responsible and subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA laws and regulations during the conduct of clinical trials of our product candidates. If such third parties do not perform clinical trials of our product candidates in a satisfactory manner, breach their obligations to us or fail to comply with applicable regulatory requirements, the development and commercialization of our product candidates may be delayed or our development program materially and irreversibly harmed. In certain cases, including the Baylor Study and other investigator-sponsored clinical studies, we cannot control the amount and timing of resources these third-parties devote to clinical trials involving our product candidates. If we are unable to rely on nonclinical and clinical data collected by our third-party collaborators, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

If our relationships with one or more of our third-party collaborators terminates, we may not be able to enter into arrangements with alternative third-party collaborators. If such third-party collaborators, including our CROs, do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to applicable clinical protocols, regulatory requirements or for other reasons, any clinical trials that such third-parties are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully develop and commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs would increase and our ability to generate revenue would be delayed.

We rely completely on third-parties to manufacture, formulate, analyze, hold and distribute supplies of our product candidates for all nonclinical and clinical studies, and we intend to continue to rely on third parties to produce all nonclinical, clinical and commercial supplies of our product candidates in the future.

By strategic design, we do not currently have, nor do we plan to acquire or develop, extensive internal infrastructure or technical capabilities to manufacture, formulate, analyze, hold or distribute supplies of our product candidates, for use in nonclinical and clinical studies or commercial scale. As a result, with respect to all of our product candidates, we rely, and will continue to rely, completely on CDMOs to manufacture API and formulate, hold and distribute final drug product. The facilities used by our CDMOs to manufacture PH94B, PH10 and AV-101 API and formulate PH94B, PH10 and AV-101 final drug product are subject to a pre-approval inspection by the FDA and other comparable foreign regulatory agencies to assess compliance with applicable regulatory guidelines and requirements, including cGMPs, and may be required to undergo similar inspections by the FDA or other comparable foreign regulatory agencies, after we submit INDs, NDAs or relevant foreign regulatory submission equivalent to the applicable regulatory agency.

We do not directly control the manufacturing process or the supply or quality of materials used in the manufacturing, analysis and formulation of our product candidates, and, with respect to all of our product candidates, we are completely dependent on our CDMOs to comply with all applicable cGMPs for the manufacturing of both API and finished drug product. If our CDMOs cannot secure adequate supplies of suitable raw materials or successfully manufacture our product candidates, including PH94B, PH10 and AV-101 API and finished drug product, that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, production of sufficient supplies of our product candidates, including PH94B, PH10 and AV-101 API and finished drug product, may be delayed and our CDMOs may not be able to secure and/or maintain regulatory approval for their manufacturing facilities, or the FDA may take other actions, including the imposition of a clinical hold. In addition, we have no direct control over our CDMOs' ability to maintain adequate quality control, quality assurance and qualified personnel. All of our CDMOs are engaged with other companies to supply and/or manufacture materials or products for such other companies, which exposes our CDMOs to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our CDMO's facilities generally or affect the timing of manufacture of PH94B, PH10 and AV-101 for required or planned nonclinical and/or clinical studies. If the FDA or an applicable foreign regulatory agency determines now or in the future that our CDMOs' facilities are noncompliant, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop, obtain regulatory approval for or market our product candidates. Our reliance on CDMOs also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

With respect to PH94B, PH10 and AV-101, we do not yet have long-term supply agreements in place with our CDMOs and each batch of PH94B, PH10 and AV-101 is or will be individually contracted under a separate supply agreement. If we engage new CDMOs, such contractors must complete an inspection by the FDA and other applicable foreign regulatory agencies. We plan to continue to rely upon CDMOs and, potentially, collaboration partners, to manufacture research and development scale, and, if approved, commercial quantities of our product candidates. Although we believe our current scale of API manufacturing for AV-101, and our contemplated scale of API manufacturing for PH94B and PH10, and the current and projected supply of PH94B, PH10 and AV-101 API and finished drug product will be adequate to support our planned nonclinical and clinical studies of PH94B, PH10 and AV-101, no assurance can be given that unanticipated supply shortages or CDMO-related delays in the manufacture and formulation of PH94B, PH10 or AV-101 API and/or finished drug product will not occur in the future.

Additionally, we anticipate that PH94B and PH10 will be considered drug-device combination products. Third-party manufacturers may not be able to comply with cGMP requirements applicable to drug/device combination products, including applicable provisions of the FDA's or a comparable foreign regulatory authority's drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation (*QSR*) or similar regulatory requirements outside the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our CDMOs to manufacture our product candidates must be approved by the FDA anf comparable foreign regulatory authorities pursuant to inspections that will or may be conducted after we submit our NDA. We do not control the manufacturing process of, and are completely dependent on, our CDMO partners for compliance with cGMPs and QSRs. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. CDMOs may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

Even if we receive marketing approval for PH94B, PH10, AV-101 or any other product candidate in the U.S., we may never receive regulatory approval to market PH94B, PH10, AV-101 or any other product candidate outside of the U.S.

In order to market PH94B, PH10, AV-101 or any other product candidate outside of the U.S., we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

If any of our product candidates are ultimately regulated as controlled substances, we, our CDMOs, as well as future distributors, prescribers, and dispensers will be required to comply with additional regulatory requirements which could delay the marketing of our product candidates, and increase the cost and burden of manufacturing, distributing, dispensing, and prescribing our product candidates.

Before we can commercialize our product candidates in the U.S. or any market outside the U.S., the U.S. Drug Enforcement Administration (*DEA*) or its foreign counterpart may need to determine whether such product candidates will be considered to be a controlled substance, taking into account the recommendation of the FDA or its foreign counterpart, as the case may be. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible, which would increase the cost associated with commercializing such products and, in turn, may have an adverse impact on our results of operations. Although we currently do not know whether the DEA or any foreign counterpart will consider any of our current or future product candidate to be controlled substances, we cannot yet give any assurance that such product candidates, including PH94B, PH10 and AV-101 will not be regulated as controlled substances.

If any of our product candidates are regulated as controlled substances, depending on the DEA controlled substance schedule in which the product candidates are placed or that of its foreign counterpart, we, our CDMOs, and any future distributers, prescribers, and dispensers of the scheduled product candidates may be subject to significant regulatory requirements, such as registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA or a foreign counterpart of the DEA as the case may be. Moreover, if any of our product candidates are regulated as controlled substances, we and our CDMOs would be subject to initial and periodic DEA inspection. If we or our CDMOs are not able to obtain or maintain any necessary DEA registrations or comparable foreign registrations, we may not be able to commercialize any product candidates that are deemed to be controlled substances or we may need to find alternative CDMOs, which would take time and cause us to incur additional costs, delaying or limit our commercialization efforts.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates, should they be deemed to contain controlled substances. Failure to comply with the applicable controlled substance laws and regulations can also result in administrative, civil or criminal enforcement. The DEA or its foreign counterparts may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings or consent decrees. Individual states also independently regulate controlled substances.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate any revenue.

We do not currently have any internal resources for the sale, marketing and distribution of pharmaceutical products, and we may not create such internal capabilities in the foreseeable future. Therefore, to market our product candidates, if approved by the FDA or any other regulatory body, we must make contractual arrangements with third parties to perform services related to sales, marketing, managerial and other non-technical capabilities relating to the commercialization of our product candidates, or establish those capabilities prior to market approval. If we are unable to establish adequate contractual arrangements for such sales, marketing and distribution capabilities, or if we are unable to do so on commercially reasonable terms, or if we are unable to establish such capabilities on our own, our business, results of operations, financial condition and prospects will be materially adversely affected.

Even if we receive marketing approval for our product candidates, our product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy and safety of our product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available therapies;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

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

Undesirable safety concerns and side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt nonclinical studies and clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Further, clinical trials by their nature utilize a sample of potential patient populations. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable safety concerns or side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and would substantially increase the costs of commercializing our product candidates and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Even if we receive marketing approval for our product candidates, we may still face future development and regulatory difficulties.

Even if we receive marketing approval for our product candidates, regulatory authorities may still impose significant restrictions on our product candidates, indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Our product candidates will also be subject to ongoing regulatory requirements governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information. The FDA and other regulatory authorities have significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA and other regulatory authorities also have the authority to require, as part of an NDA or post-approval, the submission of a REMS or comparable safety program. Any REMS or comparable safety program required by the FDA or other regulatory authority may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug and device products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and other regulations. If we or a regulatory agency discover problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where our product candidates are manufactured, a regulatory agency may impose restrictions on our product candidates, the manufacturer or us, including requiring withdrawal of our product candidates from the market or suspension of manufacturing. If we, our product candidates, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require that we initiate a product recall.

Competing therapies could emerge adversely affecting our opportunity to generate revenue from the sale of our product candidates.

The pharmaceutical industry is highly competitive. There are many public and private pharmaceutical companies, universities, governmental agencies and other research organizations actively engaged in the research and development of product candidates that may be similar to and compete with our product candidates or address similar markets. It is probable that the number of companies seeking to develop product candidates similar to and competitive with our product candidates will increase.

Currently, management is unaware of any FDA-approved oral adjunctive therapy for MDD patients with an inadequate response to standard antidepressants having the same mechanism of pharmacological action and safety profile as our orally-administered AV-101 or our intranasally-administered PH10. However, new antidepressant products with other mechanisms of pharmacological action or products approved for other indications, including the FDA-approved anesthetic ketamine hydrochloride administered intravenously, are being or may be used off-label for treatment of MDD, as well as other CNS indications for which AV-101 or PH10 may have therapeutic potential. Additionally, other non-pharmaceutical treatment options, such psychotherapy and electroconvulsive therapy (*ECT*) are used before or instead of standard antidepressant medications to treat patients with MDD. Management is also unaware of any FDA-approved rapid-onset, acute treatment of anxiety in adults with SAD having the same mechanism of pharmacological action and safety profile as our PH94B.

In the field of new generation, oral adjunctive treatments for adult patients with MDD with an inadequate response to standard FDA-approved ADs, we believe our principal competitors may be Axsome's AXS-05, Alkermes' ALKS-5461, Allergan's AGN-241751 and Sage's Sage-217. Additional potential competitors may include, but not be limited to, academic and private commercial clinics providing intravenous ketamine therapy on an off-label basis and Janssen's intranasally-administered Spravato (esketamine). With respect to PH94B and current FDA-approved treatment options for SAD in the U.S., our competition may include, but is not limited to, certain current generic ADs approved by the FDA for treatment of SAD and certain classes of drugs used on an off-label basis for treatment of SAD, including benzodiazepines such as alprazolam, and beta blockers such as propranolol.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery, and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. With respect to AV-101 and PH10, we believe that a range of pharmaceutical and biotechnology companies have programs to develop drug candidates for the treatment of depression, including MDD, Parkinson's disease levodopa-induced dyskinesia, neuropathic pain, epilepsy, and other neurological conditions and diseases, including, but not limited to, Abbott Laboratories, Acadia, Allergan, Alkermes, Aptynix, AstraZeneca, Axsome, Eli Lilly, GlaxoSmithKline, IntraCellular, Janssen, Lundbeck, Merck, Neurocrine, Novartis, Ono, Otsuka, Pfizer, Relmada, Roche, Sage, Sumitomo Dainippon, and Takeda, as well as any affiliates of the foregoing companies. With respect to PH94B, in addition to potential competition from certain current FDA-approved antidepressants and off-label use of benzodiazepines and beta blockers, we believe additional drug candidates in development for SAD may include, but potentially not be limited to, an oral fatty acid amide hydrolase inhibitor in development by Janssen. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates, such as the License and Collaboration Agreement we entered into with EverInsight Therapeutics, Inc. in June 2020 for the development and commercialization of PH94B in certain key Asian markets.

We may derive revenue from research and development fees, license fees, milestone payments and royalties under any collaborative arrangement into which we enter, including the EverInsight Agreement and/or the Bayer Agreement. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. As a result, we can expect to relinquish some or all of the control over the future success of a product candidate that we license to a third party.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of nonclinical and clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential markets for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. The terms of any collaboration or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any future collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We may not be successful in our efforts to identify or discover additional product candidates, or we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates with commercial and therapeutic potential. We may fail to pursue additional development opportunities for PH94B, PH10 or AV-101, or identify additional product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying new product candidates or our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we currently have limited financial and management resources, we necessarily focus on a limited number of research and development programs and product candidates and are currently focused primarily on development of PH94B, PH10 and AV-101, with additional limited focus on NCE drug rescue and, through a third-party collaboration, regenerative medicine. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other potential CNS-related indications for PH94B, PH10 and/or AV-101 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research and development programs to identify and advance new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, once we begin commercializing our product candidates, we may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will 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 product candidates, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal 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 healthcare programs such as Medicare and Medicaid.

- The federal False Claims Act imposes criminal and civil penalties, including those from civil whistleblower or qui tam actions, 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.

- The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- 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, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program 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 and transparency 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 healthcare providers or marketing expenditures and drug pricing.

- Foreign Corrupt Practices Act and its application to marketing and selling practices as well as to clinical trials.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were 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 and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be out of compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as PH94B, PH10 and AV-101, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive FDA marketing approval for PH94B as a treatment of SAD, physicians may prescribe PH94B to their patients in a manner that is inconsistent with the FDA-approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper off-label promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if approved, reimbursement policies could limit our ability to sell our product candidates.

Market acceptance and sales of our product candidates will depend heavily on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for those medications. Cost containment is a primary concern in the United States healthcare industry and elsewhere. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for our product candidates and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates.

In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates with other available therapies. If reimbursement for our product candidates is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

We may seek FDA Orphan Drug designation for one or more of our product candidates. Even if we have obtained FDA Orphan Drug designation for a product candidate, there may be limits to the regulatory exclusivity afforded by such designation.

We may, in the future, choose to seek FDA Orphan Drug designation for one or more of our current or future product candidates. Even if we obtain Orphan Drug designation from the FDA for a product candidate, there are limitations to the exclusivity afforded by such designation. In the U.S., the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA to market the same drug for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active moiety and is intended for the same use as the drug in question. To obtain Orphan Drug status for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties such as our collaboration with EverInsight to develop and commercialize PH94B in key Asian markets. If we commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights, different standards of patentability and different availability of prior art in some foreign countries as compared with the U.S.;
- the existence of additional potentially relevant third party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

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

We are a development stage biopharmaceutical company. We currently have no approved products and currently 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 collaborators:

- develop and obtain required regulatory approvals for commercialization of PH94B, PH10, AV-101 and/or other product candidates;
- maintain, leverage and expand our intellectual property portfolio;
- establish and maintain sales, distribution and marketing capabilities, and/or enter into strategic partnering arrangements to access such capabilities;
- gain market acceptance for our product candidates; and
- obtain adequate capital resources and manage our spending as costs and expenses increase due to research, production, development, regulatory approval and commercialization of product candidates.

Our future success is highly dependent upon our ability to successfully develop and commercialize any of our current product candidates, acquire or license additional product candidates, or discover, as well as produce, develop and commercialize proprietary NCEs using our stem cell technology, and we cannot provide any assurance that we will successfully develop and commercialize PH94B, PH10, AV-101 or acquire or license additional product candidates or discover and develop NCEs, or that, if produced, PH94B, PH10, AV-101 or any other product candidate will be successfully commercialized.

Business development and research and development programs designed to identify, acquire or license additional product candidates, or, as the case may be, produce DR NCEs require substantial technical, financial and human resources, whether or not any additional product candidate is acquired or licensed or NCEs are ultimately identified and produced.

In addition, we do not have a sales or marketing infrastructure, and we, including our executive officers, do not have any significant pharmaceutical sales, marketing or distribution experience. We may seek to collaborate with others to develop and commercialize PH94B, PH10, AV-101, drug rescue NCEs and/or other product candidates if and when they are acquired and developed, or we may seek to establish those commercial capabilities ourselves. 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 entering into arrangements with third parties to sell, market and distribute PH94B, PH10, AV-101, any drug rescue NCEs 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, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We have limited operating history with respect to drug development, including our anticipated focus on the identification and acquisition of additional product candidates or the assessment of potential NCEs and no operating history with respect to the production of NCEs, and we may never be able to produce a NCE.

If we are unable to develop and commercialize PH94B, PH10, AV-101 or acquire or license additional product candidates, or produce suitable NCEs, we may not be able to generate sufficient revenues to execute our business plan, which likely would result in significant harm to our financial position and results of operations, which could adversely impact our stock price.

With respect to drug rescue, there are a number of factors, in addition to the utility of *CardioSafe* 3D, that may impact our ability to identify and produce, develop or out-license and commercialize NCEs, independently or with partners, including:

- our ability to identify potential candidates in the public domain, obtain sufficient quantities of them, and assess them using our bioassay systems;
- if we seek to rescue drug candidates that are not available to us in the public domain, the extent to which third parties may be willing to out-license or sell certain candidates to us on commercially reasonable terms;
- our medicinal chemistry collaborator’s ability to design and produce proprietary NCEs based on the novel biology and structure-function insight we provide using *CardioSafe* 3D; and
- financial resources available to us to develop and commercialize lead NCEs internally, or, if we sell or out-license them to partners, the resources such partners choose to dedicate to development and commercialization of any NCEs they acquire or license from us.

Even if we do acquire additional product candidates or produce proprietary NCEs, we can give no assurance that we will be able to develop and commercialize them as marketable drugs, on our own or in collaboration with others. Before we generate any revenues from PH94B, PH10, AV-101 or additional acquired or licensed products candidates or any NCEs, we or our potential collaborators must complete preclinical and clinical development programs, submit clinical and manufacturing data to the FDA, qualify a third party CDMO, receive regulatory approval in one or more jurisdictions, satisfy the FDA that our CDMO 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.

If CardioSafe 3D fails to predict accurately and efficiently the cardiac effects, both toxic and nontoxic, of drug rescue candidates and drug rescue NCEs, then our drug rescue programs will be adversely affected.

Success of our subsidiary, VistaStem, is partly 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 NCEs. If *CardioSafe* 3D is not capable of providing physiologically relevant and clinically predictive information regarding human cardiac biology, our business will be adversely affected.

CardioSafe 3D may not be meaningfully more predictive of the behavior of human cells than existing methods.

Drug rescue programs are highly dependent upon *CardioSafe* 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 will be more efficient or accurate at predicting the heart safety of new drug candidates than the testing models currently used. If *CardioSafe* 3D fails to provide a meaningful difference compared to existing or new models in predicting the behavior of human heart, respectively, their utility for drug rescue will be limited and our business will be adversely affected.

We may invest in producing drug rescue NCEs for which there proves to be no demand.

To generate revenue from our drug rescue activities, we must produce proprietary NCEs for which there proves to be demand within the healthcare marketplace, and, if we intend to out-license a particular NCE for development and commercialization prior to market approval, then also among pharmaceutical companies and other potential collaborators. However, we may produce NCEs 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 business may be adversely affected.

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 hPSC technology is technically complex, and the time and resources necessary to develop various human cell types and customized bioassay systems, although not significant at present, are difficult to predict in advance. We might decide to devote significant additional personnel and financial resources to research and development activities designed to expand, in the case of DR, and explore, in the case of drug discovery and RM, potential applications of our stem cell technology platform. In particular, we may conduct exploratory nonclinical RM programs involving blood, bone, cartilage, and/or liver cells. Although we and our third-party collaborators have developed proprietary protocols to produce multiple differentiated cell types, we could encounter difficulties in differentiating and producing sufficient quantities of particular cell types, even when following these proprietary protocols. These difficulties could result in delays in production of certain cells, assessment of certain drug rescue candidates and drug rescue NCEs, design and development of certain human cellular assays and performance of certain exploratory nonclinical RM studies. In the past, our stem cell research and development projects have been significantly delayed when we encountered unanticipated difficulties in differentiating hPSCs into heart and liver 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, and liver cells could have a substantial and material adverse effect on our potential drug discovery, drug rescue and RM business opportunities and results of operations.

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

Some of our research and development programs may involve the use of human cells derived from our controlled differentiation of human embryonic stem cells (*hESC*s). 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 U.S. and elsewhere voice opposition to hESC technology and practices. We may 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 DR capabilities of our technology, which would have a material adverse effect on our business.

The use of embryonic or fetal tissue in research (including the derivation of hESCs) in other countries is regulated by the government, and such regulation 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.

The foregoing potential ethical concerns do not apply to our use of induced pluripotent stem cells *(iPSCs*) because their derivation does not involve the use of embryonic tissues.

We have assumed that the biological capabilities of 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 stem cell technology platform could be harmed.

We may use both hESCs and iPSCs to produce human cells for our customized *in vitro* assays for drug discovery and drug rescue purposes. However, we anticipate that our future exploratory research and development, if any, focused on potential regenerative medicine applications of our stem cell technology 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 programs, this would negatively affect our ability to explore expansion of our platform in that manner, 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 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 to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions, which could have a material adverse effect on our operations.

To the extent our research and development activities involve using iPSCs, 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 U.S. 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. U.S. 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 U.S., 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 U.S. In addition, both the application and interpretation of these laws and regulations are often uncertain, particularly in the rapidly evolving stem cell technology sector. Compliance with these laws and regulations can be costly, can delay or impede our research and development activities, result in negative publicity, increase our operating costs, require significant management time and attention and subject us to claims or other remedies, including fines or demands that we modify or cease existing business practices.

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

To the extent that our future stem cell research and development activities involve the use of iPSCs and the manipulation of human tissue and genetic information, the information we derive from such iPSC-related research and development activities could be used in a variety of applications, which may have underlying legal, social and ethical concerns, including the genetic engineering or modification of human cells, testing for genetic predisposition for certain medical conditions and stem cell banking. Governmental authorities could, for safety, social or other purposes, call for limits on or impose regulations on the use of iPSCs and genetic testing or the manufacture or use of certain biological materials involved in our iPSC-related research and development programs. Such concerns or governmental restrictions could limit our future research and development activities, which could have a material adverse effect on our business, financial condition and results of operations.

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

The human cells we produce from hPSCs and our customized bioassay systems using such cells, including *CardioSafe* 3D, are not currently sold, for research purposes 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 human cells we derive from hPSCs 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 RM 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.

Risks Related to Our Financial Position

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

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of approximately $20.8 million and $24.6 million million during our fiscal years ended March 31, 2020 and 2019, respectively, and a net loss of approximately $3.1 million for the three months ended June 30, 2020. At June 30, 2020, we had an accumulated deficit of approximately $205.0 million. We do not know whether or when we will become profitable. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with nonclinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we may incur significant sales, marketing and outsourced-manufacturing expenses should we elect not to collaborate with one or more third parties for such services and capabilities. As a public company, we incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate recurring revenues. Through June 30, 2020, we have generated approximately $17.7 million in revenues, consisting of receipt of non-dilutive cash payments from collaborators, sublicense revenue, and research and development grant awards from the NIH. We have not yet commercialized any product or generated any revenues from product sales, and we do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to experience sales of, PH94B, PH10, AV-101 or another future product candidate, or we enter into one or more development and commercialization agreements with respect to PH94B, PH10, AV-101 or one or more other future product candidates. Our ability to generate recurring revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete nonclinical and clinical trials that meet their prescribed endpoints;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;
- timely complete and compose successful regulatory submissions such as NDAs or comparable documents for both the U.S. and foreign jurisdictions;
- commercialize our product candidates, if approved, by developing a sales force or entering into collaborations with third parties for sales and marketing capabilities; and
- achieve market acceptance of our product candidates in the medical community and with third-party payors.

Unless we enter into a commercialization collaboration or partnership with respect to the commercialization of our product candidates, we expect to incur significant sales and marketing costs as we prepare to commercialize our product candidates. Even if we initiate and successfully complete pivotal clinical trials of our product candidates, and our product candidates are approved for commercial sale, and despite expending these costs, our product candidates may not be commercially successful. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We require additional financing to execute our business plan and continue to operate as a going concern.

Our audited consolidated financial statements for the year ended March 31, 2020 included in our Annual Report on Form 10-K filed with the SEC on June 29, 2020 were prepared assuming we will continue to operate as a going concern, although we and our auditors have indicated that our continuing losses and negative cash flows from operations raise substantial doubt about our ability to continue as such. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from this offering as well as future sales of our securities or potentially obtaining loans and grant awards from financial institutions and/or government agencies where possible. Our continued net operating losses increase the difficulty in completing such sales or securing alternative sources of funding, and there can be no assurances that we will be able to obtain any future funding on favorable terms or at all. If we are unable to obtain sufficient financing from the sale of our securities or from alternative sources, we may be required to reduce, defer, or discontinue certain or all of our research and development activities or we may not be able to continue as a going concern.

Since our inception, most of our resources have been dedicated to research and development of AV-101 and the drug rescue capabilities of VistaStem's stem cell technology platform. In particular, we have expended substantial resources on research and development of methods and processes relating to the production of AV-101 API and drug product, advancing AV-101 through IND-enabling preclinical development, Phase 1 clinical safety studies, and into ongoing Phase 2 clinical development, including the Elevate Study completed in 2019, as well as research and development and regulatory expenses related to the development and production of PH94B and PH10 and our stem cell technology platform, including development of *CardioSafe* 3D for DR and our cardiac stem cell technology for potential RM applications in connection with the Bayer Agreement, and we expect to continue to expend substantial resources for the foreseeable future developing and commercializing our product candidates on our own or in collaborations. These expenditures will include costs associated with general and administrative costs, facilities costs, research and development, acquiring new technologies, manufacturing product candidates, conducting nonclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale.

At June 30, 2020, we had cash and cash equivalents of approximately $1.5 million. We do not believe this amount, plus the net cash proceeds received from the EverInsight Agreement and from the Public Offering completed in August 2020, is sufficient to enable us to fund our planned operations for at least the twelve months following the issuance of the financial statements included elsewhere in this Report. We expect to seek additional capital to produce PH94B and PH10 study material, prepare for and launch a pivotal Phase 3 clinical trial of PH94B for acute treatment of SAD, prepare for a Phase 2B clinical study and certain nonclinical studies involving PH10, PH94B and AV-101 and prepare for and potentially launch a Phase 2B clinical trial of PH10 for MDD, acquire or license and conduct research and development of additional product candidates and to fund our internal operations.

Further, although we received the $5 million non-dilutive cash upfront payment under the EverInsight Agreement in August 2020 and expect to recognize that amount as revenue in future periods,we have no other recurring source of revenue or recurring cash flows from product sales to sustain our present activities, and we do not expect to generate sustainable positive operating cash flows until, and unless, we (i) out-license or sell a product candidate to a third-party that is subsequently successfully commercialized, (ii) enter into additional license arrangements involving our stem cell technology, or (iii) obtain approval from the FDA or other regulatory authorities and successfully commercialize, on our own or through a future collaboration, one or more of our product candidates.

As the outcome of our ongoing research and development activities, including the outcome of future anticipated nonclinical studies and clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates, on our own or in collaboration with others. As with prior periods, we will continue to incur costs associated with other development programs for PH94B, PH10 and AV-101. In addition, other unanticipated costs may arise. As a result of these and other factors, we will need to seek additional capital in the near term to meet our future operating plans and requirements, including capital necessary to develop, obtain regulatory approval for, and to commercialize our product candidates, and may seek additional capital in the event there exists favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans and requirements. We have completed in the past, and are currently considering a range of potential financing transactions, including public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches, and we may complete additional financing arrangements later in 2020 and thereafter. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans and requirements, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

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 and formulating our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other collaborative arrangements and the financial terms of such agreements;
- market acceptance of our product candidates;
- the effect of competing technological and market developments;
- our ability to obtain government funding for our research and development programs;
- the costs involved in obtaining, maintaining and enforcing patents to preserve our intellectual property;
- the costs involved in defending against such 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 may acquire or invest in additional businesses, product candidates and technologies.

Any additional fundraising efforts will divert certain members of our management team from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, our ability to engage in certain types of capital raising transactions may be limited by the Listing Rules of the Nasdaq Stock Market and/or General Instruction I.B.6 of Form S-3 if the market value of our common stock held by non-affiliates is ever below $75 million at a time we seek to utilize our effective registration statement on Form S-3. We cannot guarantee that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. The terms of any future financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity securities and the conversion, exchange or exercise of certain of our outstanding securities will dilute all of our stockholders. The incurrence of debt could result in increased fixed payment obligations and we could be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain additional funding on a timely basis and on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or product development programs or the commercialization of any product candidate or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Current volatile and/or recessionary conditions in the U.S. or abroad could adversely affect our business or our access to capital markets in a material manner.

To date, our principal sources of capital used to fund our development programs and other operations have been the net proceeds we received from sales of equity securities, as described herein. We have and will continue to use significant capital for the development of our product candidates, and, as such, we expect to seek additional capital from future issuance(s) of our securities, which may consist of issuances of equity and/or debt securities, to fund our planned operations.

Accordingly, our results of operations and the implementation of both our short-term and long-term business plan could be adversely affected by general conditions in the global economy, including conditions that are outside of our control, such as the impact of health and safety concerns from the current COVID-19 pandemic. The most recent global financial crisis caused by COVID-19 resulted in extreme volatility and disruptions in the capital and credit markets. A prolonged economic downturn could result in a variety of risks to our business and may have a material adverse effect on us, including limiting or restricting our ability to access capital on favorable terms, or at all, which would limit our ability to obtain adequate financing to maintain our operations.

We recieved funds from the Paycheck Protection Program enacted by Congres under the Coronavirus Aid, Relief and Economic Security Act, which funds must be repaid if we do not meet the criteria for forgiveness established by the U.S. Small Business Administration.

On April 22, 2020, we entered into a note payable agreement, pursuant to which we received net proceeds of approximately $224,000 from a potentially forgivable loan from the U.S. Small Business Administration (*SBA*) pursuant to the Paycheck Protection Program (*PPP*) enacted by Congress under the Coronavirus Aid, Relief, and Economic Security Act (the *CARES Act*) administered by the SBA (the *PPP Loan*). The PPP Loan provides for working capital to the Company and matures on April 22, 2022. Under the CARES Act and the PPP Loan Agreement, all payments of both principal and interest are deferred until at least October 22, 2020. The PPP Loan will accrue interest at a rate of 1.00% per annum, and interest will continue to accrue throughout the period the PPP Loan is outstanding, or until it is forgiven. The CARES Act (including subsequent guidance issued by SBA and U.S. Department of the Treasury related thereto) provides that all or a portion of the PPP Loan may be forgiven upon our request to the Lender, subject to requirements in the PPP Loan Agreement and the CARES Act. Although no assurances can be given, the Company currently believes it will be able to satisfy the applicable requirements for forgiveness of the PPP Loan and expects that the PPP Loan will be forgiven.

We have identified material weaknesses in our internal control over financial reporting, and our business and stock price may be adversely affected if we do not adequately address those weaknesses or if we have other material weaknesses or significant deficiencies in our internal control over financial reporting.

We have identified material weaknesses in our internal control over financial reporting. In particular, we concluded that (i) the size of our staff does not permit appropriate segregation of duties to (a) permit appropriate review of accounting transactions and/or accounting treatment by multiple qualified individuals, and (b) prevent one individual from overriding the internal control system by initiating, authorizing and completing all transactions, and (ii) we utilize accounting software that does not prevent erroneous or unauthorized changes to previous reporting periods and/or can be adjusted so as to not provide an adequate auditing trail of entries made in the accounting software.

The existence of one or more material weaknesses or significant deficiencies could result in errors in our financial statements, and substantial costs and resources may be required to rectify any internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, we may be unable to obtain additional financing to operate and expand our business and our business and financial condition could be harmed.

Raising additional capital will cause substantial dilution to our existing stockholders, may restrict our operations or require us to relinquish rights, and may require us to seek stockholder approval to authorize additional shares of our common stock.

We intend to pursue private and public equity offerings, debt financings, strategic collaborations and licensing arrangements during 2020 and beyond. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, or to the extent, for strategic purposes, we convert or exchange certain of our outstanding securities into common stock, our current stockholders' ownership interest in our company will be substantially diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect rights of our stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

Some of our programs have been partially supported by government grant awards, 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 (*NINDS*) and the NIMH, and the California Institute for Regenerative Medicine (*CIRM*). 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, including the impact of the ongoing COVID-19 pandemic. 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.

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

As of March 31, 2020, we had federal and state net operating loss carryforwards of approximately $125.1 million and $64.1 million, respectively, which begin to expire in fiscal 2021 and will continue to expire in future periods. Under Section 382 of the Internal Revenue Code of 1986, as amended (the *Code*), changes in our ownership may limit the amount of our net operating loss carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Any such limitation, whether as the result of future offerings, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us in the future, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study.

General Company-Related Risks

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully produce, develop and commercialize our product candidates.

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 Chief Executive Officer, President and Chief Scientific Officer, Chief Medical Officer, Chief Financial Officer, and Vice President – Corporate Development as well as our other employees, consultants and scientific collaborators. As of the date of this Report, we have nine full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. The loss of services of any of these individuals could delay or prevent the successful development of our product candidates 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 should we elect to expand our research and development and administrative activities. We may not be able to attract and retain quality personnel on acceptable terms.

In addition, we rely on a broad and diverse range of strategic consultants and advisors, including manufacturing, nonclinical and clinical development, and regulatory advisors and CROs, to assist us in designing and implementing our research and development and regulatory strategies and plans for our product candidates. 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.

As we seek to advance development of our product candidates, we may need to expand our research and development capabilities and/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.

As we develop our product candidates. either on our own or in collaboration with others, we will face inherent risks 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 product candidates. For example, we may be sued if PH94B, PH10, AV-101, any NCE, other product candidate, or RM product candidate 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 product candidates 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; or
- product recalls, withdrawals or labeling, marketing or promotional restrictions.

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 general and product 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.

As a public company, we incur significant administrative workload and expenses to comply with U.S. regulations and requirements imposed by the Nasdaq Stock Market concerning corporate governance and public disclosure.

As a public company with common stock listed on the Nasdaq Capital Market, we must comply with various laws, regulations and requirements, including certain provisions of the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC and the Nasdaq Stock Market. Complying with these statutes, regulations and requirements, including our public company reporting requirements, continues to occupy a significant amount of the time of management and involves significant accounting, legal and other expenses. Our efforts to comply with these regulations are likely to result in increased general and administrative expenses and management time and attention directed to compliance activities.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by global political conditions, as well as general conditions in the global economy and in the global financial and stock markets. Global financial and political crises cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent economic downturn triggered by the ongoing COVID-19 pandemic, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CDMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our business and operations would suffer in the event of cybersecurity or other system failures. Our business depends on complex information systems, and any failure to successfully maintain these systems or implement new systems to handle our changing needs could result in a material disruption of our product candidates' development programs or otherwise materially harm our operations.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of employees. Similarly, our third-party CROs, CDMOs and other contractors and consultants possess certain of our sensitive data. The secure maintenance of this information is material to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of our third-party CROs, CDMOs and other contractors and consultants are vulnerable to attacks by hackers, damage from computer viruses, unauthorized access, breach due to employee error, malfeasance or other disruptions, natural disasters, terrorism and telecommunication and electrical failures. Additionally, having shifted to remote working arrangements, we also face a heightened risk of cybersecurity attacks or data security incidents and are more dependent on internet and telecommunications access and capabilities. Any such attack or breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation, which could adversely affect our business.

While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for PH94B, PH10, AV-101 or other product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

We may acquire businesses or product candidates, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or product candidates, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates resulting from a strategic alliance, licensing transaction or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition or licensing transaction, we will achieve the expected synergies to justify the transaction.

Current politics in the U.S. could diminish the value of the pharmaceutical industry, thereby diminishing the value of our securities.

The current political environment in the U.S. has led many incumbents and political candidates to propose various measures to reduce the prices for pharmaceuticals. As we near the U.S. presidential 2020 elections, it is likely that these proposals will receive increasing publicity which, in turn, may cause the investing public to reduce the perceived value of pharmaceutical companies. Any decrease in the overall perception of the pharmaceutical industry may have an adverse impact on our share price and may limit our ability to raise capital needed to continue our drug development programs.

Risks Related to Our Intellectual Property Rights

If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our product candidates, their compositions and formulations, their methods of use and methods of manufacturing and any other inventions we consider important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, to defend and enforce our patents, to preserve the confidentiality of our trade secrets and to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our product candidates. We own and have licensed patents and patent applications related to product candidates PH94B, PH10, AV-101 and also to hPSC technology.

Although we own and have licensed issued and allowed patents and patent applications relating to PH94B, PH10 and AV-101 in the U.S., selected countries in the EU and other jurisdictions, we cannot yet provide any assurances that any of our pending U.S. and additional foreign patent applications will mature into issued patents and, if they do, that any of our patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage.

Moreover, other parties may have developed technologies that may be related or competitive to our approach and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent properties, for example, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. Such third-party patent positions may limit or even eliminate our ability to obtain or maintain patent protection.

The uncertainty about adequate protection includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. Moreover, relevant laws differ from country-to-country.

The patent positions of biotechnology and pharmaceutical companies, including our patent portfolio with respect to our product candidates, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any additional patent claims that we may obtain cannot be predicted with certainty.

Our ability to obtain valid and enforceable patents depends in large measure on whether the differences between our technology and the prior art allow our inventions to be patentable over relevant prior art. Such prior art includes scientific publications, investment blogs, granted patents and published patent applications. Patent uncertainty cannot be eliminated because of the potential existence of other prior art about which we are currently unaware that may be relevant to our patent applications and patents, which may prevent a pending patent application from being granted or result in an issued patent being held invalid or unenforceable.

In addition, some patent-related uncertainty exists because of the challenge in finding and addressing all of the relevant and material prior art in the biotechnology and pharmaceutical fields. For example, there are numerous reports in the scientific literature of compounds that target similar cellular receptors as certain of our product candidates or that were evaluated in early (often pre-clinical) studies. In addition, even some reports in the trade press and public announcements made by us before the filing date of our AV-101 patent applications mentioned that AV-101 was in development for certain therapeutic purposes. For example, we published a web post on the NIH clinical trials website prior to our filing of our initial AV-101 patent applications, which describes unit doses for a then future study, but does not mention treatment of depression and does not provide any preclinical or clinical study data relating to depression or any other medical condition, disease or disorder. This post was not submitted to the United States Patent and Trademark Office (*USPTO*) in our two granted U.S. patents related to (i) unit dose formulations of AV-101 effective to treat depression and (ii) methods of treating depression with AV-101, respectively. However, it was submitted in two depression-related AV-101 patent applications that have similar claims and we have received Notices of Allowance from the USPTO in those applications. We are considering entering this web post in the record of the aforementioned two issued U.S. patents. Another source of uncertainty pertains to patent properties that were in-licensed by us for which prior art submissions were under the control of the licensor. We rely on these licensors to have satisfied the relevant disclosure obligations.

In the event any previously published prior art is deemed to be invalidating prior art, it may cause certain of our issued patents to be invalid and/or unenforceable which would cause us to lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO, the European Patent Office (*EPO*) and various other foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable.

United States and foreign patents and patent applications may be subject to various types of infringement and validity proceedings, including interference proceedings, *ex parte* reexamination, *inter partes* review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, invalidity actions, or comparable proceedings lodged in various foreign, both national and regional, patent offices or courts. These proceedings could result in loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent in such a way that they no longer cover our product candidates or competitive products.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Even if a patent issues and is held to be valid and enforceable, competitors may be able to design around our patents, for example, by using pre-existing or newly developed technology. Other parties may develop and obtain patent protection for more effective technologies, designs or methods.

If we or one of our licensing partners initiated legal proceedings against a third-party to enforce a patent covering one of our product candidates, including patents related to PH94B, PH10 or AV-101, the defendant could counterclaim that the patent covering our product candidate 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 include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. 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 our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

In addition, such patent-related proceedings may be costly. Thus, any patent properties that we may own or exclusively license ultimately may not provide commercially meaningful protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates.

We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, or former or current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights also depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components or manufacturing processes that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any patents covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations would also be materially and adversely impacted.

Overall, the degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any issued patents related to PH94B, PH10, AV-101 or any pending patent applications, if issued and challenged by others, will include or maintain claims having a scope sufficient to protect PH94B, PH10, AV-101 or any other products or product candidates against generic or other competition, particularly considering that any patent rights to these compounds *per se* have expired;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will ultimately be found to be valid and enforceable, including on the basis of prior art relating to our patent applications and patents;
- any patents currently held or issued to us in the future will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents or proprietary rights of others.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, collaborators and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not discover or have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, which may prevent or delay our product development efforts and stop us from commercializing candidate products or increase the costs of commercializing them, if approved. Also, we may file counterclaims or initiate other legal proceedings against third parties to challenge the validity or scope of their intellectual property rights, the outcomes of which also would be uncertain and could have a material adverse effect on the success of our business.

We cannot assure that our business, product candidates and methods do not or will not infringe the patents or other intellectual property rights of third parties. Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights. In addition, we or our licensors or collaborators may file counterclaims in such proceedings or initiate separate legal proceedings against third parties to challenge the validity or scope of their intellectual property rights, including in oppositions, interferences, reexaminations, *inter partes* reviews or derivation proceedings before the United States or other jurisdictions.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. Success also will depend on our ability to prevail in litigation if we are sued for infringement or to resolve litigation matters with rights and at costs favorable to us.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current product candidates and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of their business strategies designed to impede our successful commercialization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, third parties may have currently pending patent applications that later result in issued patents that our product candidates may infringe, or that such third parties assert are infringed by our technologies.

The foregoing types of proceedings can be expensive and time-consuming and many of our own or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Our defense of litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States or European Union.

The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient financial resources to bring these actions to a successful conclusion.

An unfavorable outcome in the foregoing kinds of proceedings could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators.

In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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. There could also 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 material adverse effect on the price of our common stock.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcomes are uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to have willfully infringed a third party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim is successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing our product candidates.

Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products.

In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, some or all of our product candidates to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

We enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign their intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world is prohibitively expensive, and our intellectual property rights in some countries outside the U.S. could be less extensive than those in the United States, assuming that rights are obtained in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the United States or other jurisdictions. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For the pending patent applications relating to AV-101, as well as for other of the patent families that we own or license, the relevant statutory deadlines have not yet expired. Thus, for each of the patent families that we believe provide coverage for our lead product candidates or technologies, we will need to decide whether and where to pursue protection outside the U.S.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology and pharmaceuticals. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties under certain circumstances. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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. There could also 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 material adverse effect on the price of our common stock.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We are dependent, in part, on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development or payment deadlines, we could lose license rights that are important to our business.

For our PH10, PH94B and certain stem cell technologies, we are a party to a number of license agreements under which we are granted rights to intellectual properties that are or could become important to our business, and we expect that we may need to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of fees, milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products, which could be covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our current product candidates or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We have entered into several licenses, both in-license agreements and out-license agreements, to support and leverage our various stem cell technology-related programs. We may enter into additional license(s) to third-party intellectual property that are necessary or useful to our business. Our current licenses, including the EverInsight Agreement and the Bayer Agreement, and any future licenses that we may enter into impose various royalty payments, milestone, and other obligations on us. For example, the licensor may retain control over patent prosecution and maintenance under a license agreement, in which case, we may not be able to adequately influence patent prosecution or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, our licensor(s) may allege that we have breached our license agreement and may accordingly seek to terminate our license with them. In addition, future licensor(s) may decide to terminate our license at will. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms our business could suffer.

Some intellectual property which we have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed or will license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 (*Bayh-Dole Act*). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose.

In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Also, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits.

Intellectual property generated under a government funded program is further subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

In the event we apply for additional U.S. government funding, and we discover compounds or drug candidates as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

In the U.S., depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension, for example, if the active ingredient of PH94B, PH10 or AV-101 is used in another drug company's product candidate and that product candidate is the first to obtain FDA approval.

Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Similar kinds of patent term and regulatory and data protection periods are available outside of the U.S. We will pursue such opportunities to extend the exclusivity of our products, but we cannot predict the availability of such exclusivity pathways or that we will be successful in pursuing them.

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 pharmaceutical and biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. in recent years enacted and is currently implementing wide-ranging patent reform legislation: the Leahy-Smith America Invents Act, referred to as the America Invents Act. The America Invents Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that may issue from our patent applications, all of which could have a material adverse effect on our business and financial condition.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. The full impact of these decisions is not yet known. For example, on March 20, 2012 in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, the Court held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. The decision appears to impact diagnostics patents that merely apply a law of nature via a series of routine steps and it has created uncertainty around the ability to obtain patent protection for certain inventions. Additionally, on June 13, 2013 in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Court held that claims to isolated genomic DNA are not patentable, but claims to complementary DNA molecules are patent eligible because they are not a natural product. The effect of the decision on patents for other isolated natural products is uncertain.

Additionally, on March 4, 2014, the USPTO issued a memorandum to patent examiners providing guidance for examining claims that recite laws of nature, natural phenomena or natural products under the Myriad and Prometheus decisions. This guidance did not limit the application of Myriad to DNA but, rather, applied the decision to other natural products. Further, in 2015, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Court of Appeals for the Federal Circuit held that methods for detecting fetal genetic defects were not patent eligible subject matter. Other more recent court decisions and related USPTO examination guidelines must be taken into account, particularly as they relate to changes in what types of inventions are eligible for patent protection. Foreign patent and intellectual property laws also are evolving and are not predictable as to their impact on the Company and other biopharmaceutical companies.

In addition to increasing uncertainty regarding our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue in the future.

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

Certain of our current employees have been, and certain of our future employees may have been, previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We also engage advisors and consultants who are concurrently employed at universities or who perform services for other entities.

Although we are not aware of any claims currently pending or threatened against us, we may be subject to claims that we or our employees, advisors or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. We have and may in the future also be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would materially adversely affect our commercial development efforts.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

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, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of patents, should such patents issue from our patent applications;
- we might not have been the first to make the inventions covered by a pending patent application that we own;
- we might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable or be narrowed, as a result of legal challenges by our competitors;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

With regard to our stem cell technology, if, instead of identifying DR candidates based on information available to us in the public domain, we seek to in-license DR 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 DR NCEs that we may produce and develop. If we are unable to obtain ownership or substantial economic participation rights over intellectual property related to DR NCEs we produce and develop, our DR business may be adversely affected.

Risks Related to our Securities

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

On January 31, 2020, we were notified by the Nasdaq Stock Market, LLC (*Nasdaq*) that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The notification provided that we had 180 calendar days, or until July 29, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2) (the *Bid Price Rule*). To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days.

On April 17, 2020, in response to the extraordinary market conditions caused by the COVID-19 pandemic, Nasdaq instituted a longer period of time for companies such as ours to regain compliance with certain continued listing requirements, including the Bid Price Rule. As a result, we now have until October 12, 2020 to regain compliance with the Bid Price Rule. If we do not regain compliance with the Bid Price Rule by October 12, 2020, an additional 180 days may be granted to regain compliance, so long as we meet the remaining Nasdaq Capital Market continued listing requirements and notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period. If we do not qualify for the second compliance period or fail to regain compliance during the second 180-day period, then Nasdaq will notify us of its determination to delist our common stock, at which point we will have an opportunity to appeal the delisting determination to a hearings panel.

No assurance can be given that we will meet applicable Nasdaq continued listing standards. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our common stock, which could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the inability to advance our drug development programs, potential loss of confidence by investors and employees, and fewer business development opportunities.

Market volatility may affect our stock price and the value of your investment.

The market price for our common stock, similar to other biopharmaceutical companies, is likely to be highly volatile. The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including, among others:

- volatility resulting from uncertainty and general ecomnic conditions caused by the ongoing COVID-19 pandemic;
- plans for, progress of or results from nonclinical and clinical development activities related to our product candidates;
- the failure of the FDA or other regulatory authority to approve our product candidates;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other CNS therapies;
- regulatory or legal developments in the U.S. and other countries;
- announcements regarding our intellectual property portfolio;
- failure of our product candidates, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;

- our ability to raise additional capital and the terms on which we can raise it;
- sales or purchases of large blocks of our common stock, including sales or purchases by our executive officers, directors and significant stockholders;
- establishment of short positions by holders or non-holders of our stock or warrants;
- additions or departures of key personnel;
- discussion of us or our stock price by the press and by online investor communities; and
- other risks and uncertainties described in these risk factors.

Future sales and issuances of our common stock may cause our stock price to decline.

Sales or issuances of a substantial number of shares of our common stock in the public market, or the perception that such sales or issuances are occurring or might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

The stock market in general, and small biopharmaceutical companies like ours in particular, have frequently experienced significant 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 actual operating performance. In certain 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. Additionally, if the trading volume of our common stock remains low and limited there will be an increased level of volatility and you may not be able to generate a return on your investment.

A 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. Historically, there has been a limited public market for shares of our common stock. Future sales and issuances of a substantial number of shares of our common stock in the public market, including shares issued upon the conversion of our Series A Preferred, Series B Preferred or Series C Preferred, and the exercise of outstanding options and warrants for common stock which are issuable upon exercise, in the public market, or the perception that these sales and issuances are occurring or might occur, could significantly reduce the market price for our common stock and impair our ability to raise adequate capital through the sale of equity securities.

A limited number of institutional stockholders could limit your ability to influence the outcome of key transactions, including changes in control.

A limited number of institutional stockholders own a substantial portion of our outstanding preferred stock, consisting of shares of our Series A Preferred, Series B Preferred, and Series C Preferred, all of which is convertible, at the option of the holders (but subject to certain beneficial ownership restrictions), into a substantial number of shares of our common stock. Accordingly, should a few of these institutional holders convert their shares of preferred stock into common stock, such stockholders may exert influence over us and over the outcome of any corporate actions requiring approval of holders of our common stock, including the election of directors and amendments to our organizational documents, such as increases in our authorized shares of common stock, 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 the Company, even if such a change of control is approved by our Board and would benefit our other stockholders. Furthermore, the interests of such institutional stockholders may not always coincide with your interests or the interests of other common stockholders and an institutional holder may act in a manner that advances its best interests and not necessarily those of other stockholders.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or if such analysts issue other unfavorable commentary or cease publishing reports about us or our business.

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

Our Restated Articles of Incorporation, as amended (the *Articles*), permit us to issue up to 10.0 million shares of preferred stock. Our Board has authorized the issuance of (i) 500,000 shares of Series A Preferred, all of which shares are issued and outstanding at June 30, 2020; (ii) 4.0 million shares of Series B 10% Convertible Preferred stock, of which approximately 1.2 million shares remain issued and outstanding at June 30, 2020; and (iii) 3.0 million shares of Series C Convertible Preferred Stock, of which approximately 2.3 million shares are issued and outstanding at June 30, 2020. Our Board 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.

We do not intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders purchased them.

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

We are 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 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 resources 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 on companies that are not "smaller reporting companies" under federal securities laws are rigorous and, once we are no longer a smaller reporting company, we may not be able 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 applicable 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 6. EXHIBITS

Exhibit Number	Description
1.1	Underwriting Agreement, dated August 2, 2020, by and between VistaGen Therapeutics, Inc. and Maxim Group LLC, incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed on August 6, 2020.
10.1	Note Payable Agreement by and between VistaGen Therapeutics, Inc and Silicon Valley Bank, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 27, 2020.
10.2 +*	License and Collaboration Agreement, by and between VistaGen Therapeutics, Inc. and EverInsight Therapeutics Inc., dated June 24, 2020, filed herewith.
31.1	Certification of the Principal Executive Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of the Principal Executive and Financial Officers required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

+ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit (indicated by "[*****]") have been omitted as the Company has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Company if publicly disclosed.

* This exhibit was filed as Exhibit 10.1 to the Current Report on Form 8-K filed on June 26, 2020 and is being re-filed to correct an immaterial typographical error.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

VISTAGEN THERAPEUTICS, INC.

/s/ Shawn K. Singh
Shawn K. Singh
Chief Executive Officer (Principal Executive Officer)

/s/ Jerrold D. Dotson
Jerrold D. Dotson
Chief Financial Officer (Principal Financial and Accounting Officer)

Dated: August 13, 2020

EXHIBIT 10.2

LICENSE AND COLLABORATION AGREEMENT

BETWEEN

VISTAGEN THERAPEUTICS, INC.

AND

EVERINSIGHT THERAPEUTICS INC.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (this "Agreement") is made as of June 24, 2020 ("Effective Date"), by and among VistaGen Therapeutics, Inc., a company organized under the laws Nevada ("VistaGen"), and having an Affiliate of the same name, and EverInsight Therapeutics Inc., a company incorporated under the laws of the British Virgin Islands ("EverInsight") and having a registered address at Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands. VistaGen and EverInsight are referred to individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, VistaGen owns or controls certain intellectual property and associated data and materials relating to a pharmaceutical compound known as PH94B, which is an intranasal synthetic neuroactive steroid product being developed for the treatment of social anxiety disorder and other anxiety-related disorders;

WHEREAS, VistaGen wishes to grant a license to EverInsight, and EverInsight wishes to take a license, under such intellectual property and associated items to develop, manufacture and commercialize PH94B in certain territories in accordance with the terms and conditions set forth below;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency which are hereby acknowledged, the Parties hereby agree as follows.

ARTICLE 1 DEFINITIONS

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

1.1 "**Active Pharmaceutical Ingredient**" or "**API**" means any substance intended to be used in a pharmaceutical product that when used becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions in man or animal; but excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies.

1.2 "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with that Party, but for only so long as such control exists. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" and "under common control") means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) direct or indirect beneficial ownership of more than fifty percent (50%), or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction, of the voting share capital or other equity interest in such entity; provided however that, notwithstanding the foregoing, EverInsight's Affiliates shall not include CBC Group or any of its portfolio companies.

1.3 "**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, federal, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, arbitrator, Regulatory Authority or Government Authority having jurisdiction over or related to the subject item, including the FFDCA, DAL, and the Provisions for Drug Registration of NMPA.

1.4 "**Auditor**" has the meaning set forth in Section 8.10 (Audit Dispute).

1.5 "**Business Day**" means a day other than a Saturday, Sunday or a bank or other public holiday in Mainland China, Hong Kong or the State of California in the United States.

1.6 "**Calendar Quarter**" means each respective period of three (3) consecutive months ending on 31 March, 30 June, 30 September, and 31 December, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first 1 January, 1 April, 1 July or 1 October to occur after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.7 "**Calendar Year**" means each successive period of 12 calendar months commencing on 1 January and ending on 31 December except that the first Calendar Year of the Term shall commence on the Effective Date and end on 31 December of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on 1 January of the year in which the Term ends and end on the last day of the Term.

1.8 "**CFR**" means the U.S. Code of Federal Regulations.

1.9 "**Challenge**" means to contest or assist, directly or indirectly, in the contesting of the validity or enforceability of any of the VistaGen Patents or EverInsight Patents (as applicable), in whole or in part, in any court, arbitration proceeding or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. For the avoidance of doubt, the term "contest" includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patents; (b) citation to the United States Patent and Trademark Office pursuant to 35 U.S.C. § 301 of prior art patents or printed publications or statements of the patent owner concerning the scope of any such Patents; (c) filing a request under 35 U.S.C. § 302 for re-examination of any such Patents; (d) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter parties review of any such Patents or any portion thereof; (e) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of such Patents or any portion thereof; (f) provoking or becoming a party to an interference or a derivation proceeding with an application for any such Patents pursuant to 35 U.S.C. § 135; (g) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against any such Patents in any country; or (h) any foreign equivalents of subsection (a) through (g) applicable in the Territory; provided however, notwithstanding the foregoing, "Challenge" shall not include (i) any action taken by a Party in response to an action by the other Party to enforce such Patents against such Party, or (ii) any argument made by a Party in the course of patent prosecution that distinguish the inventions claimed in such Party's Patents from those inventions claimed in the other Party's Patent.

1.10 "**Claims**" means all Third Party demands, claims, actions, proceedings and liabilities (whether criminal or civil, in contract, tort or otherwise) for losses, damages, legal costs and other expenses of any nature.

1.11 "**CMC**" means chemistry, manufacturing, and controls.

1.12 "**Combination Product**" means any Licensed Product comprised of the following, either formulated together (*i.e.*, a fixed dose combination), packaged together and sold for a single price, or co-administered or jointly provided to patients, whether or not packaged together: (a) the Compound, and (b) at least one other API.

1.13 "**Commercialization**" means the conduct of all activities undertaken before and after Regulatory Approval has been obtained relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting for commercial sales, customs clearance, warehousing, invoicing, handling and delivering the Licensed Product to customers) of the Compound or the Licensed Product, including: (a) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training, and sales and distribution; and (b) scientific and medical affairs. For clarity, Commercialization does not include any Development activities, whether conducted before or after Regulatory Approval. "Commercialize" and "Commercializing" have correlative meanings.

1.14 "**Commercialization Plan**" has the meaning set forth in Section 7.2 (Commercialization Plan).

1.15 "**Commercially Reasonable Efforts**" means, with respect to each Party's obligations under this Agreement relating to the Development, Manufacturing, and Commercialization activities with respect to the Compound or the Licensed Product, the carrying out of such activities using efforts and resources that are consistent with the exercise of customary scientific and business practices as applied in the biopharmaceutical industry for a company of a similar stage and size as the entity and having similar resources, for development, regulatory, manufacturing and commercialization activities conducted with respect to products at a similar stage of development or commercialization and having similar commercial potential, taking into account relative safety and efficacy, product profile, the regulatory environment, payers' policies and regulations, competitiveness of the marketplace and the market potential of such products, the nature and extent of market exclusivity, including patent coverage and regulatory data protection, and price and reimbursement status. The Parties hereby agree that the level of effort may be different for different markets and may change over time, reflecting changes in the status of the aforementioned attributes and potential of the Compound and the Licensed Product. When used regarding obligations under this Agreement other than the Development, Manufacturing, and Commercialization activities with respect to the Compound or the Licensed Product, the term "Commercially Reasonable Efforts" shall mean the carrying out of such activities using commercially reasonable efforts and financial, personnel and other resources that are consistent with the exercise of customary business practices as applied in the carrying out of such activities generally by and on behalf of biopharmaceutical companies of a similar stage and size and having similar resources.

1.16 "**Compound**" means PH94B, and all salt, free acid/base, solvate, hydrate, prodrug, metabolite, stereoisomer, and enantiomer thereof, and polymorphic forms thereof.

1.17 "**Confidential Information**" of a Party means all Know-How, Inventions, unpublished patent applications and other information and data of a financial, commercial, business, operational or technical nature of such Party that is disclosed or made available by or on behalf of such Party or any of its Affiliates to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic or other form. The terms of this Agreement are the Confidential Information of both Parties.

1.18 "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents, Regulatory Documentation or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise, other than by virtue of any license granted to such Party by the other Party pursuant to this Agreement) to grant a license, sublicense, access or other right (as applicable) under such Know-How, Patents, Regulatory Documentation or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party, infringing third party intellectual property, or misappropriating third party trade secrets.

1.19 "**Controlling Party**" has the meaning set forth in Section 9.6 (Invalidity or Unenforceability Defenses or Actions).

1.20 "**Corporate Names**" has the meaning set forth in Section 1.81 (Licensed Trademarks).

1.21 "**Cost of Goods**" means, with respect to any Compound or any Licensed Product, **[*****].**

1.22 "**CTA**" means a Clinical Trial Application that is required to initiate a clinical trial for registering a drug product under the Drug Administration Law of the People's Republic of China and the Provisions for Drug Registration of NMPA, and equivalents thereof under future Chinese laws and regulations, and the laws and regulations of other countries and jurisdictions in the Territory, in each as the same may be amended from time to time.

1.23 "**DAL**" means the Drug Administration Law of the People's Republic of China and the equivalent laws of other countries and jurisdictions in the Territory, in each as the same may be amended from time to time.

1.24 "**Develop**" or "**Development**" means to develop (including clinical, non-clinical and CMC development), analyze, test and conduct preclinical, clinical and all other regulatory trials for the Compound or Licensed Product, including all post-approval clinical trials, as well as all related regulatory activities and any and all activities pertaining to new Indications, pharmacokinetic studies and all related activities including work on new formulations, new methods of treatment and CMC activities including new manufacturing methods. "Developing" and "Development" have correlative meanings.

1.25 "**Development Plan**" has the meaning set forth in Section 4.2 (Development Plan).

1.26 "**Disclosing Party**" has the meaning set forth in Section 10.1(a) (Duty of Confidence - subsection (a)).

1.27 "**Dispute**" has the meaning set forth in Section 14.10(a) (Dispute Resolution - subsection (a)).

1.28 "**Dollars**" means U.S. dollars, and "$" shall be interpreted accordingly.

1.29 "**EverInsight Development Data**" means any non-clinical or clinical data that are generated by EverInsight through the Development, Manufacture and Commercialization of the Compound and Licensed Product under this Agreement, Controlled by EverInsight, and related to the Compound or any Licensed Product or otherwise included in, or filed in support of, the Regulatory Documentation filed by EverInsight, its Affiliates or Sublicensees in the Territory.

1.30 "**EverInsight Know-How**" means all Know-How that is generated by EverInsight through the Development, Manufacture and Commercialization of the Compound and Licensed Product under this Agreement, Controlled by EverInsight as of the Effective Date or during the Term, and necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of any Compound or Licensed Product in the Licensed Field, including EverInsight Sole Inventions, EverInsight's interest in any Joint Inventions, EverInsight Development Data and EverInsight's Regulatory Documentation.

1.31 "**EverInsight Indemnitees**" has the meaning set forth in Section 13.1 (Indemnification by VistaGen).

1.32 "**EverInsight Patents**" means EverInsight Sole Invention Patents and EverInsight's interest in the Joint Patents, in each case necessary or reasonably useful for the Development, Manufacture, Commercialization, or other Exploitation of the Compound or any Licensed Product for use in the Licensed Field.

1.33 "**EverInsight Sole Inventions**" means any Inventions that are conceived and reduced to practice solely by employees of, or consultants or service providers to, EverInsight and its Affiliates, at any time during the Term of this Agreement.

1.34 "**EverInsight Sole Invention Patents**" means any Patents that contain one or more claims that cover EverInsight Sole Inventions.

1.35 "**EverInsight Technology**" means the EverInsight Patents and the EverInsight Know-How.

1.36 "**Excluded Claim**" has the meaning set forth in Section 14.10(g) (Dispute Resolution - subsection (g)).

1.37 "**Executive Officers**" has the meaning set forth in Section 3.3(a) (JSC Decision Making - subsection (a)).

1.38 "**Exploit**" means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of.

1.39 "**Exploitation**" means the act of Exploiting the Compound, product or process.

1.40 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.41 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.42 "**First Commercial Sale**" means, with respect to any Licensed Product in any jurisdiction in the Territory, the first arm's length sale of such Licensed Product by EverInsight, its Affiliates or Sublicensees to a Third Party for monetary value for use or consumption of such Licensed Product by the end user in the general public after Regulatory Approval for such Licensed Product in such jurisdiction has been granted. Sales prior to receipt of Regulatory Approval for such Licensed Product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.43 "**GAAP**" means the then-current Generally Accepted Accounting Principles or International Financial Reporting Standards (IFRS), whichever is adopted as the standard financial accounting guideline in the United States for public companies, as consistently applied.

1.44 "**Generic Competition**" means **[*****].**

1.45 "**Generic Product**" means, with respect to a Licensed Product, any product that contains the same Compound as such Licensed Product and that is sold under an approved Marketing Authorization Application granted by a Regulatory Authority to a Third Party that is not a Sublicensee of EverInsight or its Affiliates and did not obtain such product in a chain of distribution that includes any of EverInsight, its Affiliates, or its Sublicensees.

1.46 "**Good Manufacturing Practices**" or "**GMP**" shall mean all applicable Good Manufacturing Practices standards, including, as applicable, those standards required by any Regulatory Authority in the Territory.

1.47 "**Government Authority**" means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.48 "**Hong Kong**" means the Hong Kong Special Administrative Region of the People's Republic of China.

1.49 "**IND**" means a CTA or any other investigational new drug application, clinical trial application, clinical trial exemption or similar or equivalent application or submission for approval to conduct human clinical investigation filed with or submitted to the Regulatory Authority in the relevant jurisdiction in conformance with the requirements of such Regulatory Authority, including the FDA in the US and NMPA in Mainland China.

1.50 "**Indemnification Claim Notice**" has the meaning set forth in Section 13.3(a) (Notice of Claim).

1.51 "**Indemnified Party**" has the meaning set forth in Section 13.3(a) (Notice of Claim).

1.52 "**Indemnifying Party**" has the meaning set forth in Section 13.3(a) (Notice of Claim).

1.53 "**Indication**" means a separate and distinct disease, disorder, illness or health condition for which a separate MAA approval is required.

1.54 "**Indirect Costs**" means, with respect to a multi-regional clinical trial, all Third Party costs and expenses incurred by VistaGen or EverInsight to conduct such multi-regional clinical trial that are not directly allocable to a Party's territory (or to clinical sites within a Party's territory), including, without limitation, fees, costs and expenses for data management, clinical evaluation committees, data safety monitoring boards, physician consulting, investigator meetings, travel, document translation and other technology solutions and services that are not specific to a territory or a clinical site within a territory.

1.55 "**Initiation**" means, with respect to a clinical trial, the first dosing (whether with investigational drug, comparator drug or placebo) of the first subject in such clinical trial.

1.56 "**Initial Supply Agreement**" has the meaning set forth in Section 6.3 (Supply Agreement).

1.57 "**In-License Agreement**" has the meaning set forth in Section 2.4(b) (In-License Agreements).

1.58 "**Invention**" means any technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology process, composition of matter, article of manufacture, discovery or finding, that is or may be patentable, that is made, generated, conceived or otherwise invented as a result of a Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents or independent contractors, including all rights, title and interest in and to the intellectual property rights therein. For clarity, "Invention" does not include VistaGen Development Data or EverInsight Development Data.

1.59 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 3.1 (Joint Steering Committee).

1.60 "**Joint Inventions**" means any Inventions that are conceived and reduced to practice by employees of, or consultants or service providers to, VistaGen or its Affiliates, on the one hand, jointly with employees of, or consultants or service providers to, EverInsight or its Affiliates, on the other hand, at any time during the Term of this Agreement and that are made, generated, conceived or otherwise invented as a result of VistaGen and EverInsight exercising their rights or carrying out their obligations under this Agreement, whether directly or via their Affiliates, agents or independent contractors.

1.61 "**Joint Patents**" means any Patents that contain one or more claims that cover Joint Inventions.

1.62 "**Know-How**" means any information, including discoveries, improvements, modifications, processes, methods, techniques, protocols, formulas, data, inventions, know-how, trade secrets and results, patentable or otherwise, including physical, chemical, biological, toxicological, pharmacological, safety, and preclinical and clinical data, dosage regimens, control assays, and product specifications, but excluding any Patents.

1.63 "**Licensed Field**" means all uses in humans.

1.64 "**Licensed Know-How**" means all Know-How that VistaGen (or its Affiliates) Controls as of the Effective Date or during the Term that is necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of the Compound or any Licensed Product for use in the Licensed Field in the Territory, including all VistaGen Sole Inventions, VistaGen's interest in any VistaGen Joint Inventions in the Territory, VistaGen Development Data and VistaGen's Regulatory Documentation (with respect to Compound or a Licensed Product).

1.65 "**Licensed Manufacturing Know-How**" has the meaning set forth in Section 6.4 (Manufacturing Technology Transfer).

1.66 "**Licensed Patents**" means all Patents Controlled by VistaGen or its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful for the Development, Manufacture, Commercialization, or other Exploitation of the Compound or any Licensed Product for use in the Licensed Field in the Territory, including any VistaGen Sole Invention Patents and VistaGen's interest in the Joint Patents in the Territory. **[*****].**

1.67 "**Licensed Product**" means any pharmaceutical product that contains the Compound, alone or in combination with one or more other molecules or agents in any dosage form or formulation. For purposes of this Agreement, with respect to a Licensed Product that has been approved for an initial Indication, the approval of such License Product for one or more additional Indications shall not constitute a new and separate Licensed Product.

1.68 "**Licensed Technology**" means the Licensed Patents and the Licensed Know-How.

1.69 "**Licensed Trademarks**" means any corporate name or corporate logo ("**Corporate Names**") of VistaGen or its or Affiliates, and any Trademark that consists of or includes any Corporate Name of VistaGen or its Affiliates, including the Trademarks, names and logos identified on Exhibit B hereto and such other Trademarks, names and logos as VistaGen may designate for Licensed Product in a writing sent to EverInsight from time to time during the Term.

1.70 "**MAA**" or "**Marketing Authorization Application**" means an application to the appropriate Regulatory Authority for approval to market a Licensed Product (but excluding Pricing Approval) in any particular jurisdiction, and all amendments, renewals and supplements thereto, including, without limitation, an NDA filed with the FDA in the U.S. and an NDA (or any future equivalent thereto as defined in the DAL and the Provisions for Drug Registration) filed with the NMPA in Mainland China.

1.71 "**Mainland China**" means the People's Republic of China, including Hainan Island, but excluding Hong Kong, the Macau Special Administrative Region of the People's Republic of China and Taiwan.

1.72 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, in-process and finished testing, shipping, storing, or release of a product or any ingredient or intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, test method development and stability testing, formulation, quality assurance and quality control of the any compound, product or intermediate, and regulatory affairs with respect to the foregoing.

1.73 "**Manufacturing Transfer Period**" has the meaning set forth in Section 6.2.

1.74 "**Milestone Event**" has the meaning set forth in Section 8.2(a) - (8.2 Development and Regulatory Milestone Payments - clause (a)).

1.75 "**Milestone Payment**" has the meaning set forth in Section 8.2(a) - (8.2 Development and Regulatory Milestone Payments - clause (a)).

1.76 "**NDA**" means a New Drug Application (as more fully defined in 21 C.F.R. §314.5 *et seq.* or successor regulation) and all amendments and supplements thereto filed with the FDA and any other equivalent filing(s) in the Territory.

1.77 "**Net Sales**" means, **[*****]**

1.78 "**NMPA**" means the National Medical Products Administration of the People's Republic of China, formerly known as the China Food and Drug Administration, or its successor.

1.79 "**Patent**" means all patents and patent applications, including all provisionals, divisionals, reissues, reexaminations, renewals, continuations, continuations-in-part, substitute applications, priority applications and inventors' certificates, extensions and supplemental certificates and any and all foreign equivalents of the foregoing.

1.80 "**Payment**" has the meaning set forth in Section 8.8(b).

1.81 "**Person**" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

1.82 "**PH94B**" means the compound known as PH94B and having the chemical structure shown in Exhibit C.

1.83 "**Phase 1 Clinical Trial**" means a human clinical trial that would satisfy the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations) or any equivalent regulations in jurisdictions in the Territory, regardless of where such clinical trial is conducted.

1.84 "**Phase 3 Clinical Trial**" means a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations) or any equivalent regulations in jurisdictions in the Territory, regardless of where such clinical trial is conducted.

1.85 "**Pricing Approval**" means such governmental approval, agreement, determination or decision establishing prices for a Licensed Product that can be charged and/or reimbursed in a regulatory jurisdiction where the applicable Government Authority approves or determines the price and/or reimbursement of pharmaceutical products and where such approval or determination is necessary for the commercial sale of such Licensed Product in such jurisdiction.

1.86 "**Product Infringement**" has the meaning set forth in Section 9.4(a) (Notice).

1.87 "**Product Trademarks**" means the Trademark(s) used or to be used by EverInsight or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Product in the Licensed Field in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any Corporate Names of EverInsight, its Affiliates or its or their Sublicensees and any Licensed Trademarks that consist of or include any Corporate Name of VistaGen or its Affiliates or (sub)licensees).

1.88 "**Receiving Party**" has the meaning set forth in Section 10.1(a) (Duty of Confidence - subsection (a)).

1.89 "**Regulatory Approval**" means, with respect to a jurisdiction in the Territory, any and all approvals (including approvals of Marketing Authorization Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such jurisdiction, including, where applicable: (a) pricing or reimbursement approval in such jurisdiction; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); and (c) labelling approval.

1.90 "**Regulatory Authority**" means any applicable Government Authority responsible for granting Regulatory Approvals for any Licensed Product, including the FDA, the NMPA, and any corresponding national or regional regulatory authorities.

1.91 "**Regulatory Documentation**" means: all (a) applications (including all Regulatory Filings, INDs, CTAs and Marketing Authorization Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing; in each case (a), (b) and (c)) relating to the Compound or a Licensed Product.

1.92 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical product other than Patents, and including, without limitation, orphan drug exclusivity, new chemical entity exclusivity, data exclusivity or pediatric exclusivity.

1.93 "**Regulatory Filings**" means, with respect to the Compound or Licensed Product, any submission to a Regulatory Authority of any appropriate regulatory application specific to the Compound or Licensed Product, and shall include, without limitation, any submission to a regulatory advisory board and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings shall include any IND, CTA, NDA, MAA, Regulatory Approval or the corresponding application in any other country or jurisdiction.

1.94 "**Representative**" has the meaning set forth in Section 10.1(c) (Duty of Confidence - Subsection (c)).

1.95 "**Respective Territory**" means, in the case of EverInsight, the Territory, and in the case of VistaGen, all countries of the world outside the Territory.

1.96 "**Retained Rights**" means, with respect to the Compound and Licensed Product, the rights of VistaGen, its Affiliates and its and their licensors, (sub)licensees and contractors to:

(a) perform VistaGen's obligations under this Agreement;

(b) Manufacture and have Manufactured (including CMC and manufacturing process development work) the Compound or Licensed Product within the Territory solely for Exploitation outside the Territory;

(c) Develop and have Developed the Compound and Licensed Product in the Territory but only as part of a global Phase 3 Clinical Trial that EverInsight elects to participate in pursuant to Section 4.4(b); and

(d) Develop, Manufacture, Commercialize and otherwise Exploit the Compound and Licensed Product for any and all purposes outside the Territory.

1.97 "**Royalty Term**" has the meaning set forth in Section 8.4(b) (Royalty Term).

1.98 "**SEC**" has the meaning set forth in Section 10.5 (Publicity/Use of Names - subsection (a)).

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

1.99 "**Sublicense**" means a license or sublicense granted by EverInsight (or a Sublicensee) to Develop, make, use, import, promote, offer for sale or sell the Compound or any Licensed Product, including any license given to any of the rights granted to EverInsight under Section 2.1(Licenses to EverInsight).

1.100 "**Subcontractor**" has the meaning set forth in Section 2.8 (Subcontracting).

1.101 "**Sublicensee**" means a Third Party to whom EverInsight or its Affiliate has granted a Sublicense in accordance with the terms of this Agreement.

1.102 "**Tax**" or "**Taxes**" means any (a) all federal, provincial, territorial, state, municipal, local, foreign or other taxes, imposts, rates, levies, assessments and other charges in the nature of a tax (and all interest and penalties thereon and additions thereto imposed by any Government Authority), including without limitation all income, excise, franchise, gains, capital, real property, goods and services, transfer, value added, gross receipts, windfall profits, severance, ad valorem, personal property, production, sales, use, license, stamp, documentary stamp, mortgage recording, employment, payroll, social security, unemployment, disability, escheat, estimated or withholding taxes, and all customs and import duties, together with all interest, penalties and additions thereto imposed with respect to such amounts, in each case whether disputed or not; (b) any liability for the payment of any amounts of the type described in subsection (a) as a result of being or having been a member of an affiliated, consolidated, combined or unitary group; and (c) any liability for the payment of any amounts as a result of being party to any tax sharing agreement or arrangement or as a result of any express or implied obligation to indemnify any other person with respect to the payment of any amounts of the type described in subsection (a) or (b).

1.103 "**Term**" has the meaning set forth in Section 11.1 (Term).

1.104 "**Territory**" means Greater China (Mainland China, Taiwan, Hong Kong and Macau), South Korea, Southeast Asia (Singapore, Malaysia, Thailand, Indonesia, Philippines, and Vietnam).

1.105 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.106 "**Third Party Infringement Claim**" has the meaning set forth in Section 9.5 (Infringement claims by Third Parties).

1.107 "**Trademark**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration rights, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source, origin or quality, whether or not registered, and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.108 "**Transfer Tax**" has the meaning set forth in Section 8.8(c) (Transfer Tax).

1.109 "**United States**" or "**U.S.**" means the United States of America including its territories and possessions.

1.110 "**Valid Claim**" means, with respect to any jurisdiction in the Territory, a claim of an issued and unexpired Licensed Patent (as may be extended through supplementary protection certificate or patent term extension or the like) that has not been cancelled, revoked, held invalid or unenforceable by a decision of a patent office or other Government Authority of competent jurisdiction from which no appeal can be taken (or from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; provided that in any jurisdiction in the Territory, a Valid Claim shall cease to be a Valid Claim in such jurisdiction if its scope is such that it does not reasonably block or prevent the entry, or Commercialization, of Generic Products.

1.111 "**VistaGen CMO**" has the meaning set forth in Section 6.2 (Manufacturing Technology Transfer)

1.112 "**VistaGen Development Data**" means any nonclinical or clinical data that are Controlled by VistaGen and related to the Compound or any Licensed Product or otherwise included in, or filed in support of, the Regulatory Documentation filed by VistaGen, its Affiliates, licensees or sublicensees outside of the Territory.

1.113 "**VistaGen Indemnitees**" has the meaning set forth in Section 13.2 (Indemnification by EverInsight).

1.114 "**VistaGen Sole Inventions**" means any Inventions that are conceived and reduced to practice solely by employees of, or consultants or service providers to, VistaGen, at any time during the Term of this Agreement and that are made, generated, conceived or otherwise invented as a result of a Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents or independent contractors.

1.115 "**VistaGen Sole Invention Patents**" means any Patents that contain one or more claims that cover VistaGen Sole Inventions.

1.116 Interpretation. In this Agreement, unless otherwise specified:

(a) "includes" and "including" shall mean, respectively, includes without limitation and including without limitation;

(b) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(c) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear; and

(d) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall include references to the Exhibits and attachments.

ARTICLE 2 LICENSES

2.1 **License to EverInsight**.

(a) Subject to the terms and conditions of this Agreement, VistaGen hereby grants to EverInsight an exclusive (even as to VistaGen), royalty-bearing license and sublicense, as the case may be, under the Licensed Technology solely to Exploit Licensed Product in the Licensed Field in the Territory, with the right to grant sublicenses in accordance with Section 2.3 (Sublicense Rights).

(b) In addition, VistaGen hereby grants to EverInsight a non-exclusive license and sublicense, as the case may be, under the Licensed Technology to Manufacture and have Manufactured the Compound and Licensed Product outside the Territory solely for Exploitation in the Territory, with the right to grant sublicenses in accordance with Section 2.3 (Sublicense Rights).

2.2 **License to VistaGen**. Subject to the terms and conditions of this Agreement, EverInsight hereby grants to VistaGen an exclusive (even as to EverInsight), royalty-free license under the EverInsight Technology solely to Exploit Licensed Product in the Licensed Field outside the Territory, with the right to grant sublicenses in accordance with Section 2.3 (Sublicense Rights).

2.3 **Sublicense Rights**.

(a) **Affiliates**. Subject to the terms of this Section 2.3 (Sublicense Rights), EverInsight may grant a sublicense of the license granted in Section 2.1 (License to EverInsight) through multiple tiers to Affiliates of EverInsight without prior notice to or the prior consent of VistaGen; provided that (i) Licensed Know-How may only be sublicensed along with the Licensed Patents; (ii) EverInsight shall cause each Affiliate to comply with the applicable terms and conditions of this Agreement, as if such Affiliate were a Party to this Agreement; and (iii) EverInsight shall be responsible for all actions, activities and obligations to VistaGen of such Affiliate. Subject to the terms of this Section 2.3 (Sublicense Rights), VistaGen may grant a sublicense of the license granted in Section 2.2 (License to VistaGen) through multiple tiers to Affiliates of VistaGen without prior notice to or the prior consent of EverInsight; provided that (i) EverInsight Know-How may only be sublicensed along with the EverInsight Patents; (ii) VistaGen shall cause each Affiliate to comply with the applicable terms and conditions of this Agreement, as if such Affiliate were a Party to this Agreement; and (iii) VistaGen shall be responsible for all actions, activities and obligations to EverInsight of such Affiliate.

(b) **Third Parties**. Upon the prior written consent of VistaGen, such consent not to be unreasonably withheld, conditioned, or delayed, EverInsight may grant a sublicense of the rights granted under the license in Section 2.1 (License to EverInsight) through multiple tiers to any Third Party; provided that (i) Licensed Know-How may only be sublicensed along with the Licensed Patents (other than in the case of a sublicense to a fee-for-service Subcontractor in the context of subcontracting pursuant to Section 2.8 (Subcontracting)); (ii) each sublicense granted to a Third Party shall be in writing, and shall incorporate terms and conditions that are consistent with, and expressly made subject to, the terms and conditions of this Agreement; (iii) VistaGen shall be provided by EverInsight with a copy of such sublicense agreement within thirty (30) days of execution, which copy may redact any financial or other proprietary terms; and (iv) EverInsight shall be responsible to VistaGen for a breach of this Agreement due to the breach by such Third Party of such sublicense agreement. EverInsight hereby waives any requirement that VistaGen exhaust any right, power or remedy, or proceed against any such sublicensee for any obligation or performance under this Agreement prior to proceeding directly against EverInsight. Upon the prior written consent of EverInsight, such consent not to be unreasonably withheld, conditioned, or delayed, VistaGen may grant a sublicense of the rights granted under the license in Section 2.2 (License to VistaGen) through multiple tiers to any Third Party; provided that (i) EverInsight Know-How may only be sublicensed along with the EverInsight Patents (other than in the case of a sublicense to a fee-for-service Subcontractor pursuant to Section 2.8 (Subcontracting)); (ii) each sublicense granted to a Third Party shall be in writing, and shall incorporate terms and conditions that are consistent with, and expressly made subject to, the terms and conditions of this Agreement; (iii) EverInsight shall be provided by VistaGen with a copy of such sublicense agreement within thirty (30) days of execution, which copy may redact any financial or other priority terms; and (iv) VistaGen shall be responsible to EverInsight for a breach of this Agreement due to the breach by such Third Party of such sublicense agreement. VistaGen hereby waives any requirement that EverInsight exhaust any right, power or remedy, or proceed against any sublicensee for any obligation or performance under this Agreement prior to proceeding directly against VistaGen.

2.4 **VistaGen's Retained Rights; Limitations of License Grants**.

(a) **Retained Rights**.

(i) Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted by or reserved to VistaGen pursuant to any other term or condition of this Agreement, VistaGen hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its and their direct and indirect Third Party licensors under any In-License Agreement, (sub)licensees and contractors) all right, title and interest in and to the Licensed Patents, the Licensed Know-How, VistaGen Development Data, VistaGen's interests in and to Joint Patents and Joint Know-How, Regulatory Documentation of VistaGen and the Corporate Names of VistaGen and their Affiliates, in each case, for purposes of performing or exercising the Retained Rights.

(ii) Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted by or reserved to EverInsight pursuant to any other term or condition of this Agreement, EverInsight hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its and their direct and indirect Third Party licensors under any In-License Agreement, (sub)licensees and contractors) all right, title and interest in and to the EverInsight Patents, the EverInsight Know-How, EverInsight Development Data, EverInsight's interests in and to Joint Patents and Joint Know-How, Regulatory Documentation of EverInsight and the Corporate Names of EverInsight and their Affiliates, in each case, for purposes of performing its obligations or exercising its rights under this Agreement, and also for purposes of Manufacturing or having Manufactured the Compound and Licensed Product outside the Territory solely for Exploitation in the Territory.

(b) **In-License Agreements**.

(1) If VistaGen or any of its Affiliates negotiates with a Third Party at arms' length to obtain a license to any Know-How or Patent that are necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of the Compound or any Licensed Product (such Know-How or Patent, "**VistaGen Third Party IP**", such license, an "**In-License Agreement**"), then VistaGen shall promptly notify EverInsight and identify the relevant VistaGen Third Party IP, with a copy to the JSC. The applicable VistaGen Third Party IP shall be included in the license granted to EverInsight under Section 2.1 (License to EverInsight) and considered VistaGen Patents and VistaGen Know-How, respectively, only if VistaGen discloses the substantive terms of the In-License Agreement to EverInsight, which VistaGen hereby agrees to do, and EverInsight agrees in writing to (A) comply with all the relevant obligations of such In-License Agreement, and (B) pay **[*****]** of the portion of all upfront, milestone, royalty and other payments under the In-License Agreement that are allocable to the Development, Manufacture or Commercialization of the Compound or any Licensed Product in the Licensed Field in the Territory; provided, however, that, such upfront, milestone, royalty and other payments should be (x) at fair market value for such a license in the Territory; and (y) directly attributable to the Development, Manufacture or Commercialization of the Compound or any Licensed Product in the Licensed Field in the Territory by EverInsight or any of its Affiliates or any Sublicensees; and (z) for any such payment that is applicable to the Respective Territories of both Parties (such as upfront payment), such payment shall be allocated between the Parties' Respective Territories based on the relative value of the market for the Licensed Product in each Party's Respective Territory, and EverInsight shall pay **[*****]** of the portion allocable to the Territory (for clarity, VistaGen shall be solely responsible for, and EverInsight shall have no obligation to pay any portion of, all such payment that is not allocable to the Territory, such as royalty payment for the sale of Licensed Product outside the Territory). For the avoidance of doubt, if EverInsight reasonably determines that such VistaGen Third Party IP under the In-License Agreement is not necessary for the Development, Manufacture or Commercialization of the Compound or any Licensed Product in the Licensed Field in the Territory, EverInsight has the right not to pay any costs associated with such In-License Agreement, in which case such VistaGen Third Party IP shall not be included in the license granted to EverInsight under Section 2.1 (License to EverInsight) and shall not be considered to be VistaGen Patents and VistaGen Know-How.

(2) If EverInsight or any of its Affiliates or Sublicensees negotiates with a Third Party at arms' length to obtain a license to any Know-How or Patent that are necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of the Compound or any Licensed Product and actually applies such Know-How or Patent in the Development, Manufacture, Commercialization or other Exploitation of the Compound or any Licensed Product (such Know-How or Patent, "**EverInsight Third Party IP**", such license, an "**EverInsight In-License Agreement**"), then EverInsight shall promptly notify VistaGen and identify the relevant EverInsight Third Party IP, with a copy to the JSC. The applicable EverInsight Third Party IP shall be included in the license granted by EverInsight to VistaGen under Section 2.2 (License to VistaGen) and considered EverInsight Patents and EverInsight Know-How, respectively, only if EverInsight discloses the substantive terms of such EverInsight In-License Agreement to VistaGen, which EverInsight hereby agrees to do, and VistaGen agrees in writing to (A) comply with all the relevant obligations of such EverInsight In-License Agreement; (B) pay **[*****]** of the portion of all upfront, milestone, royalty and other payments under the EverInsight In-License Agreement that are allocable to the Development, Manufacture or Commercialization of the Compound or any Licensed Product in the Licensed Field in the Territory, which VistaGen hereby agrees to do; and (C) pay **[*****]** of the portion of all upfront, milestone, royalty and other payments applicable to the Development, Manufacture or Commercialization of the Compound or any Licensed Product in the Licensed Field outside the Territory; provided, however, that, such upfront, milestone, royalty and other payments under clause (B) above should be (x) at fair market value for such a license in the Territory; and (y) directly attributable to the Development, Manufacture or Commercialization of the Compound or any Licensed Product in the Licensed Field in the Territory by EverInsight or any of its Affiliates or any Sublicensees; and (z) for any such payment that is applicable to the Respective Territories of both Parties (such as upfront payment), such payment shall be allocated between the Parties' Respective Territories based on the relative value of the market for the Licensed Product in each Party's Respective Territory, and VistaGen shall pay **[*****]** of the portion allocable to the Territory (for clarity, pursuant to clause (C) above, VistaGen shall be solely responsible for, and shall reimburse EverInsight for, all such payment that is not allocable to the Territory, such as royalty payment for the sale of Licensed Product outside the Territory). For the avoidance of doubt, if VistaGen reasonably determines that such EverInsight Third Party IP is not necessary for the Development, Manufacture or Commercialization of the Compound or any Licensed Product in the Licensed Field outside the Territory, VistaGen has the right not to pay the costs associated with such EverInsight In-License Agreement outside the Territory under clause (C) above (for further clarity, VistaGen shall remain obligated to pay its share of the costs associated with such EverInsight In-License Agreement in the Territory under clause (B) above), in which case such EverInsight Third-Party IP shall not be included in the license granted to VistaGen under Section 2.2 (License to VistaGen) and shall not be considered to be EverInsight Patents and EverInsight Know-How. In the event that VistaGen does agree to accept such Third-Party license outside of the Territory, the provisions of clauses (3), (4) and (5) of this Section 2.4(b) (In-License Agreements) shall apply, mutatis mutandis, to any such Third Party license.

(3) Subject to this Section 2.4(b) (In-License Agreements), the licenses granted by VistaGen in Section 2.1 (License to EverInsight) include sublicenses solely under the applicable license rights granted to VistaGen or its Affiliates by Third Parties under the In-License Agreements. Any Sublicense with respect to Know-How or Patents of a Third Party hereunder and any right of EverInsight (if any) to grant a further sublicense thereunder, shall be subject and subordinate to the terms and conditions of the In-License Agreement under which such sublicense is granted and shall be effective solely to the extent permitted under the terms of such agreement. Without limitation of the foregoing, in the event and to the extent that any In-License Agreement requires that particular terms or conditions of such In-License Agreement be contained or incorporated in any agreement granting a sublicense thereunder, such terms and conditions are hereby deemed to be incorporated herein by reference and made applicable to the sublicense granted herein under such In-License Agreement.

(4) The Parties shall cooperate with each other in good faith to support each other in negotiating rights under EverInsight Third Party IP in order for VistaGen to obtain such rights outside of the Territory and in complying with VistaGen's and its Affiliates' obligations under each In-License Agreement. Without limitation to the foregoing, (A) the Parties shall, from time to time, upon the reasonable request of either Party, discuss the terms of an In-License Agreement and agree upon, to the extent reasonably possible, a consistent interpretation of the terms of such In-License Agreement in order to, as fully as possible, allow VistaGen and its Affiliates to comply with the terms of such In-License Agreement; (B) to the extent there is a conflict between any terms of this Agreement and any terms of any In-License Agreement (including with respect to sublicensing rights, diligence obligations, prosecution, maintenance, enforcement, defense, any obligations for a counterparty to such In-License Agreement to maintain a Party's information as confidential and any obligations for a Party to maintain as confidential the information of a counterparty to such In-License Agreement), the terms of such In-License Agreement shall control with respect to the relevant Know-How, Patents or other rights granted to EverInsight hereunder; and (C) EverInsight and its Affiliates and Sublicensees shall comply with any applicable reporting and other requirements under the In-License Agreements, and the provisions regarding currency conversion, international payments and late payments, and any other relevant definitions and provisions, of the relevant In-License Agreements shall apply to the calculation of the payments due under the relevant In-License Agreements.

(5) On an In-License Agreement-by-In-License Agreement basis, from and after the date on which EverInsight agrees in writing pursuant to Section 2.4(b)(1) to accept the Patents and Know-How covered by such In-License Agreement as Licensed Technology under this Agreement, VistaGen shall maintain such In-License Agreement in full force and effect, shall not enter into any subsequent agreement with any other party to such In-License Agreement that modifies or amends such In-License Agreement in any way that would materially adversely affect EverInsight's rights or interest under this Agreement without EverInsight's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, and shall provide EverInsight with a copy of all modifications to or amendments of such In-License Agreement, regardless of whether EverInsight's consent was required with respect thereto.

2.5 **Transfer of Know-How**. Within **[*****]** days following the Effective Date, VistaGen shall commence disclosing and making available to EverInsight the Licensed Know-How (including the VistaGen Development Data therein) necessary or reasonably required for EverInsight to file a CTA covering a Licensed Product and to Develop the Compound and Licensed Product in the Licensed Field in the Territory. In addition, throughout the Term of this Agreement, VistaGen shall promptly disclose and make available to EverInsight any Licensed Know-How (including the VistaGen Development Data therein) that has not previously been provided to EverInsight, or is developed or generated or otherwise comes into VistaGen's Control after the Effective Date. Such disclosure and transfer shall be made at no additional cost to EverInsight and according to a timeline mutually agreed by EverInsight and VistaGen, each of which shall cooperate with each other in good faith to enable a smooth transfer of the Licensed Know-How from VistaGen to EverInsight. Upon EverInsight's reasonable request during such transfer, VistaGen shall provide reasonable technical assistance, at no additional cost to EverInsight, including making appropriate employees available to EverInsight at reasonable times, places and frequency, and upon reasonable prior notice, for the purpose of assisting EverInsight to understand and use the Licensed Know-How in connection with EverInsight's filing of such CTA covering such Licensed Product and the Development of the Compound and Licensed Product in the Licensed Field in the Territory.

2.6 **No Implied Licenses; Negative Covenant**. Except as set forth herein, no Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Know-How, Patents, trademarks or other intellectual property rights owned or Controlled by any other Party. EverInsight hereby covenants not to practice, and not to permit or cause any of its Affiliates or any Third Party to practice, any Licensed Technology for any purpose other than as expressly authorized in this Agreement.

2.7 **Non-Diversion**.

(a) EverInsight hereby covenants and agrees that it will not, and will ensure that its Affiliates will not, and will ensure its Sublicensees and subcontractors are bound by contractual obligations not to, either directly or indirectly, promote, market, solicit, distribute, import, sell or have sold Licensed Product outside the Territory. In furtherance of the foregoing, EverInsight shall not and will ensure that its Affiliates do not, and shall use Commercially Reasonable Efforts to ensure that its or their Sublicensees or distributors do not knowingly distribute, market, promote, offer for sale or sell the Compound or any Licensed Product directly or indirectly to any Person outside the Territory or to any Person inside the Territory that EverInsight or any of its Affiliates or any of its or their Sublicensees or distributors knows has directly or indirectly distributed, marketed, promoted, offered for sale or sold, or has reasonable grounds to believe intends to directly or indirectly distribute, market, promote, offer for sale or sell, the Compound or any Licensed Product for use outside the Territory. If EverInsight or any of its Affiliates receives or becomes aware of the receipt by it or any Sublicensee or distributor of any orders for the Compound or any Licensed Product for use outside the Territory, such Person shall refer such orders to VistaGen.

(b) VistaGen hereby covenants and agrees that it will not, and shall ensure that its Affiliates will not, and will ensure its licensees and sublicensees (other than EverInsight, its Affiliates and Sublicensees) and subcontractors are bound by contractual obligations not to, either directly or indirectly, promote, market, solicit, distribute, import, sell or have sold Licensed Product in the Territory. In furtherance of the foregoing, VistaGen shall not and will ensure that its Affiliates do not, and shall use Commercially Reasonable Efforts to ensure that its or their licensees and sublicensees (other than EverInsight, its Affiliates and Sublicensees) or distributors do not knowingly distribute, market, promote, offer for sale or sell the Compound or any Licensed Product directly or indirectly to any Person in the Territory or to any Person outside the Territory that VistaGen or any of its Affiliates or any of its or their licensees or sublicensees (other than EverInsight, its Affiliates and Sublicensees) or distributors knows has directly or indirectly distributed, marketed, promoted, offered for sale or sold, or has reasonable grounds to believe intends to directly or indirectly distribute, market, promote, offer for sale or sell, the Compound or any Licensed Product for use in the Territory. If VistaGen or any of its Affiliates receives or becomes aware of the receipt by it or any licensees, sublicensee (other than EverInsight, its Affiliates and Sublicensees) or distributor of any orders for the Compound or any Licensed Product for use in the Territory, such Person shall refer such orders to EverInsight.

2.8 **Non-Compete**. During the Term of this Agreement, neither Party shall, and each Party shall cause its Affiliates and their respective Sublicensees not to, directly or indirectly, enable or assist any Person that is not a Party to this Agreement to, Develop, Manufacture or Commercialize any intra-nasal formulation of Androstadienol in the Territory for the treatment of social anxiety disorder, other than the Compound and the Licensed Product in accordance with this Agreement (the "**Competing Product**"). If EverInsight requests a waiver of this Section with regard to a particular product and/or a particular transaction, VistaGen will in good faith give due consideration to such request. Notwithstanding the foregoing, if EverInsight is acquired by or merges or consolidates with a Third Party that, at the time of such acquisition, is actively Developing, Manufacturing and/or Commercializing a Competing Product in the Territory, then the activities of EverInsight, its Affiliates and their respective Sublicensees under and in accordance with the terms of such license agreement and the activities of such Third Party acquirer for the continued development, manufacturing and/or commercialization of the Competing Product, respectively, shall not be deemed to breach this Section 2.8.

2.9 **Subcontracting**. Notwithstanding Section 2.3 (Sublicense Rights), each Party may, without the other Party's consent, subcontract on a fee-for-service basis with a Third Party to perform any or all of its obligations hereunder (a "**Subcontractor**"), including by appointing one or more distributors, and grant a sublicense to the Subcontractor solely to the extent necessary to perform such subcontracted obligations; provided that (a) no such permitted subcontracting shall relieve the subcontracting Party of any obligation hereunder (except to the extent satisfactorily performed by such Subcontractor) or any liability and the subcontracting Party shall be and remain fully responsible and liable therefor; (b) the agreement pursuant to which the subcontracting Party engages any Subcontractor must be consistent in all material respects with this Agreement, including terms consistent with the confidentiality, restrictions on use and intellectual property provisions of this Agreement, and (c) the subcontracting Party shall be responsible to the other Party for the breach of this Agreement due to breach of any subcontracting agreement by its Subcontractors. The subcontracting Party hereby waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any Subcontractor for any obligation or performance under this Agreement prior to proceeding directly against the subcontracting Party.

2.10 **Statements and Compliance with Applicable Laws**. Each Party shall and shall cause its Affiliates and its and their respective licensees and Sublicensees to comply with all Applicable Laws with respect to the Exploitation of Licensed Product, including the extranational application of U.S. laws and regulations as related, for example, to regulatory matters, export controls and transfer of technology to certain countries and to foreign corrupt practices. Each Party shall, and shall cause its Affiliates to, and shall use Commercially Reasonable Efforts to cause its and their licensees, Sublicensees, employees, representatives, agents, and distributors to avoid taking, or failing to take, any actions that such Party knows or reasonably should know would jeopardize the goodwill or reputation of the other Party or its Affiliates or the Licensed Product or any Trademark associated therewith. Without limitation to the foregoing, each Party shall in all material respects conform its practices and procedures relating to the Commercialization of the Licensed Product and educating the medical community in its Respective Territory with respect to the Licensed Product to any applicable industry association regulations, policies and guidelines, as the same may be amended from time to time, and Applicable Laws. Each Party agrees that in performing its obligations under this Agreement, it will not employ or engage any Person who has been debarred or disqualified by any Regulatory Authority, or, to its knowledge, is the subject of debarment or disqualification proceedings by a Regulatory Authority.

2.11 **Section 365(n).** All rights and licenses granted under or pursuant to this Agreement by VistaGen or EverInsight are, and will otherwise be deemed to be, for the purposes of Section 365(n) of the U.S. Bankruptcy Code, and any similar law in the Territory, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or any similar law in the Territory. The Parties agree that each Party, as licensees of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any similar law in the Territory. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any similar law in the Territory, the Party that is not a party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in their possession, will be promptly delivered to them (a) upon any such commencement of a bankruptcy proceeding upon their written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject party.

2.12 **Technology Escrow**. Promptly after the Effective Date, VistaGen shall deposit all existing Licensed Know-How (for clarity, including all Licensed Manufacturing Know-How) with an escrow agent selected by EverInsight and reasonably acceptable to VistaGen and pursuant to an escrow agreement that requires the escrow agent to release the Licensed Know-How to EverInsight upon the commencement of a bankruptcy proceeding by or against VistaGen under the U.S. Bankruptcy Code or any similar law in the Territory. Throughout the term of this Agreement, VistaGen shall periodically (no less than annually) update such technology escrow to include any new Licensed Know-How that is developed or generated or otherwise comes into VistaGen's Control after the Effective Date. The Parties shall share equally the cost of establishing and maintaining such technology escrow.

ARTICLE 3 GOVERNANCE

3.1 **Joint Steering Committee**. As soon as practicable after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**"), composed of equal number of representatives of VistaGen and representatives of EverInsight, to coordinate the Development and Commercialization of the Compound and Licensed Product in the Licensed Field in the Territory. Each JSC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. The JSC shall:

(a) serve as a forum for discussing Development of the Compound and Licensed Product in the Licensed Field in the Territory, including by reviewing the Development Plan and coordinating the conduct of the Development activities;

(b) serve as a forum for discussing the Manufacture and supply of Compound and Licensed Product in the Licensed Field in the Territory, including by reviewing the Development strategy and Commercialization strategy for the Territory and coordinating the conduct of the Manufacturing and supply activities;

(c) serve as a forum for discussing Development of the Compound and Licensed Product in the Licensed Field in the Territory, including by (i) providing EverInsight with a forum at each meeting to disclose EverInsight's, or its Affiliates' or Sublicensees' activities with respect to achieving Regulatory Approvals of Licensed Product in the Territory; material clinical study results; and the Marketing Authorization Applications that EverInsight or any of its Affiliates reasonably expect to make, seek or attempt to obtain in the Territory; (ii) reviewing the current Development Plan and, with the JSC's approval, making any amendments or updates to the Development Plan; and (iii) coordinating the conduct of the Development activities;

(d) serve as a forum to keep EverInsight updated on the Development of the Compound and Licensed Product in the Licensed Field outside the Territory, including material clinical study results and any Marketing Authorization Application for the Licensed Product filed outside the Territory;

(e) coordinate the activities of VistaGen and EverInsight under this Agreement;

(f) establish a Joint Manufacturing Committee to enable regular information exchange on CMC issues, discuss possible costs reductions and review potential CMOs and prepare joint manufacturing plans, transfers and selections of joint manufacturing partners, and a Joint Commercialization Committee for discussing and coordinating the launch activities for the Licensed Product (for clarity, neither such subcommittee nor the JSC shall have any decision making authority over commercialization of the Licensed Product anywhere in the Territory); and

(h) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. For clarity, the JSC shall not have any right, power or authority: (i) to determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (ii) to modify or amend the terms and conditions of this Agreement.

3.2 **JSC Membership and Meetings**.

(a) **JSC Members**. Each Party will designate equal number (at least two) of representatives to the JSC within thirty (30) days after the Effective Date. Each Party may replace its JSC representatives on written notice to the other Party, but each Party shall strive to maintain continuity. The Alliance Managers shall jointly prepare and circulate the meeting agenda at least five (5) Business Days in advance of each meeting, and shall also promptly, but in no event later than thirty (30) days after such meeting, prepare and circulate for review and approval of the Parties the minutes of such meeting.

(b) **JSC Meetings**. The JSC will hold its first meeting within thirty (30) days of establishment of the JSC pursuant to Section 3.1 (Joint Steering Committee). At this first meeting, the JSC will address the initial transfer of Licensed Know-How provided for in Section 2.5 (Transfer of Know-How) and any other topics the Parties deem appropriate. Thereafter, the JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once per Calendar Quarter. Meetings may be held in person, or by audio or video teleconference; provided, that unless otherwise agreed by VistaGen and EverInsight, at least one (1) meeting per year shall be held in person, and all in-person JSC meetings shall be held at locations mutually agreed upon by VistaGen and EverInsight. Each Party shall be responsible for all of its own expenses of participating in JSC meetings.

(c) **Non-Member Attendance**. Each of VistaGen and EverInsight may from time to time invite a reasonable number of participants, in addition to its representatives, to attend JSC meetings in a non-voting capacity; provided, that if either VistaGen or EverInsight intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least five (5) Business Days' prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement. The Party inviting any such Third Party shall be responsible for all of such Third Party's costs and expenses of participating in JSC meetings, unless such invitation is mutually made by VistaGen and EverInsight, in which case they shall equally share such costs and expenses.

3.3 **JSC Decision-Making**. All decisions of the JSC shall be made by unanimous vote, with VistaGen's representatives and EverInsight's representatives each collectively having one (1) vote. If after reasonable discussion and good faith consideration of each of their views on a particular matter before the JSC, the representatives of VistaGen and EverInsight cannot reach an agreement as to such matter within thirty (30) calendar days after such matter was brought to the JSC for resolution, such disagreement shall:

(a) be referred to the Chief Executive Officer of VistaGen (or his or her designee) and the Chief Executive Officer of EverInsight (or his or her designee) (collectively, the "**Executive Officers**") for resolution, who shall use good faith efforts to resolve such matter within forty-five (45) calendar days after it is referred to them and, if such matter is resolved by the Executive Officers, such resolution shall be implemented by and binding on the Parties.

(b) If the Executive Officers are unable to reach consensus on any such matter during such forty-five (45) calendar day period, then

(i) the Chief Executive Officer of EverInsight shall have the right to make the final decision if such matter (A) involves the Development of, Regulatory Approval for, Commercialization or other Exploitation of the Compound or a Licensed Product in the Territory and (B) is not reasonably expected to have a material adverse effect on the Development of, Regulatory Approval for, Commercialization or Exploitation of the Compound or a Licensed Product outside the Territory;

(ii) the Chief Executive Officer of VistaGen shall have the right to make the final decision if such matter (A) involves the Development of, Regulatory Approval for, Commercialization or other Exploitation of the Compound or a Licensed Product outside the Territory, and (B) is not reasonably expected to have a material adverse effect on the Development of, Regulatory Approval for, or Commercialization or Exploitation of the Compound or a Licensed Product in the Territory; or

(iii) in all other cases, such matter will be resolved in accordance with Section 14.10 (Dispute Resolution).

(c) If the Parties dispute whether a matter subject to the decision making mechanism set forth above is reasonably expected to have a material adverse effect on the Development of, Regulatory Approval for, or Commercialization or Exploitation of the Compound or a Licensed Product in a Party's Respective Territory, such dispute shall be resolved by an independent, impartial and conflicts-free Third Party expert, who shall be experienced in the global aspects of the development, manufacture and commercialization of pharmaceutical products similar to the Licensed Product (the "**Expert**"). For clarity, such dispute shall not be subject to the dispute resolution mechanism set forth in Section 14.10. Within fifteen (15) days after a Party alleges material adverse impact in its Respective Territory as set forth above and the other Party disagrees with such allegation, the Parties shall mutually agree upon the Expert and, as promptly as possible thereafter, the Parties shall jointly retain the Expert. If the Parties are unable to agree on a mutually acceptable Expert within such fifteen (15) day period, each Party will select one (1) Expert and those two (2) Party selected Experts will select a third Expert within ten (10) days thereafter, and such third Expert shall be the sole Expert to resolve such dispute in accordance with this Section 3.3(c). Each Party shall bear its own costs associated such Expert decision and share the costs of the Expert equally. The determination of the Expert shall be binding on the Parties and the Parties shall act in accordance with the Expert's decision.

3.4 **Alliance Manager**. Each Party will assign an Alliance Manager, who will be a non-voting member of the JSC and the primary contact for all non-technical matters of governance, who will organize JSC meetings as reasonably necessary and lead the drafting of minutes. Either Alliance Manager may also call for ad-hoc meetings if one of the Parties deems that necessary.

ARTICLE 4 DEVELOPMENT

4.1 **General**. Subject to the terms and conditions of this Agreement (including without limitation the Retained Rights), EverInsight shall be solely responsible for the Development of the Compound and Licensed Product in the Licensed Field in the Territory, including the performance of preclinical and clinical studies of any Compound or any Licensed Product in the Licensed Field in the Territory. Notwithstanding the foregoing, VistaGen shall be solely responsible for conducting a six (6) month rat toxicology study in China, which study will be conducted by **[*****]** at VistaGen's own cost and expense.

4.2 **Development Plan**. EverInsight's initial plan for the Development of the Compound and Licensed Product (the "**Development Plan**") is attached hereto as Exhibit D. The Development Plan will include, among other things, critical activities to be undertaken, certain timelines, go/no go decision points and relevant decision criteria and certain allocations of responsibilities between the Parties to facilitate the registration, launch, and Commercialization of the Compound and Licensed Product in the Territory. The Development Plan will be focused on efficiently obtaining Regulatory Approval for a Licensed Product in the Licensed Field in the Territory, with an emphasis on Mainland China and South Korea. EverInsight shall conduct all Development of the Compound and Licensed Product in the Licensed Field in the Territory in accordance with the Development Plan. The Development Plan also shall take into consideration Development, Regulatory Approval, or commercial impacts on the Licensed Product outside the Licensed Field and Territory. From time to time, but at least once per Calendar Year, EverInsight will, with the assistance of the JSC, update the Development Plan and submit such updated plan to the JSC for review, discussion, and approval. Any disagreement or dispute in the JSC regarding the Development Plan shall be resolved in the manner set forth in Section 3.3 (JSC Decision-Making). If any updated or new terms of the Development Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

4.3 **Diligence**.

(a) **Commercially Reasonable Efforts by EverInsight**. EverInsight, directly and/or with or through its Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for the Compound and the Licensed Product in the Licensed Field in Mainland China and South Korea in accordance with the Development Plan.

(b) **Commercially Reasonable Efforts by VistaGen**. VistaGen, directly and/or with or through its Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for the Compound and the Licensed Product in the Licensed Field in the U.S.

4.4 **Development Costs**.

(a) As between the Parties, EverInsight shall be solely responsible for the cost for the Development of the Compound and the Licensed Product in the Licensed Field in the Territory and VistaGen shall be solely responsible for the cost for the Development of the Compound and the Licensed Product in the Licensed Field outside the Territory, except as otherwise provided in Section 4.1 and 4.4(b). For clarity, VistaGen shall be responsible for the cost of the toxicology study to be conducted in China as described in Section 4.1.

(b) EverInsight shall have the option, but not the obligation, to participate in global Phase 3 Clinical Trial and long-term safety study in social anxiety disorder conducted by VistaGen (or its Affiliates or (sub)licensees) to support Regulatory Approval in the Territory. VistaGen shall keep EverInsight informed on its global development plan for the Compound and Licensed Product. Before initiating any global Phase 3 Clinical Trial and long-term safety study for the Licensed Product, VistaGen shall notify EverInsight and provide EverInsight with relevant study plan and protocol for review and consideration. If EverInsight elects to participate in such global Phase 3 Clinical Trial or long-term safety study, then the Parties shall ensure that sufficient number of subjects in the Territory are enrolled in such clinical trial in order to support Regulatory Approval in the Territory, and EverInsight shall (i) be responsible for the conduct of, and all direct costs and expenses of conducting, such clinical trial in the Territory (provided however that if VistaGen requests in writing that EverInsight enrolls in the Territory more subjects than the minimum number required for Regulatory Approval in the Territory, then the Parties shall discuss such request in good faith, and if EverInsight agrees to enroll such excess subjects, VistaGen shall reimburse EverInsight for the clinical trial cost for such excess subjects); and (ii) pay or reimburse VistaGen for a *pro rata* portion (based on the number of subject enrolled in the Territory vs worldwide in such clinical trial) of all of the Indirect Costs of such global clinical trial outside of the Territory, not to exceed **[*****]** of the total Indirect Costs of such global clinical trial. VistaGen shall provide EverInsight with reasonable supporting documents (including Third Party invoices) for the Indirect Costs of such global clinical trial. For clarity and notwithstanding the foregoing, the cost sharing in this subsection (b) shall not apply to the first U.S. Phase 3 Clinical Trial, the cost of which shall be solely born by VistaGen.

4.5 **Development Records and Reports**.

(a) EverInsight shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner, complete and accurate records and reports pertaining to Development of Licensed Product hereunder, in sufficient detail for VistaGen to verify EverInsight's compliance with its obligations under this Agreement. Such records and reports shall (i) be summarized in English in sufficient detail for VistaGen to verify EverInsight's compliance with its obligations under this Agreement and for VistaGen to properly use such records and reports for patent and regulatory purposes, (ii) be appropriate for patent and regulatory purposes; (iii) be in compliance with Applicable Laws; (iv) properly reflect all work done and results achieved in the performance of its Development activities hereunder; (v) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement; and (vi) be retained by EverInsight for at least five (5) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Laws.

(b) Starting on **[*****]**, EverInsight shall provide VistaGen with an annual written report summarizing in sufficient detail for VistaGen to verify EverInsight's compliance with its obligations under this Agreement (i) the Development activities conducted in the preceding Calendar Year by it and its Affiliates and Sublicensees, and (ii) the Development activities planned to be conducted in such Calendar Year by it and its Affiliates and Sublicensees. If at any time VistaGen's representatives on the JSC are not fully able to perform their rights and duties on the JSC in the absence of a review of any of such books and records, EverInsight shall, upon reasonable written request from such JSC representative, provide a copy of such records to the JSC.

ARTICLE 5 REGULATORY

5.1 **Regulatory Responsibilities**. EverInsight shall be responsible, at its cost and subject to the Retained Rights and except as set forth in this ARTICLE 5, for all regulatory activities necessary to prepare, obtain and maintain Marketing Authorization Applications, Regulatory Filings and other Regulatory Approvals for the Compound and Licensed Product in the Licensed Field in the Territory. EverInsight shall keep VistaGen informed of regulatory developments related to the Compound or Licensed Product in the Licensed Field in the Territory via the JSC.

5.2 **Regulatory Reports**. Starting on **[*****]**, EverInsight shall provide VistaGen with an annual written report summarizing the clinical data and safety results generated from the regulatory activities performed in the preceding Calendar Year by it and its Affiliates and Sublicensees, in sufficient detail for VistaGen to verify EverInsight's compliance with its obligations under this Agreement and for VistaGen to properly use data and results for patent and regulatory purposes.

5.3 **Regulatory Cooperation**.

(a) **EverInsight**. EverInsight shall notify VistaGen of all material Regulatory Documentation submitted or received by EverInsight or its Affiliates or Sublicensees that are related to any Licensed Product in the Territory reasonably prior to such submission or reasonably after receipt. Moreover, with respect to Regulatory Filings in the Territory, EverInsight will provide VistaGen with the draft of such Regulatory Filings and an English summary thereof reasonably prior to submission so that VistaGen may have reasonable opportunity to review and comment on them. EverInsight shall consider all comments of VistaGen in good faith, taking into account the best interests of the Development, Regulatory Approval and/or Commercialization of the Licensed Product, but has no obligation to accept any comments of VistaGen, except to the extent that ignoring such comment could reasonably be expected to have a material adverse effect on the Development of, Regulatory Approval for, or Commercialization or Exploitation of the Compound or a Licensed Product outside the Territory. Material submissions made by EverInsight to, or correspondence with, Regulatory Authorities will be provided to VistaGen reasonably in advance to enable translation by VistaGen, if any such submissions or correspondence are not available in English. VistaGen shall not provide any Regulatory Documentation of EverInsight, its Affiliates, or Sublicensees to any of VistaGen's sublicensees who does not agree pursuant to Section 5.3(b) (VistaGen) to permit its Regulatory Documentation to be shared with EverInsight, its Affiliates, and its Sublicensees.

(b) **VistaGen**. VistaGen shall provide or make available to EverInsight copies of all material Regulatory Documentation submitted or received by VistaGen or its Affiliates that are related to any Licensed Product outside the Territory reasonably after such submission or receipt. VistaGen shall use Commercially Reasonable Efforts to negotiate an agreement with each sublicensee to make available to EverInsight copies of all material Regulatory Documentation that are related to any Licensed Product outside the Territory that are Controlled by its such sublicensee. Upon reasonable request, VistaGen will support EverInsight's regulatory filing efforts, as necessary, and in alignment with VistaGen's formal role as the global study sponsor. This may include participation in certain meetings with regulatory authorities, if requested by EverInsight, and signing or co-signing the clinical study site contracts, if global sponsor's signature is required by the study site in the Territory. Due to requirement by many leading clinical trial hospitals in China that the global sponsor listed on the protocol is a party to the site contracts, VistaGen agrees to accept this responsibility. EverInsight shall indemnify VistaGen for such contractual liabilities in the Territory.

(c) **Confidentiality**. Any information of a Party to which the other Party obtains access pursuant to this Section 5.3 (Regulatory Cooperation) shall, subject to ARTICLE 10 (Confidentiality; Publication), be deemed the Confidential Information of such first Party.

5.4 **Rights of Reference**.

(a) Without any additional consideration to VistaGen, VistaGen hereby grants to EverInsight and its Affiliates and Sublicensees a Right of Reference and Use, as that term is defined in 21 C.F.R. § 314.3(b) and any foreign counterpart to such regulation, to all VistaGen Regulatory Documentation and the VistaGen Development Data to the extent necessary or reasonably useful for EverInsight to Exploit the Compound or Licensed Product in the Licensed Field in the Territory.

(b) Without any additional consideration to EverInsight, EverInsight hereby grants to VistaGen and its Affiliates, and any current or future direct or indirect (sub)licensee of VistaGen with respect to the Compound or a Licensed Product, a Right of Reference and Use, as that term is defined in 21 C.F.R. § 314.3(b) and any foreign counterpart to such regulation, to the EverInsight Development Data to the extent necessary or reasonably useful for VistaGen to Exploit the Compound, Licensed Product(s) in the Licensed Field outside of the Territory.

(c) Promptly after a Party, its Affiliate or its or their licensees or Sublicensees generate(s) any VistaGen Development Data or EverInsight Development Data (as applicable), such Party shall provide the other Party with copies of such data, and the other Party may use such data pursuant to the license granted to it under Section 2.1 or 2.2 (as applicable).

(d) Each Party will provide a signed statement to this effect, if requested by the other Party, that is consistent with the requirements of 21 C.F.R. § 314.50(g)(3) or any foreign counterpart to such regulation, in the case of a request by either Party, for the limited purpose described in this Section 5.4 (Rights of Reference).

(e) Other than as expressly set forth in this Section 5.4 (Rights of Reference), nothing in this Section 5.4 shall require either Party to take, or forbear to take, any action.

(f) Any information of a Party to which the other Party obtains access pursuant to this Section 5.4 (Rights of Reference) shall, subject to Sections 10.1 (Duty of Confidence) and 10.2 (Exceptions), be deemed the Confidential Information of such first Party. For avoidance of doubt, a Party's submission of information of the other Party to which such Party obtains access pursuant to this Section 5.4 (Rights of Reference) to a Regulatory Authority shall be governed by and subject to the terms of ARTICLE 10 (Confidentiality; Publication).

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

5.5 **Recalls, Suspensions or Withdrawals**. Each Party shall notify the other Party promptly following its determination that any event, incident or circumstance has occurred that would reasonably be expected to result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the Licensed Field and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, EverInsight shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Licensed Field in the Territory; provided that prior to any implementation of such a recall, market suspension or market withdrawal, EverInsight shall consult with VistaGen and shall consider VistaGen's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the Territory, as between the Parties, EverInsight shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Laws. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 5.5 (Recalls, Suspensions or Withdrawals), as between the Parties, EverInsight shall be solely responsible for the execution thereof. Subject to ARTICLE 13 (Indemnification; Liability), EverInsight shall be responsible for all costs and expenses of any such recall, market suspension or market withdrawal. Notwithstanding the foregoing, any recall, market suspension or market withdrawal that relates to the Manufacture and supply of a Compound or Licensed Product by VistaGen to EverInsight shall be governed by the terms and conditions of the Initial Supply Agreement.

5.6 **Pharmacovigilance Agreement; Global Safety Database**. The Parties shall enter into a pharmacovigilance agreement at least **[*****]** days prior to the Initiation of any Clinical Trial of Licensed Product(s) by EverInsight in the Territory providing for the terms pursuant to which (i) VistaGen shall establish, hold and maintain (at VistaGen's sole cost and expense) the global safety database for Licensed Product and (ii) the Parties will establish a mutually agreed procedure for safety data sharing, adverse event reporting and prescription events monitoring related to the Licensed Product(s), which procedure shall be in accordance with, and enable the Parties to fulfill, their respective regulatory reporting obligations under, all applicable laws. Each Party shall be responsible for reporting safety data, adverse events, quality complaints related to the Products to the global safety database and to the applicable Regulatory Authorities in its Respective Territory, as well as responding to safety issues and to all requests of Regulatory Authorities related to the Licensed Product in its Respective Territory, in each case at its own cost. VistaGen shall provide EverInsight with access to the global safety database to allow EverInsight to comply with its regulatory reporting obligations under applicable laws in the Territory.

5.7 **Regulatory Inspections**. If any Regulatory Authority (i) contacts a Party, its Affiliates or their respective licensees or Sublicensees with respect to the alleged improper Development, Manufacture or Commercialization of any Licensed Product; (ii) conducts, or gives notice of its intent to conduct, an inspection at such Party's, its Affiliate's or licensee's or Sublicensee's facilities used in the Development or Manufacturing of Licensed Product or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of such Party, its Affiliates or licensees or Sublicensees that could reasonably be expected to materially adversely affect any Development, Manufacture or Commercialization activities with respect to the Licensed Product, whether in or outside the Territory, then such will promptly notify the other Party of such contact, inspection or notice and shall provide the other Party with copies of all materials, correspondence, statements, forms and records filed with or received from the Regulatory Authority in connection therewith.

ARTICLE 6 SUPPLY

6.1 **Supply**. Subject to the first sentence of Section 6.2(a), before the completion of the manufacturing technology transfer under Section 6.2(b), EverInsight shall exclusively obtain its supply of Licensed Product from VistaGen, and VistaGen shall supply to EverInsight all the Licensed Product requested by EverInsight for Development in the Territory **[*****]**. Nothing will prevent VistaGen from manufacturing or having manufactured all or any portion of the Licensed Product in the Territory.

6.2 **Potential Alternative Suppliers**.

(a) The Parties will collaborate and jointly explore opportunities for identification and qualification of alternative suppliers of the Licensed Product with the mutual intent of reducing substantially the Cost of Goods for the supply of the Licensed Product, for EverInsight, its Affiliates, licensees and sublicensees after Regulatory Approval in the Territory and for VistaGen and its Affiliates, licensees and sublicensees outside the Territory after Regulatory Approval. Upon mutual identification and qualification of such alternative supplier(s) capable of reducing substantially the Cost of Goods for the supply of the Licensed Product, VistaGen shall, pursuant to Section 6.4, conduct a technology transfer of all relevant manufacturing process it possesses to such alternative supplier(s) to allow the Parties to obtain supply of Licensed Product from such alternative supplier(s) at reduced Cost of Goods.

(b) If the Parties are unable to agree on the alternative supplier(s) under Section 6.2(a) before the **[*****]**, then, at EverInsight's option and at no additional cost, VistaGen will, pursuant to Section 6.4, conduct a technology transfer of all relevant manufacturing processes it possesses to EverInsight or a Third Party manufacturer(s) that has been chosen by EverInsight for commercial supply in the Territory. VistaGen shall make a good faith effort to complete such technology transfer within **[*****]** days of EverInsight's selection of the manufacturer(s) ("**Manufacturing Transfer Period**"). The Parties agree on a timely and proactive sharing of manufacturing data to facilitate such manufacture technology transfer. This data sharing might be done through the JSC or through a Joint Manufacturing Committee that may be established by the Parties.

6.3 **Supply Agreement**.

(a) **Initial Supply Agreement**. VistaGen and EverInsight agree to negotiate in good faith within **[*****]** days after the Effective Date a separate agreement concerning the short-term supply of the Compound and Licensed Product for EverInsight's Development use (including preclinical and/or clinical use) (the "**Initial Supply Agreement**"), **[*****].** Under this Initial Supply Agreement, EverInsight shall provide written notice to VistaGen with rolling forecasts (at least quarterly) promptly following its decision on initiating preclinical experiments or clinical trials. Notwithstanding the foregoing, nothing in this Agreement nor the Initial Supply Agreement shall restrict, impair or otherwise limit VistaGen's ability to manufacture the Compound or Licensed Product in the Territory for use outside the Territory. The Initial Supply Agreement shall include language on VistaGen's Commercially Reasonable Efforts to reduce the manufacturing costs and an audit right for EverInsight to review such manufacturing costs

(b) **Commercial Supply Agreement**. Upon EverInsight's request, VistaGen shall introduce EverInsight to VistaGen's contract manufacturer(s) and reasonably cooperate with EverInsight in its negotiation of a commercial supply agreement for the Licensed Product directly with such contract manufacturer(s).

(c) **Quality Agreement**. In connection with negotiation of the Initial Supply Agreement, VistaGen and EverInsight agree to negotiate in good faith a separate agreement concerning the quality of the Compound and Licensed Product supplied by VistaGen to EverInsight (the "Quality Agreement"). The Quality Agreement might either be an attachment of the Initial Supply Agreement or a stand-alone-agreement. Such Quality Agreement will include language about the acceptance criteria and ways to handle failures of the quality criteria among other terms.

6.4 **Manufacturing Technology Transfer**. In order to enable the Parties to have Manufactured the Compound and Licensed Product by the mutually-designated Third-Party manufacturer(s) consistent with the terms of Section 6.2(a) (Potential Alternative Suppliers), or if such mutually agreed Third-Party manufacturer cannot be found by the **[*****]**, to enable EverInsight to Manufacture or have Manufactured the Compound and Licensed Product for the Territory pursuant to Section 6.2(b), VistaGen shall (a) perform or facilitate technology transfer to such mutually-designated Third Party manufacturer, EverInsight or the Third Party manufacturer selected by EverInsight (the "**Designated Manufacturer(s)**") as is necessary or reasonably useful in the Manufacture of the Compound and Licensed Product and as of such date are being used by VistaGen or VistaGen CMO (as defined below) to Manufacture the Compound and Licensed Product (the "**Licensed Manufacturing Know-How**") solely for the Designated Manufacturer(s) to Manufacture the Compound and Licensed Products in accordance with the terms and conditions of this Agreement; (b) identify in writing all Subcontractors who Manufacture Compounds or Licensed Product for VistaGen (each, an "**VistaGen CMO**"); and (c) provide technical assistance (both on site and otherwise) in the transfer and demonstration of the Licensed Manufacturing Know-How that is necessary to Manufacture the Compound and Licensed Product. To the extent that any Licensed Manufacturing Know-How is in the Control of VistaGen but is in the possession of a VistaGen CMO (and is not in VistaGen's possession), then during the Manufacturing Transfer Period, VistaGen will use Commercially Reasonable Efforts to facilitate the transfer of such Licensed Manufacturing Know-How from such VistaGen CMO to the Designated Manufacturer(s), and/or cause such VistaGen CMO to make such Licensed Manufacturing Know-How available to the Designated Manufacturer(s). VistaGen shall be solely responsible for the cost and expense of such technology transfer and no payment shall be due from EverInsight to VistaGen or any Third Party (including VistaGen CMO) for such technology transfer.

ARTICLE 7 COMMERCIALIZATION

7.1 **General**. Subject to the terms and conditions of this Agreement and the Commercialization Plan, EverInsight shall be responsible for all aspects of the Commercialization of the Licensed Product in the Licensed Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Government Authorities regarding the price and reimbursement status of the Licensed Product and obtaining and maintaining Pricing Approvals; (c) marketing, medical affairs, and promotion; (d) booking sales and distribution and performance of related services; (e) subject to the provisions of Section 5.5 (Recalls, Suspensions or Withdrawals) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of Licensed Product in the Licensed Field in the Territory. As between the Parties, EverInsight shall be solely responsible for the costs and expenses of Commercialization of the Licensed Product in the Licensed Field in the Territory.

7.2 **Commercialization Plan**. EverInsight shall conduct all Commercialization of Compound and Licensed Product in the Licensed Field in the Territory in accordance with a commercialization plan (as amended from time to time in accordance with this Agreement, the "**Commercialization Plan**"), the initial version of which EverInsight will prepare and provide to the JSC no later than **[*****]** prior to the anticipated First Commercial Sale of Licensed Product in the Licensed Field in the Territory and which initial Commercialization Plan shall be subject to the review (but not approval) of the Parties through the JSC. From time to time, but at least once every Calendar Year, EverInsight will update the Commercialization Plan and submit such updated plan to the JSC for review and discussion. If any updated Commercialization Plan omits details that a VistaGen representative reasonably believes is necessary for (i) the proper functioning of the JSC or (ii) to verify EverInsight's compliance with its obligations under this Agreement, then EverInsight shall take into reasonable consideration such comments and, if necessary, further update such Commercialize Plan. If the terms of the Commercialization Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

7.3 **Commercial Diligence**. Upon Regulatory Approval of a Licensed Product in mainland China or South Korea, EverInsight, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Commercialize such Licensed Product in the Licensed Field in such jurisdiction.

ARTICLE 8 FINANCIAL PROVISIONS

8.1 **Upfront Payment**.

(a) As partial consideration of the rights granted by VistaGen to EverInsight hereunder, within thirty (30) Business Days after the Effective Date, EverInsight shall pay to VistaGen a one-time, non-refundable and non-creditable upfront payment of five million Dollars ($5,000,000).

8.2 **Regulatory Milestone Payments**.

(a) As additional consideration of the rights granted by VistaGen to EverInsight hereunder, within **[*****]** calendar days after the first achievement of the regulatory milestone events below ("**Regulatory Milestone Events**") by or on behalf of EverInsight or any of its Affiliates or Sublicensees, EverInsight or its Affiliate or Sublicensee shall notify VistaGen of the achievement of such Regulatory Milestone Event. The Regulatory Milestone Event triggers the corresponding milestone payment due to VistaGen ("**Milestone Payment**") and VistaGen shall invoice EverInsight for the applicable non-refundable, non-creditable Milestone Payment corresponding to the Regulatory Milestone Event as shown below, and EverInsight shall remit payment within **[*****]** Business Days of the receipt of such invoice, as described in Section 8.6 (Currency; Exchange Rate; Payments). For clarity, each Regulatory Milestone Payment set forth above shall be due and payable only once upon the first achievement of the corresponding Regulatory Milestone Event, regardless of how many times such Regulatory Milestone Event is achieved in the Territory.

- Regulatory Milestone Event for Licensed Product Regulatory Milestone Payment (in U.S. Dollars):

  (1) **[*****].**

  (2) **[*****].**

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

8.3 **Commercial Milestones**.

(a) Within **[*****]** calendar days after the end of the first Calendar Year in which aggregate annual Net Sales for that Calendar Year for the Licensed Product in the Territory reach any threshold indicated in the Commercial Milestone Events listed below, EverInsight shall notify VistaGen of the achievement of such Commercial Milestone Event and VistaGen shall invoice EverInsight for the corresponding non-refundable, non-creditable Milestone Payment set forth below and EverInsight shall remit payment to VistaGen within **[*****]** Business Days after the receipt of the invoice, as described in Section 8.6 (Currency; Exchange Rate; Payments).

Annual Net Sales Milestones for Licensed Product Milestone Payments (in Dollars) (each a "**Commercial Milestone Event**"):

(1). **[*****]**

(2). **[*****]**

(3). **[*****]**

(4). **[*****]**

(5). **[*****]**

(b) For the purposes of determining whether a Net Sales Milestone Event has been achieved, Net Sales of Licensed Product(s) in the Territory shall be aggregated. For clarity, the annual Net Sales Milestone Payments set forth in this Section 8.3 (Commercial Milestones) shall be payable only once, upon the first achievement of the applicable Commercial Milestone Event, regardless of how many times such Commercial Milestone Event is achieved.

(c) If a Commercial Milestone Event in Section 8.3 (Commercial Milestones) is achieved and payment with respect to any previous Commercial Milestone Event in Section 8.3 has not been made, then such previous Commercial Milestone Event shall be deemed achieved and EverInsight shall notify VistaGen within fifteen (15) calendar days of such achievement. VistaGen shall then invoice EverInsight for such unpaid previous Commercial Milestone Event(s) and EverInsight shall pay VistaGen such unpaid previous milestone payment(s) within thirty (30) Business Days of receipt of such invoice.

(d) In the event that, VistaGen believes any Commercial Milestone Event under Section 8.3(a) has occurred but EverInsight has not given VistaGen the notice of the achievement of such Commercial Milestone Event, it shall so notify EverInsight in writing and shall provide to EverInsight data, documentation or other information that supports its belief. Any dispute under this Section 8.3(d) (Commercial Milestones - subsection (d)) that relates to whether or not a Commercial Milestone Event has occurred shall be referred to the JSC to be resolved in accordance with ARTICLE 3 (Governance) and shall be subject to resolution in accordance with Section 14.10 (Dispute Resolution). The Milestone Payments made for each Commercial Milestone Event shall be non-creditable and non-refundable.

8.4 **Royalty Payments**.

(a) **Royalty Rate**. Subject to the terms and conditions of this Agreement (including Section 8.5), in partial consideration of the rights granted by VistaGen to EverInsight hereunder, EverInsight shall pay to VistaGen non-refundable, non-creditable royalties based on the aggregate Net Sales of all Licensed Product sold by EverInsight, its Affiliates and/or its or their respective Sublicensees in the Territory during a Calendar Year at the rates set forth in the table below. The obligation to pay royalties will be imposed only once with respect to the same unit of a Licensed Product.

Calendar Year Net Sales (in Dollars) for all Licensed Product in the Territory Royalty Rates as a Percentage (%) of Net Sales

(1). **[*****]**

(2). **[*****]**

(b) **Royalty Term**. Royalties under this Section 8.4 (Royalty Payments) shall be payable on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis from the First Commercial Sale of a Licensed Product in a jurisdiction until the latest to occur of: (i) expiration of the last-to-expire Valid Claim that effectively provides market exclusivity of such Licensed Product in such jurisdiction in the Territory; (ii) expiration of Regulatory Exclusivity for such Licensed Product in such Jurisdiction in the Territory; and (iii) ten (10) years after the First Commercial Sale of the Licensed Product in such jurisdiction in the Territory (the "**Royalty Term**" for the Licensed Product in the relevant jurisdiction). After expiration of the Royalty Term for a particular Licensed Product in a particular jurisdiction, the license granted by VistaGen to EverInsight hereunder shall continue and shall become fully paid-up, royalty free, perpetual and irrevocable with respect to such Licensed Product in such jurisdiction.

(c) **Royalty Reports and Payment**. Within ninety (90) calendar days after each Calendar Quarter of each Calendar Year, commencing with the Calendar Quarter during which the First Commercial Sale of any Licensed Product is made anywhere in the Territory, EverInsight shall provide VistaGen with a report that contains the following information for the applicable Calendar Quarter, on a jurisdiction-by-jurisdiction basis: (A) Net Sales in the Territory; (B) a calculation of the royalty payment due on Net Sales in the Territory; and (C) the exchange rates used. After the receipt of such royalty report, VistaGen shall invoice EverInsight for the royalty payment set forth in such royalty report. Within thirty (30) Business Days after the receipt of the invoice, EverInsight will pay VistaGen all royalties owed with respect to Net Sales for such Calendar Quarter. If, during the following Calendar Quarter, EverInsight discovers that it reported an incorrect amount of Net Sales in the Territory and/or the amounts payment due on such Net Sales in the immediately preceding Calendar Quarter, then EverInsight may, subject to review by VistaGen, adjust and reconcile any such calculation of Net Sales and/or any such underpayment or overpayment of royalty payments due, and shall timely report the same within thirty (30) calendar days after such following Calendar Quarter.

8.5 **Royalty Adjustments**. Except as otherwise set forth in this Agreement, royalties due hereunder are subject to adjustment as set forth below (such adjustments to be prorated for the Calendar Quarter in which the adjustment becomes applicable):

(a) **Royalty Adjustment for Patent Expiration.** In the event that in any jurisdiction in the Territory in any Calendar Quarter during the Royalty Term for a Licensed Product, there is no Valid Claim that provides effective market exclusivity for such Licensed Product (or the Compound contained in such Licensed Product) in such jurisdiction in such Calendar Quarter, then the royalty rate set forth in Section 8.4(a) (Royalty Rate) with respect to such Licensed Product in such jurisdiction in such Calendar Quarter shall be reduced by **[*****]**;

(b) **Royalty Adjustment for Generic Competition**. In the event that in any jurisdiction in the Territory in any Calendar Quarter during the Royalty Term for a Licensed Product, there is Generic Competition for such Licensed Product in such jurisdiction in such Calendar Quarter, then the royalty rate set forth in Section 8.4(a) (Royalty Rate) with respect to such Licensed Product in such jurisdiction in such Calendar Quarter shall be reduced by **[*****]** (provided however that the royalty reduction under Section 8.5(a) shall not apply to such Licensed Product in such jurisdiction in such Calendar Quarter if the royalty reduction under Section 8.5(b) applies).

8.6 **Currency; Exchange Rate; Payments**. All payments required to be made by EverInsight under this Agreement shall be made in Dollars. All payments payable to, or invoiced from or on behalf of, VistaGen shall be paid bank wire transfer in immediately available funds to one or more bank accounts of VistaGen as designated in written notice from VistaGen. If any currency conversion shall be required in connection with any payment hereunder, such conversion shall be made by using the exchange rates at the closing on the last Business Day of the Calendar Quarter to which such payment relates as reported in The Wall Street Journal on the following day.

8.7 **Late Payments**. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at an annual rate equal to two (2) percentage points above the prime rate as published by The Wall Street Journal or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue calculated on the number of days such payment is delinquent.

8.8 **Taxes**.

(a) **Taxes on Income**. Notwithstanding anything else set forth in this Section 8.8 (Taxes), each Party shall solely bear and pay all Taxes imposed on such Party's net income or gain (however denominated) arising directly or indirectly from the activities of the Parties under this Agreement.

(b) **Tax Payments**. The upfront payment, milestone payments, royalties, and any other payment payable by EverInsight to VistaGen pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all Taxes (which, for clarity, shall be the responsibility of EverInsight), except for any Taxes required by Applicable Laws to be withheld or deducted. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce Tax withholding or similar obligations in respect of the payments made under this Agreement. To the extent EverInsight is required to deduct and withhold Taxes on any payment to VistaGen, EverInsight shall deduct those Taxes from the remittable payment, pay the Taxes to the proper tax authority in a timely manner, and promptly send proof of payment to VistaGen. VistaGen shall provide EverInsight any tax forms that may be reasonably necessary in order for EverInsight to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. VistaGen shall use reasonable efforts to provide any such tax forms to EverInsight in advance of the due date.

8.9 **Financial Records and Audit**. EverInsight shall (and shall ensure that its Affiliates and Sublicensees will) maintain complete and accurate books and records pertaining to the Commercialization of Licensed Product hereunder, including books and records of invoiced sales and Net Sales of Licensed Product, in sufficient detail to calculate and verify all amounts payable hereunder and in sufficient detail to permit VistaGen to confirm the accuracy of any royalty payments, other amounts paid or payable under this Agreement and to verify the achievement of Milestone Events under this Agreement. EverInsight shall and shall cause its Affiliates and its and their Sublicensees to, retain such books and records until the later of (a) three (3) years after the end of the period to which such books and records pertain; (b) the expiration of the applicable tax statute of limitations (or any extensions thereof); and (c) for such period as may be required by Applicable Laws. Upon at least thirty (30) Business Days' prior notice, such records shall be open for examination, during regular business hours, for a period of three (3) Calendar Years from the end of the Calendar Year to which such records pertain, and not more often than once each Calendar Year, by an independent and internationally recognized certified public accountant selected by VistaGen and reasonably acceptable to EverInsight, for the sole purpose of verifying for VistaGen the accuracy of the financial reports furnished by EverInsight under this Agreement or of any payments made, or required to be made, by EverInsight to VistaGen pursuant to this Agreement. The independent public accountant shall disclose to VistaGen only (x) the accuracy of Net Sales reported and the basis for royalty, Milestone Payments and any other payments made to VistaGen under this Agreement and (y) the difference, if any, by which such reported and paid amounts vary from amounts determined as a result of the audit and the details concerning such difference. Except as required by Applicable Laws, no other information shall be provided to VistaGen. No record may be audited more than once. VistaGen shall bear the full cost of such audit unless such audit reveals an underpayment by EverInsight of more than one hundred thousand Dollars ($100,000) or five percent (5%) of the amount actually due (whichever is greater) for any Calendar Year being audited, in which case EverInsight shall reimburse VistaGen for the reasonable costs and expenses for such audit. Unless disputed pursuant to Section 8.10 (Audit Dispute), EverInsight shall pay to VistaGen any underpayment discovered by such audit within thirty (30) days after the accountant's report, plus interest (as set forth in Section 8.7 (Late Payments)) from the original due date. If the audit reveals an overpayment by EverInsight, then EverInsight may take a credit for such overpayment against any future payments due to VistaGen and, if there will be no future payment due, VistaGen shall promptly refund such overpayment to EverInsight.

8.10 **Audit Dispute**. If EverInsight disputes the results of any audit conducted pursuant to Section 8.9 (Financial Records and Audit), the Parties shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such procedure shall be borne between the Parties in such manner as the Auditor shall determine. If the Auditor determines that there has been an underpayment by EverInsight, EverInsight shall pay to VistaGen the underpayment within thirty (30) days after the Auditor's decision, plus interest (as set forth in Section 8.7 (Late Payments)) from the original due date. If the Auditor determines that there has been an overpayment by EverInsight, then EverInsight may take a credit for such overpayment against any future payments due to VistaGen and, if there will be no future payment due, VistaGen shall promptly refund such overpayment to EverInsight.

ARTICLE 9 INTELLECTUAL PROPERTY RIGHTS

9.1 **Ownership of Intellectual Property**

(a) **Ownership of Technology**. As between the Parties:

(1) VistaGen shall solely own on a worldwide basis all right, title and interest in and to any and all VistaGen Sole Inventions, whether or not patented or patentable, and any and all VistaGen Sole Invention Patents; and

(2) EverInsight shall solely own on a worldwide basis all right, title and interest in and to any and all EverInsight Sole Inventions, whether or not patented or patentable, and any and all EverInsight Sole Invention Patents.

For clarity, each Party shall own on a worldwide basis and retain all right, title and interest in and to any and all Know-How, Inventions, Patents and other intellectual property rights that are owned or otherwise Controlled (other than pursuant to the license grants set forth in Section 2.1 (Licenses to EverInsight) and 2.2 (License to VistaGen)) by such Party or its Affiliates or its or their (sub)licensees (or Sublicensees) (as applicable) outside of this Agreement.

(b) **Ownership of Joint Patents and Joint Inventions**. As between the Parties:

(1) Each of VistaGen and EverInsight shall own an equal, undivided interest in any and all Joint Inventions and Joint Invention Patents; and

(2) Each of VistaGen and EverInsight shall promptly disclose to the other in writing, and shall cause its Affiliates and its and their respective Sublicensees to so disclose, the development, making, conception or reduction to practice of any Joint Inventions. Subject to the licenses granted under Section 2.1 (License to EverInsight) and Section 2.2 (License to VistaGen), each of VistaGen and EverInsight shall have the right to Exploit the Joint Inventions and Joint Invention Patents without the duty of accounting or seeking consent from the other Party.

(c) **United States Law**. The determination of whether Inventions, Know-How and other intellectual property rights are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Laws in the United States as such law exists as of the Effective Date irrespective of where or when such conception, discovery, development or making occurs; provided that if the application of such United States Applicable Laws prevents or materially impairs the proper prosecution or maintenance of Patent Rights in any jurisdiction in the Territory, then the Parties shall mutually agree to the application of an appropriate Applicable Laws in order to best advance and maintain the prosecution and maintenance of such Patents in such jurisdiction in the Territory. Each of VistaGen and EverInsight shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees and Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions, Know-How, Patents and other intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole or joint ownership as provided for in Section 9.1(a) (Ownership of Technology) or 9.1(b) (Ownership of Joint Patents and Joint Inventions); subject to the license granted under this Agreement.

(d) **Assignment Obligation**. Each Party shall cause all Persons who perform Development activities, Manufacturing activities or regulatory activities for such Party under this Agreement or who conceive, discover, develop or otherwise make any Inventions, Know-How or other intellectual property rights by or on behalf of either Party or its Affiliates or its or their (sub)licensees (or Sublicensees) under or in connection with this Agreement to be under an obligation to assign to such Party their rights in any Inventions, Know-How, Patents and other intellectual property to the extent related to the Compound or Licensed Product, except where Applicable Laws requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment and except in the case of generally applicable (i.e., applicable generally to products other than the Licensed Product) Inventions, Know-How, Patents and other intellectual property (in each case, a suitable license or right to obtain such a license, shall be obtained).

(e) **Ownership of Product Trademarks**. Subject to Section 11.3 (Effect of Termination), as between the Parties, (i) EverInsight shall own all right, title and interest in and to the Product Trademarks in the Territory, (ii) EverInsight shall have the right to market the Licensed Product in the Licensed Field in the Territory under the Product Trademarks and all goodwill associated therewith will inure to the benefit of EverInsight and (iii) VistaGen may not use the Product Trademarks without obtaining a proper trademark license from EverInsight (except to the extent necessary to perform its obligations under this Agreement).

(f) **Ownership of Corporate Names**. As between the Parties, each Party shall retain all right, title and interest in and to its Corporate Names.

(g) **Ownership of Development Data**. Subject to ARTICLE 2 (Licenses) and Section 11.3 (Effect of Termination), EverInsight shall own EverInsight Development Data and VistaGen shall own VistaGen Development Data.

9.2 **Patent Prosecution and Maintenance**.

(a) VistaGen shall have the first right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all Licensed Patents and Joint Patents, both in and outside the Territory, by counsel of its own choice, except that such counsel in the Territory shall be reasonably acceptable to EverInsight (such acceptance not to be unreasonably withheld, delayed or conditioned). VistaGen shall consult with EverInsight and keep EverInsight informed of the status of such Patents in the Territory and also in the US and EU, and shall promptly provide EverInsight with all material correspondence received from any patent authority in the Territory and also in the US and EU in connection therewith. In addition, VistaGen shall promptly provide EverInsight with drafts of all proposed material filings and correspondence to any patent authority in the Territory and also in the US and EU with respect to such Patents for EverInsight's review and comment at least thirty (30) days prior to the submission of such proposed filings and correspondence. VistaGen shall confer with EverInsight and consider in good faith EverInsight's comments prior to submitting such filings and correspondence, provided that EverInsight provides such comments within fifteen (15) days (or a shorter period reasonably designated by VistaGen if fifteen (15) days is not practicable given the filing deadline) of receiving the draft filings and correspondence from VistaGen. VistaGen shall also keep EverInsight informed as to the payment schedule for patent maintenance fee for the Licensed Patents and Joint Patents. VistaGen shall be responsible for the costs and expenses incurred by VistaGen for the preparation, filing, prosecution and maintenance of the Licensed Patents and Joint Patents both in and outside the Territory. For the avoidance of doubt, VistaGen shall be responsible for all costs incurred prior to the Effective Date with respect to the prosecution and maintenance of any Licensed Patents. If EverInsight reasonably determines that a Licensed Patent added after the Effective Date (other than Patent Rights added by an In-License Agreement that EverInsight has accepted pursuant to Section 2.4(b)(1) (In-License Agreements)) or Joint Patent that EverInsight subsequently determines is of low value to EverInsight, then EverInsight has the right upon at least sixty (60) days' prior written notice to remove such Licensed Patent or Joint Patent from the Licensed Technology hereunder, in which case, following delivery of such notice to VistaGen, (1) the license of Licensed Technology to EverInsight under Section 2.1 (License to EverInsight) as to such Licensed Patent or Joint Patent shall be terminated; (2) the claims of such Licensed Patent or Joint Patent, as the case may be, shall be excluded from Valid Claim; and (3) if requested by VistaGen, EverInsight shall assign, and shall cause its Affiliates and its and their (sub)licensees and Sublicensees to so assign, to VistaGen, without additional compensation, EverInsight's right, title and interest in and to the relevant Joint Patent (provided that EverInsight shall retain a non-exclusive, fully paid, royalty free, sublicenseable (through multiple tiers), perpetual and irrevocable license and right under the Joint Patent assigned to VistaGen).

(b) In the event that VistaGen desires to abandon or cease prosecution or maintenance of any Licensed Patent in the Territory (or any jurisdiction therein) or any Joint Patent anywhere in the world, VistaGen shall provide reasonable prior written notice to EverInsight of such intention to abandon (which notice shall, to the extent possible, be given no later than thirty (30) days prior to the next deadline for any action that must be taken with respect to any such Patent in the relevant patent office). In such case, upon EverInsight's written election provided no later than twenty (20) days after such notice from VistaGen, EverInsight shall have the right to assume prosecution and maintenance of such Licensed Patent or Joint Patent at EverInsight's sole cost and expense. If EverInsight does not provide such election within twenty (20) days after such notice from VistaGen, VistaGen may, in its sole discretion, abandon or cease prosecution and maintenance of such Patent in the Territory (or the relevant jurisdiction).

(c) EverInsight shall have the sole right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all EverInsight Patents throughout the world, at EverInsight's own cost and expense.

9.3 **Cooperation of the Parties**. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Patents under Section 9.2 (Patent Prosecution and Maintenance), at its own cost. Such cooperation includes: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the applicable Party to apply for and to prosecute patent applications in any country as permitted by Section 9.2 (Patent Prosecution and Maintenance); and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

9.4 **Infringement by Third Parties**.

(a) **Notice**. In the event that either VistaGen or EverInsight becomes aware of any infringement or threatened infringement by a Third Party of any Licensed Patent or Joint Patent in and/or outside the Territory, which infringing activity involves the using, making, importing, offering for sale and/or selling of a Licensed Product or any product that falls within the scope of the Licensed Patents (regardless of whether or not EverInsight and/or VistaGen is currently Developing using, making, importing, offering for sale, selling, and/or otherwise Commercializing the same Licensed Product), or the submission to a Party or a Regulatory Authority in and/or outside the Territory of an application for a product referencing a Licensed Product, or any declaratory judgment or equivalent action challenging any Licensed Patent or Joint Patent in and/or inside the Territory in connection with any such infringement (each, a "**Product Infringement**"), it will promptly notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, by such Third Party.

(b) **Enforcement of Licensed Patents and Joint Patents**. To the extent permitted by the Pherin License, EverInsight shall have the first right, as between VistaGen and EverInsight, but not the obligation, to bring an appropriate suit or take other action against any Person or entity engaged in, or to defend against, such Product Infringement in the Territory of any Licensed Patent or Joint Patent, at its own expense and by counsel of its own choice. VistaGen shall have the right, at its own expense, to be represented in any such action in the Territory by counsel of its own choice, and EverInsight and its counsel will reasonably cooperate with VistaGen and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If EverInsight fails to bring an action or proceeding in the Territory with respect to such Product Infringement of any Licensed Patent or Joint Patent within (A) ninety (90) days following the notice of alleged infringement or declaratory judgment or (B) sixty (60) days before the time limit, if any, set forth in the Applicable Laws for the filing of such actions, whichever comes first, VistaGen shall have the right, but not the obligation, to bring and control any such action in the Territory at its own expense and by counsel of its own choice, and EverInsight shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Product Infringement of any Licensed Patent or Joint Patent, or settlement of the same, shall be used (A) first, to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding; and (B) any remainder after such reimbursement is made shall be retained by the enforcing Party, provided, that if EverInsight is the enforcing Party, then to the extent that any award or settlement (whether by judgment or otherwise) with respect to any Licensed Patent or Joint Patent is attributable to loss of sales or profits with respect to a Licensed Product in the Licensed Field in the Territory, such amounts (except punitive damages) that may be recovered or realized by EverInsight after reimbursement of enforcement cost shall be considered Net Sales and subject to the royalty obligations under Section 8.4 (Royalty Payments) and the commercial Milestone Payment obligations under Section 8.3 (Commercial Milestones) (provided that such amount shall be evenly spread (on Calendar Quarterly basis) over the time period during which the lost sales or profits occurred for the purpose of determine aggregate annual Net Sales, royalty tiers and achievement of commercial milestones). Notwithstanding anything to the contrary in this Article 9, in the event that patent enforcement or patent defense litigation regarding the Licensed Patents occurs in multiple countries, within or outside the Territory, then VistaGen shall have the first right but not the obligation to bring an appropriate suit or take other appropriate action.

(c) **Cooperation**. In the event a Party brings an action in accordance with this Section 9.4 (Infringement by Third Parties), the other Party shall cooperate fully at its own expense, including, if required to bring such action, and providing access to relevant documents and other evidence including, without limitation, making its employees available at reasonable business hours to the Party's counsel for all pre-trial and trial proceedings, as well as the furnishing of a power of attorney or being named as a party to such action as may reasonably be necessary.

(d) **Other Infringement**. VistaGen shall have the sole right, but not the obligation, to bring and control, at its own cost and expense, any legal action in connection with any Product Infringement of any Licensed Patent or Joint Patent outside the Territory and any legal action in connection with any infringement of any Licensed Patent that is not a Product Infringement; provided, however, that such legal action is not combined with a legal action involving a Product Infringement. The Parties shall jointly control any legal action in connection with any infringement of any Joint Patent anywhere in the world that is not a Product Infringement and is not combined with a Product Infringement legal action. Any recovery or damages realized as a result of such action or proceeding with respect to Product Infringement of any Licensed Patent or Joint Patent shall be used (A) first, but only if a Joint Patent was the subject of such legal action, to reimburse the Parties' documented out-of-pocket legal expenses relating to such action or proceeding; and (B) any remainder after such reimbursement, if applicable, shall be retained by the Party initiating such action or proceeding (or, in the case of Joint Patent, shared by the Parties equally).

(e) **Effect of Pherin License.** The Parties acknowledge that provisions of the Pherin License may affect the standing and ability of a Party to bring and control infringement litigation, notwithstanding the contemplated allocation of litigation-related enforcement rights as between the Parties in this Agreement.

9.5 **Infringement Claims by Third Parties**. If the Exploitation of a Licensed Product in the Licensed Field in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party against EverInsight or any of its Affiliates or Sublicensees alleging infringement by EverInsight or any of its Affiliates or its or their Sublicensees, distributors or customers (a "**Third Party Infringement Claim**"), including any defense or counterclaim in connection with a Product Infringement action initiated pursuant to Section 9.4(b) (Enforcement of Licensed Patents and Joint Patents), the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing. As between the Parties, subject to ARTICLE 13 (Indemnification; Liability): (a) VistaGen shall be responsible for defending any such claim, suit or proceeding at its sole cost and expense, using counsel of VistaGen's choice; (b) EverInsight may participate in any such claim, suit or proceeding with counsel of its choice at its sole cost and expense; provided that VistaGen shall retain the right to control such claim, suit or proceeding; (c)EverInsight shall, and shall cause its Affiliates to, assist and co-operate with VistaGen, as VistaGen may reasonably request from time to time, in connection with its activities set forth in this Section 9.5 (Infringement Claims by Third Parties), including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that VistaGen shall reimburse EverInsight for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith; (d) VistaGen shall keep EverInsight reasonably informed of all material developments in connection with any such claim, suit or proceeding; (e) VistaGen agrees to provide EverInsight with copies of all material pleadings filed in such action and to allow EverInsight reasonable opportunity to participate in the defense of the Claims; and (f) any damages, or awards, including royalties, incurred or awarded in connection with any Third Party Infringement Claim defended under this Section 9.5 (Infringement Claims by Third Parties) shall be borne by VistaGen, and VistaGen shall indemnify and hold EverInsight Indemnitee harmless from such Third Party Infringement Claim pursuant Section 13.1(d).

9.6 **Invalidity or Unenforceability Defenses or Actions**. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patents, Joint Patents or EverInsight Patents worldwide, by a Third Party and of which such Party becomes aware. As between the Parties: (a) VistaGen and EverInsight shall coordinate with each other to defend and control the defense of the validity and enforceability of any Joint Patents in the Territory and share the cost and expense thereof; (b) VistaGen shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of any Licensed Patents, at its sole cost and expense, using counsel of VistaGen's choice; (c) EverInsight shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of any EverInsight Patents, at its sole cost and expense, using counsel of EverInsight's choice; provided however that, notwithstanding the foregoing, Section 9.4 shall control with respect to any such claim that is a Product Infringement or is a counter claim in an enforcement action against a Project Infringement. For purposes of this Section 9.6 (Invalidity or Unenforceability Defenses or Actions), the Party defending and controlling the defense of the validity and enforceability pursuant to the foregoing sentence with respect to a Patent shall be the "Controlling Party". With respect to any such claim, suit or proceeding in the Territory under this Section 9.6 (Invalidity or Unenforceability Defenses or Actions), the non-Controlling Party may participate in such claim, suit or proceeding with counsel of its choice at its sole cost and expense; provided that the Controlling Party shall retain control of the defense in such claim, suit or proceeding. If the Controlling Party elects not to defend the applicable Patents in a suit, then the Controlling Party shall notify the non-Controlling Party of such election at least sixty (60) days before the time limit, if any, set forth in Applicable Laws for defending such actions, with the proviso that if the Controlling Party is VistaGen, then, to the extent permitted under the Pherin License, EverInsight shall have the right, but not the obligation, for any such Invalidity or Unenforceability Defenses or Actions, to assume control of the defense of any such claim, suit or proceeding at its sole cost and expense. The non-Controlling Party in such an action shall, and shall cause its Affiliates to, assist and co-operate with the Controlling Party, as such Controlling Party may reasonably request from time to time. in connection with its activities set forth in this Section 9.6 (Invalidity or Unenforceability Defenses or Actions), including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that the Controlling Party shall reimburse the non-Controlling Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. In connection with any activities with respect to a defense, claim or counterclaim relating to the Licensed Patents, EverInsight Patents or Joint Patents licensed under Section 2.1 (License to EverInsight) or Section 2.2 (License to VistaGen), the Controlling Party shall (i) consult with the non-Controlling Party as to the strategy for such activities, (ii) consider in good faith any comments from the non-Controlling Party and (iii) keep the non-Controlling Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense, claim or counterclaim.

9.7 **Consent for Settlement**. Neither Party shall unilaterally enter into any settlement or compromise of any action or proceeding under this ARTICLE 9 (Intellectual Property Rights) that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement or otherwise without the prior written consent of such other Party, which shall not be unreasonably withheld, conditioned or delayed.

9.8 **Common Ownership under Joint Research Agreement**. Notwithstanding anything to the contrary in this ARTICLE 9, no Party shall have the right to make an election under 35 U.S.C. 102(c) when exercising its rights under this ARTICLE 9 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall co-ordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. 100(h).

9.9 **Patent Extensions**. VistaGen and EverInsight shall jointly, following consultation with each other, have decision making authority regarding, and they shall cooperate with each other, in obtaining, patent term restoration, supplemental protection certificates or their equivalents, and patent term extensions with respect to the Licensed Patents, Joint Patents, and EverInsight Patents in the Territory where applicable. If mutually agreed, EverInsight shall file for such extensions at the Parties' shared cost and expense. If the Parties cannot agree, the matter will be referred to the JSC for decision pursuant to Section 3.3 (JSC Decision Making).

9.10 **Trademarks**. VistaGen and EverInsight shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks or Licensed Trademarks in the Territory and of any actual or threatened Claim that the use of the Product Trademarks or Licensed Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware. EverInsight shall have the right to select and register, and shall own and be responsible for, at its expense, all Product Trademarks, trade names, branding or logos related to the Compound or Licensed Product in the Licensed Field in the Territory. EverInsight shall have the sole right to take such action as EverInsight deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory at its sole cost and expense and using counsel of its own choice and EverInsight shall retain any damages or other amounts collected in connection therewith.

9.11 **Licensed Trademarks**. If EverInsight is lawfully required by any Regulatory Authority or otherwise desires to use any of the Licensed Trademarks or any other Trademark used by VistaGen (either in connection with or in lieu of Product Trademarks selected by EverInsight) to market, promote, distribute and/or sell any Licensed Product in the Licensed Field outside the Territory for the purpose of Commercialization of the relevant Licensed Product in a jurisdiction in the Territory, EverInsight shall promptly notify VistaGen, and VistaGen shall immediately grant EverInsight an exclusive, fully-paid, royalty-free and sublicensable license to use such Licensed Trademark or such other Trademark solely in connection with the Commercialization of the relevant Licensed Product in the Licensed Field in such jurisdiction in the Territory; provided that any such license shall automatically terminate upon the expiration or termination of this Agreement with respect to such Licensed Product in such jurisdiction.

ARTICLE 10 CONFIDENTIALITY; PUBLICATION

10.1 **Duty of Confidence**. Subject to the other provisions of this ARTICLE 10 (Confidentiality; Publication):

(a) all Confidential Information disclosed by a Party (the "**Disclosing Party**") or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party (the "**Receiving Party**") and its Affiliates using at least the same standard of care as the Receiving Party uses to protect its own proprietary or Confidential Information (but in no event less than reasonable care);

(b) the Receiving Party, its Affiliates and Representatives may only use any such Confidential Information for the purposes of performing its obligations or exercising its rights under this Agreement; and

(c) the Receiving Party may disclose Confidential Information of the Disclosing Party only to: (i) the Receiving Party's Affiliates; and (ii) employees, directors, agents, contractors, Subcontractors, consultants and advisers of the Receiving Party and its Affiliates and, in the case of EverInsight as the Receiving Party, its Sublicensees, in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement (collectively, the "**Representatives**"); provided, that such Representatives are bound to maintain the confidentiality, and not to make any unauthorized use, of the Confidential Information in a manner consistent with this ARTICLE 10 (Confidentiality; Publication).

10.2 **Exceptions**. The foregoing obligations as to particular Confidential Information of a Disclosing Party shall not apply to the extent that the Receiving Party can demonstrate by competent evidence that such Confidential Information:

(a) is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party, as demonstrated by documentation or other competent proof of the Receiving Party, but excluding Joint Inventions or the terms of this Agreement;

(b) is in the public domain by use and/or publication before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of, or breach of this Agreement by, the Receiving Party;

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

(c) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party who, to the Receiving Party's knowledge after reasonable inquiry, may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(d) is developed by the Receiving Party independently and without use of or reference to any Confidential Information disclosed to, or materials provided to, it by or on behalf of the Disclosing Party, as shown by contemporaneous written documents of the Receiving Party.

10.3 **Authorized Disclosures**. Notwithstanding the obligations set forth in Section 10.1 (Duty of Confidence), the Receiving Party may disclose Confidential Information of the Disclosing Party and the terms of this Agreement to the extent such disclosure is reasonably necessary for such Disclosing Party to perform its obligations or exercise its rights under this Agreement, in the following instances:

(a) filing or prosecuting of Patents as permitted by this Agreement;

(b) enforcing the Receiving Party's rights under this Agreement or performing the Receiving Party's obligations under this Agreement;

(c) in Regulatory Filings for Licensed Product that such Party has the right to file under this Agreement;

(d) prosecuting or defending litigation as permitted by this Agreement;

(e) to the Receiving Party's Representatives and actual or potential Sublicensees (in the case of EverInsight), in each case, who have a need to know such Confidential Information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement; provided, in each case, that any such Person agrees to be bound by terms of confidentiality and non-use (or, in the case of the Receiving Party's attorneys and independent accountants, such Person is obligated by applicable professional or ethical obligations) at least as restrictive as those set forth in this ARTICLE 10 (Confidentiality; Publication);

(f) to actual or potential investors, investment bankers, lenders, other financing sources or acquirers (and attorneys and independent accountants thereof) in connection with potential investment, acquisition, collaboration, merger, public offering, due diligence or similar investigations by such Third Parties or in confidential financing documents; provided, in each case, that any such Third Party agrees to be bound by terms of confidentiality and non-use (or, in the case of the Receiving Party's attorneys and independent accountants, such Third Party is obligated by applicable professional or ethical obligations) that are no less stringent than those contained in this Agreement (except to the extent that a shorter confidentiality period is customary in the industry); and

(g) such disclosure is required by court order, judicial or administrative process or Applicable Laws; provided that in such event the Receiving Party shall promptly inform the Disclosing Party of such required disclosure and provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed as required by court order, judicial or administrative process or Applicable Laws shall remain otherwise subject to the confidentiality and non-use provisions of this ARTICLE 10 (Confidentiality; Publication), and the Receiving Party shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

10.4 **Publication**. Prior to publishing or presenting the results of any studies carried out under this Agreement or otherwise related to the Compound or Licensed Product, the publishing or presenting Party shall submit the draft of the publication or presentation to the other Party no later than forty-five (45) calendar days prior to the planned submission for publication or presentation for the other Party's review and comment. The publishing or presenting Party shall: (a) consider in good faith any comments thereto provided by the other Party within such review period; and (b) remove any Confidential Information of the other Party if requested by the other Party. The other Party shall be deemed to have consented to such publication or presentation if it has not sent any response to the publishing or presenting Party's request within thirty (30) calendar days of receipt of the draft publication or presentation from the publishing or presenting Party. The other Party may reasonably request a reasonable delay in publication or presentation in order to protect patentable information. If the other Party reasonably requests a delay, then the publishing or presenting Party shall, and shall ensure that its Affiliate(s) or the Sublicensee(s) shall, delay submission or presentation for a period of sixty (60) calendar days (or such shorter period as may be mutually agreed by the Parties) to enable the other Party to file patent applications protecting the other Party's rights in such information.

10.5 **Publicity/Use of Names**. The Parties intend to agree upon the content of one (1) or more press releases, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Other than as set forth in the prior sentence, no other disclosure of the existence, or the terms, of this Agreement may be made by either Party or its Affiliates, and neither Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Laws. Notwithstanding the above, each Party and its Affiliates may disclose on its website, in news releases, its promotional materials and other disclosures relating to this Agreement that the other Party is a development and commercialization partner of such Party for the Licensed Product in the Territory and may use the other Party's name and logo in conjunction with such disclosure. Notwithstanding the foregoing:

(a) A Party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in news releases and securities filings with the U.S. Securities and Exchange Commission ("SEC") (or equivalent foreign agency) to the extent required by Applicable Laws after complying with the procedure set forth in this Section 10.5 (Publicity/Use of Names). In such event, the Party seeking to make such disclosure will prepare a draft of such disclosure together with, if applicable, a confidential treatment request to request confidential treatment for this Agreement and proposed redacted version of this Agreement, and the other Party agrees to promptly (and in any event, no less than three (3) Business Days after receipt of such request for disclosure required for 8-K and no less than five (5) Business Days for other disclosure, including, if applicable, proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines prescribed by applicable SEC regulations. The Party seeking such disclosure shall exercise Commercially Reasonable Efforts to obtain confidential treatment of this Agreement from the SEC as represented by the redacted version reviewed and agreed upon in good faith by the other Party.

(b) Further, each Party acknowledges that the other Party may be legally required, or may be required by the listing rules of any exchange on which the other Party's or its Affiliate's securities are traded or advised by its counsel, to make public disclosures (including in filings with the SEC or other agency) of certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by law, listing rules or advice; provided that the Party seeking such disclosure shall provide the other Party with a copy of the proposed text of such disclosure sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment thereon.

(c) If either Party desires to issue a press release or make a public announcement concerning the material terms of this Agreement or the Development, Commercialization or Exploitation of the Compound or the Licensed Product under this Agreement, such as the achievement of Regulatory Approvals of the Licensed Product or data from a clinical trial, such Party shall provide the other Party with the proposed text of such announcement for prior review and, except to the extent such press release or public announcement is permitted by subsection (a) or (b) above, approval by such other Party.

(d) The Parties agree that after a public disclosure has been made or a press release or other public announcement has been issued in compliance with subsection (a), (b) or (c) hereof, each Party may make subsequent public disclosures or issue press releases or other public announcements disclosing the same content without having to obtain the other Party's prior consent and approval.

10.6 **Reporting of Financial Information**. From and after the Effective Date, to the extent required by the SEC (or equivalent foreign agency) in connection with EverInsight or an Affiliate of EverInsight registering securities in a public offering, VistaGen shall (a) cooperate with EverInsight or its Affiliates and their respective accountants and auditors by providing copies of books, and records related to the Licensed Product as EverInsight may reasonably request in connection with the preparation by EverInsight or its Affiliates of historical and pro forma financial statements related to the Licensed Product as may be required to be included in any filing made by EverInsight or any of its Affiliates under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder, including Regulation S-X (or equivalent foreign laws and regulations) and (b) without limiting the foregoing, shall provide EverInsight with such information as is required for EverInsight or its Affiliates to prepare audited "carve out" financial statements related to the Licensed Product, for the three (3) Calendar Years prior to the Effective Date (or such shorter period as agreed to by EverInsight) and information requested by EverInsight and reasonably necessary to prepare any applicable pro forma financial information required to be filed by EverInsight with the SEC (or equivalent foreign agency). EverInsight may also derive such "carve out" financial statements from VistaGen's historical financial statements and accurately present in all material respects the financial position of the Licensed Product in the Licensed Field in the Territory as of the dates thereof. EverInsight shall (i) submit to VistaGen any proposed filing containing or incorporating by reference any financial statements provided to EverInsight under this Section 10.6 (Reporting of Financial Information) as far in advance as reasonably practicable (and in no event, unless inconsistent with Applicable Laws, less than fifteen (15) days prior to the anticipated date of filing) so as to provide VistaGen a reasonable opportunity to comment thereon and (ii) in good faith consider incorporating such comments. All information of VistaGen obtained by or on behalf of EverInsight under this Section 10.6 (Reporting of Financial Information) shall be deemed Confidential Information of VistaGen.

10.7 **Privileged Communications**. In furtherance of this Agreement, it is expected that the Parties may, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this ARTICLE 10 (Confidentiality; Publication), that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between VistaGen and EverInsight, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of the Licensed Patents, EverInsight Patents and Joint Patents. In the event of any litigation (or potential litigation) with a Third Party related to this Agreement or the subject matter hereof, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense or common interest agreement. In any event, each Party shall consult in a timely manner with the other Party before engaging in any conduct (e.g., producing Information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Section 10.7 (Privileged Communications), nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to the Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely by this Section 10.7 (Privileged Communications).

ARTICLE 11 TERM AND TERMINATION

11.1 **Term**. Unless earlier terminated as permitted by this Agreement, the term of this Agreement will commence upon the Effective Date and continue in full force and effect, on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis, until expiration of the Royalty Term for such Licensed Product in such jurisdiction the Territory (the "**Term**"). Following the expiration (but not the earlier termination) of the Royalty Term for a Licensed Product in a jurisdiction in the Territory, the grants in Section 2.1 (Licenses to EverInsight) shall continue and become exclusive, fully-paid, royalty-free, and irrevocable for such Licensed Product (existing at the time of such expiration) in such jurisdiction. For clarity, (a) upon the expiration (but not the earlier termination) of the Term, the grants in Section 2.1 (Licenses to EverInsight) shall become exclusive, fully-paid, royalty-free, and irrevocable in their entirety solely as to the Licensed Product in the Territory at the time of such expiration and (b) upon the expiration (but not the earlier termination) of the Term, the grant in Section 2.2 (License to VistaGen) shall become an exclusive, perpetual, fully-paid, royalty-free and irrevocable license under the EverInsight Technology to Exploit the Licensed Product (existing at the time of such expiration) in the Licensed Field outside the Territory, in each case with the right to grant sublicenses.

11.2 **Termination**.

(a) **Automatic Termination for Nonpayment of Upfront Payment**. If EverInsight fails to pay VistaGen the upfront payment set forth in Section 8.1 (Upfront Payment) within thirty (30) Business Days after the Effective Date; then, in any such case, this Agreement will automatically and immediately terminate.

(b) **Termination by EverInsight for Convenience**. At any time, EverInsight may terminate this Agreement (either in its entirety or on a Licensed Product-by-Licensed Product and jurisdiction-by-jurisdiction basis), at its sole discretion and for any reason or no reason, by providing written notice of termination to VistaGen, which notice includes an effective date of termination at least **[*****]** after the date of the notice.

(c) **Termination for Cause**. If either VistaGen or EverInsight believes that the other Party is in material breach of its obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party. The allegedly breaching Party shall have (i) **[*****]** Business Days in the case of a payment breach and or (ii) **[*****]** Business Days in the case of a non-payment breach, to cure such breach from the receipt of the notice. If the allegedly breaching Party fails to cure that breach within the applicable period set forth above, or has not undertaken reasonable steps to cure the breach if a complete cure is not reasonably to be expected within such period, then the Party originally delivering the notice of breach may terminate this Agreement on written notice of termination. Any right to terminate this Agreement under this Section 11.2(c) (Termination for Cause) shall be stayed and the applicable cure period tolled in the event that, during such cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Section 14.10 (Dispute Resolution) with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Section 14.10 (Dispute Resolution). If a Party is determined to be in material breach of this Agreement, the other Party may terminate this Agreement if the breaching Party fails to cure the breach within thirty (30) Business Days after the conclusion of the dispute resolution procedure (and such termination shall then be effective upon written notification from the notifying Party to the breaching Party).

(d) **Termination for Patent Challenge**. VistaGen may terminate this Agreement immediately upon prior written notice to EverInsight if EverInsight or its Affiliates or its or their Sublicensees, individually or in association with any other person or entity, directly or indirectly, commences or participates in a Challenge to the validity or enforceability of any Licensed Patents, unless EverInsight, such Affiliate or Sublicensee dismisses or withdraws such Challenge within **[*****]** days, or in the case of a Challenge by a Sublicensee, EverInsight terminates the sublicense agreement with such Sublicensee within **[*****]** days. EverInsight may terminate the license granted by EverInsight to VistaGen this Agreement (but retain the license granted by VistaGen to EverInsight hereunder) immediately upon prior written notice to VistaGen if VistaGen or its Affiliates or its or their Sublicensees, individually or in association with any other person or entity, directly or indirectly, commences or participates in a Challenge to the validity or enforceability of any EverInsight Patents, unless VistaGen, such Affiliate or Sublicensee dismisses or withdraws such Challenge within **[*****]** days, or in the case of a Challenge by a Sublicensee, VistaGen terminates the sublicense agreement with such Sublicensee within **[*****]** days.

(e) **Termination for Bankruptcy**. This Agreement may be terminated at any time during the Term by either Party upon the other Party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within **[*****]** days after the filing thereof.

11.3 **Effect of Termination**. Upon termination of this Agreement by either Party, the following consequences shall apply and shall be effective as of the effective date of such termination (if this Agreement is terminated on a Licensed Product-by-Licensed Product and jurisdiction-by-jurisdiction basis, then this Section 11.3 shall only apply to the terminated Licensed Product in the terminated jurisdiction):

(a) EverInsight's license under Section 2.1 (License to EverInsight) shall terminate and all milestone and any other payments accruing prior to the effective date of termination will be paid by EverInsight on or before the termination date and all reports and accountings that are due prior to the effective date of termination shall be submitted by EverInsight on or before the termination date.

(b) If this Agreement is terminated in its entirety by VistaGen pursuant to Section 11.2(c) (Termination for Cause), 11.2(d) (Termination for Patent Challenge), or 11.2(e) (Termination for Bankruptcy), or if this Agreement is terminated by EverInsight in its entirety pursuant to Section 11.2(b) (Termination by EverInsight for Convenience), then EverInsight hereby grants to VistaGen, effective only upon such termination, an exclusive (even as to EverInsight), royalty-free, fully-paid, perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the EverInsight Technology, EverInsight Development Data and EverInsight Regulatory Documentation, to Develop, make, have made, use, import, offer for sale, sell and otherwise Commercialize or Exploit the Compound and any product containing the Compound anywhere in the world in all fields of use. During a reasonable period of time (but no more than six (6) months) after termination, EverInsight shall reasonably cooperate with VistaGen to facility the transfer of the Development and regulatory activities for the Compound and Licensed Product to VistaGen.

(c) If this Agreement is terminated by EverInsight pursuant to Section 11.2(c) (Termination for Cause), or 11.2(e) (Termination for Bankruptcy), then VistaGen may request, within **[*****]** days of such termination, that EverInsight enter into good faith negotiations for no more than **[*****]** days concerning the terms of an agreement with EverInsight granting to VistaGen an exclusive (even as to EverInsight) license under the EverInsight Technology, EverInsight Development Data and EverInsight Regulatory Documentation. If no agreement is reached, then the license to VistaGen under Section 2.2 (License to VistaGen) shall terminate.

(d) If this Agreement is terminated in its entirety, VistaGen shall be solely responsible for all future worldwide Development, Manufacture and Commercialization of the Compound and Licensed Product in the Licensed Field, at its sole cost and expense.

(e) If this Agreement is terminated in its entirety, each Party shall return to the other Party or destroy, at the other Party's election, all Confidential Information of the other Party, including all copies thereof and all materials, substances and compositions delivered or provided by or on behalf of the other Party; except that (i) each Party may retain one copy of the other Party's Confidential Information for legal archival purpose, and neither Party shall be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by automatic or routine archiving and back-up procedures; and (ii) if the Parties reach agreement with respect to a license grant by EverInsight to VistaGen under clause (c) or VistaGen has license rights under clause (b), then VistaGen shall not be required to return or destroy EverInsight's Confidential Information to the extent VistaGen has the right to use such Confidential Information solely as necessary to practice such license.

(f) If VistaGen automatically has license rights under clause 11.3(b) or the Parties reach agreement with respect to a license grant by EverInsight to VistaGen under clause 11.3(c) then:

(i) EverInsight shall deliver to VistaGen all Regulatory Filings and Regulatory Approvals for the Compound and any Licensed Product, all EverInsight Development Data and all EverInsight Know-How.

(ii) EverInsight shall (1) disclose to VistaGen all EverInsight Know-How, EverInsight Development Data and all Joint Inventions to the extent not already known to VistaGen, which may be necessary or reasonably useful for VistaGen to continue to Develop, Manufacture and Commercialize the Compound and Licensed Product in the Licensed Field; and (2), at VistaGen's request, provide reasonable technical assistance and transfer all EverInsight Know-How, EverInsight Development Data and Joint Inventions necessary to Manufacture the Compound or Licensed Product to VistaGen or its designee; provided that VistaGen shall reimburse EverInsight for the reasonable cost and expense of such technical assistance.

(iii) EverInsight shall, at VistaGen's request and election, introduce VistaGen to EverInsight's Third Party providers of clinical research, manufacturing and/or distribution services and assign any contracts with such entities to VistaGen to the extent such contracts (or portions thereof, such as a work order under a master services agreement) relate solely to the Licensed Product and are assignable to VistaGen.

(iv) EverInsight shall transfer to VistaGen all units of the Compound and the Licensed Product in its possession, provided that VistaGen shall reimburse EverInsight for the Cost of Goods of such units.

(v) EverInsight shall, and hereby does, effective on such termination, assign to VistaGen all of EverInsight's and its Affiliates' right, title and interest in and to any and all Product Trademarks and other trademarks used by EverInsight and its Affiliates in the Territory in connection with its Development, Manufacture or Commercialization of Licensed Product (excluding any such trademarks that include, in whole or part, any corporate name or logo of EverInsight or its Affiliates), including all goodwill therein, and EverInsight shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment.

11.4 **Survival**. Expiration or termination of this Agreement shall not relieve any Party of any obligation accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the provisions of ARTICLE 1 (Definitions), subclauses (b) through (d) of Section 5.4 (Rights of Reference), Section 8.8 (Taxes), Section 8.9 (Financial Records and Audit), Section 8.10 (Audit Dispute), Section 9.1 (Ownership of Intellectual Property); ARTICLE 10 (Confidentiality; Publicity), Section 11.3 (Effect of Termination), this Section 11.4 (Survival), ARTICLE 13 (Indemnification; Liability), and ARTICLE 14 (General Provisions) hereof shall survive the expiration or termination of this Agreement. In addition, in the event that the this Agreement is terminated by EverInsight pursuant to Section 11.2(c) (Termination for Cause) and, pursuant to Section 11.3 (Effect of Termination), either VistaGen does not timely request that EverInsight enter into good faith negotiations concerning the terms of an agreement with VistaGen granting VistaGen a license under the EverInsight Technology and EverInsight Development Data, or if no agreement is timely reached, then the provisions of Sections 9.2 through 9.9 of ARTICLE 9 (Intellectual Property), solely with respect to Joint Inventions, shall also survive the expiration or termination of this Agreement.

11.5 **Termination Not Sole Remedy**. Termination is not the sole remedy under this Agreement and, whether or not termination is effected, and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein.

11.6 **Alternative Remedy for VistaGen's Breach.** In the event EverInsight would be entitled to terminate this Agreement pursuant Section 11.2(c) for VistaGen's uncured material breach, but if EverInsight does not desire to exercise such termination right, then, EverInsight may, in its sole discretion and without waiving or releasing any right, claim or remedy for such breach, elect to maintain this Agreement in full force and effect and reduce all future payments due to VistaGen hereunder by **[*****]**.

ARTICLE 12 REPRESENTATIONS AND WARRANTIES

12.1 **Representations and Warranties of Each Party**. Each Party represents and warrants to each other Parties as of the Effective Date that:

(a) it has the full right, power and authority to enter into this Agreement, to perform its obligations hereunder;

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;

(c) this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

(d) it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder; and

12.2 **Mutual Covenants**.

(a) **Employees, Consultants and Contractors**. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement.

(b) **Debarment**. Each Party represents, warrants and covenants to the other Parties that it is not debarred or disqualified under the FFDCA, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it has not employed or used, does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to the Compound or any Licensed Product. In the event that any Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Parties in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) **Compliance**. Each Party covenants as follows:

(1) In the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws, including all export control, anti-corruption and anti-bribery laws and regulations, and shall not cause such other Party to be in violation of any Applicable Laws.

(2) Such Party and its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including, without limitation, either Party. Each Party represents and warrants that as of the Effective Date, such Party, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of such Party's obligations under this Agreement, and each Party covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing.

(3) Each Party shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that the other Party, in connection with performance of such other Party's obligations under this Agreement, has materially violated any anti-corruption or anti-bribery laws or regulations.

(4) Each Party shall not, during the Term, assign, transfer, convey or otherwise encumber its right, title and interest in (A) Licensed Technology, in the case of VistaGen, in a manner that is inconsistent with the exclusive license granted to EverInsight under Section 2.1 (Licenses to EverInsight) or (B) EverInsight Technology, in the case of EverInsight, in a manner that is inconsistent with the exclusive license granted to VistaGen under Section 2.2 (License to VistaGen), in each case without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed)

(5) Each Party shall not grant any right to any Third Party under the (A) Licensed Technology (in the case of VistaGen) that would conflict with the rights granted to EverInsight hereunder, or (B) EverInsight Technology (in the case of EverInsight) that would conflict with the rights granted to VistaGen hereunder.

12.3 **Representations and Warranties by VistaGen**. VistaGen represents and warrants to EverInsight as of the Effective Date that:

(a) The patents and patent applications listed on Exhibit A constitute all Licensed Patents existing as of the Effective Date (the "**Existing Licensed Patents**");

(b) Except for **[*****],** VistaGen is the sole and exclusive owner of all Licensed Technology, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sales agreements, encumbrances, charges or claims of any kind, and has the right to grant the license to EverInsight as purported to be granted under this Agreement;

(c) The Licensed Technology is complete, accurate, effective and capable of achieving the Development and Manufacturing of the Compound and the Licensed Product. The Parties hereby irrevocably agree that the Licensed Technology shall be deemed to be complete, accurate, effective and capable of achieving the Development and Manufacturing of the Compound and the Licensed Product (and the foregoing representation and warranty shall be satisfied) if, after the completion of relevant technology transfer, EverInsight (or its contractor) is able to produce the Compound or the Licensed Products (as the case may be) in a manner that (1) complies with the specifications contained in (i) the technical documents VistaGen provided to EverInsight for evaluation and (ii) IND(s) submitted to the applicable Regulatory Authority(ies) and (2) does not infringe or misappropriate any intellectual property of any Third Party.

(d) VistaGen has not received any notice from a Third Party that the Development or Manufacture of the Compound or any Licensed Product conducted by or on behalf of VistaGen prior to the Effective Date has infringed any Patents of any Third Party or infringed or misappropriated any other intellectual property of any Third Party. Based on VistaGen's understanding as of the Effective Date of the Compound and the Licensed Product and their intended use as disclosed to EverInsight as of the Effective Date, the Development, Manufacture, use or sale of any Compound or any Licensed Product pursuant to this Agreement does not and will not, to the knowledge of VistaGen, (y) infringe any Patents of any Third Party or (z) infringe or misappropriate any other intellectual property of any Third Party.

(e) To the knowledge of VistaGen, the use of Licensed Trademark in connection with Commercialization of the Licensed Product will not violate the rights of any Third Party. No claim or action has been brought or, to VistaGen's knowledge, threatened in writing, by any Governmental Authority or Third Party (i) that any Licensed Trademark violates the rights of a Third Party or (ii) currently challenging the enforceability or validity of any Licensed Trademark;

(f) VistaGen has not as of the Effective Date granted any right to any Third Party under the Licensed Technology or Licensed Trademark that would conflict with the rights granted to EverInsight hereunder;

(g) VistaGen has no knowledge as of the Effective Date of any Third Party that is infringing or misappropriating any of the Licensed Technology or Licensed Trademark;

(h) no claim or action has been brought or, to VistaGen's knowledge, threatened in writing by any Third Party involving any Compound, Licensed Product and/or Licensed Technology, including any claim or action alleging that the issued patents in the Licensed Patent Rights are invalid or unenforceable, and any interference, opposition, cancellation or other protest proceeding involving any Licensed Patents anywhere in the world;

(i) to VistaGen's knowledge, as of the Effective Date, there is no Know-How owned or controlled by VistaGen that is necessary for the Development of the Compound that is not within the Licensed Know-How; and

(j) to VistaGen's knowledge, (x) all development works for the Compound and Licensed Product, including clinical trials, conducted by VistaGen or its Affiliates (including their contractors) prior to the Effective Date have been in compliance in all material respects with all Applicable Laws, and (y) no data or other information generated or otherwise received from such clinical trials conducted up to the Effective Date has, or is reasonably expected to have, any materially negative impact on the Exploitation of any Licensed Product in the Territory.

(k) To the knowledge of VistaGen, VistaGen has obtained all necessary government approvals required for the grant of the license and the transfer of the Licensed Know-How to EverInsight, including such approvals required by applicable technology export control laws, and VistaGen will do and execute or procure to be done and executed all such further acts, things, agreements and other documents as may be necessary to give effect to the terms of this Agreement, including to comply with the applicable technology import and export laws and regulations in the United States and the Territory;

(l) Except for the Pherin License, there is no agreement between VistaGen or its Affiliates and any Third Party pursuant to which VistaGen or its Affiliates have obtained any right or license to the Compound, Licensed Product or Licensed Technology. VistaGen has provided EverInsight with a copy of the Pherin License that is complete with regard to the relevant provisions of this Agreement. The Pherin License is in full force and effect. No notice of default or termination has been received or given under the Pherin License. There is no act or omission by VistaGen that would provide a right to terminate the Pherin License;

(m) During the Term of this Agreement, VistaGen shall maintain **[*****]** each In-License Agreement in full force and effect and shall not terminate, amend, waive or otherwise modify (or consent to any of the foregoing) its rights under **[*****]** any In-License Agreement in any manner that materially diminishes the rights or licenses granted to EverInsight hereunder, without EverInsight's express written consent, which shall not be unreasonably withheld, conditioned or delayed, and VistaGen shall provide EverInsight with a copy of all modifications to or amendments thereto, regardless of whether EverInsight's consent was required with respect thereto. In the event of any notice of breach of **[*****]** any In-License Agreement by VistaGen, VistaGen shall immediately notify EverInsight in writing, and if VistaGen fails to cure such breach in a timely manner, EverInsight shall have the right, but not the obligation, to cure such breach and to seek reimbursement of or offset any reasonable amount incurred or paid by EverInsight in connection with the cure against amount payable to VistaGen hereunder. In the event of any notice of breach of **[*****]** any In-License Agreement by the applicable Third Party in a manner that will or is likely to materially affect EverInsight's rights or obligations under this Agreement, VistaGen shall immediately notify EverInsight in writing and take such actions as reasonably requested by EverInsight to enforce the **[*****]** In-License Agreement; and

(n) All information provided by VistaGen to EverInsight for due diligence purposes in relation to this Agreement is complete and accurate in all material respects. Without limiting the foregoing, VistaGen has disclosed or made available to EverInsight for review all material non-clinical and clinical data for the Compound and Licensed Product, and all other material information (including relevant correspondence with the FDA and other Regulatory Authorities) relating to the Compound and Licensed Product, in each case that would be material for EverInsight to assess the safety and efficacy of the Compound and Licensed Product.

12.4 **Representations and Warranties by EverInsight**. EverInsight represents and warrants to VistaGen as of the Effective Date that:

(a) EverInsight has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in EverInsight Technology in a manner that is inconsistent with the exclusive license granted to VistaGen under Section 2.2 (License to VistaGen);

(b) EverInsight has not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the EverInsight Technology that would conflict with the rights granted to VistaGen hereunder;

(c) EverInsight has no knowledge as of the Effective Date of any Third Party that is infringing or misappropriating any of the EverInsight Technology;

(d) no claim or action has been brought or, to EverInsight's knowledge, threatened in writing by any Third Party alleging that the EverInsight Patents are invalid or unenforceable, and no EverInsight Patent is the subject of any interference, opposition, cancellation or other protest proceeding; and

(e) as of the Effective Date, EverInsight reasonably believes it has or will have the capability and sufficient access to the financial resources necessary to perform its obligations under this Agreement, including without limitation, its obligations to (i) use Commercially Reasonable Efforts to Develop, Exploit, Commercialize and obtain Regulatory Approval for the Compounds and each Licensed Product in the Licensed Field in the Territory and (ii) make the required payments to VistaGen hereunder.

12.5 **No Other Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NO PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

ARTICLE 13 INDEMNIFICATION; LIABILITY

13.1 **Indemnification by VistaGen**. VistaGen shall indemnify, defend and hold EverInsight, its Affiliates, and their respective officers, directors, agents and employees ("**EverInsight Indemnitees**") harmless from and against any Claims against them to the extent arising or resulting from:

(a) the material breach by VistaGen of this Agreement;

(b) the gross negligence or willful misconduct on the part of VistaGen or its Affiliates or its or their respective officers, directors, agents or employees in performing its obligations under this Agreement; or

(c) the Exploitation by VistaGen or any of its Affiliates or its or their sublicensees or its or their distributors or contractors of the Compound or the Licensed Product outside the Territory; or

(d) any Third Party Infringement Claim that VistaGen is responsible for defending pursuant to Section 9.5;

except, in each case (a), (b) and (c) above, for those Claims for which EverInsight has an obligation to indemnify VistaGen pursuant to Section 13.2 (Indemnification by EverInsight) hereof or, to the extent such Claims result from the material breach by EverInsight of any covenant, representation, warranty or other agreement made by EverInsight in this Agreement or the negligence or willful misconduct of any EverInsight Indemnitee. Notwithstanding the above, VistaGen will have no obligation to defend or indemnify EverInsight or its Affiliates for any claim brought by a shareholder or a class of shareholders of EverInsight or its Affiliates including, but not limited to, securities fraud claims, shareholder direct claims, and shareholder derivative claims, except to the extent resulting from the gross negligence or willful misconduct on the part of VistaGen or any Affiliate.

13.2 **Indemnification by EverInsight**. EverInsight shall indemnify, defend and hold VistaGen, its Affiliates, and their respective officers, directors, agents and employees ("**VistaGen Indemnities**") harmless from and against any Claims arising under or related to this Agreement against them to the extent arising or resulting from:

(a) the material breach by EverInsight of this Agreement;

(b) the gross negligence or willful misconduct on the part of EverInsight or its Affiliates or its or their respective officers, directors, agents or employees in performing its obligations under this Agreement; or

(c) the Exploitation by EverInsight or any of its Affiliates or its or their Sublicensees or its or their distributors or contractors of the Compound or the Licensed Product in the Territory;

except, in each case (a), (b) and (c) above, those Claims for which VistaGen has an obligation to indemnify EverInsight pursuant to Section 13.1 (Indemnification by VistaGen) hereof or, to the extent such Claims result from the material breach by VistaGen of any covenant, representation (other than the representation set forth in Section 12.3(d), warranty or other agreement made by VistaGen in this Agreement or the negligence or willful misconduct of any VistaGen Indemnitee. Notwithstanding the above, EverInsight will have no obligation to defend or indemnify VistaGen or its Affiliates for any claim brought by a shareholder or a class of shareholders of VistaGen or its Affiliates including, but not limited to, securities fraud claims, shareholder direct claims, and shareholder derivative claims, except to the extent resulting from the gross negligence or willful misconduct on the part of EverInsight or any Affiliate.

13.3 **Indemnification Procedure.**

(a) **Notice of Claim**. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the other Party (the "**Indemnifying Party**") a prompt written notice (an "**Indemnification Claim Notice**") of any Claims or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this ARTICLE 13 (Indemnification; Liability) within **[*****]** days from written receipt of such Claim or discovery of facts that that might give rise to such Claim. Each Indemnification Claim Notice must contain a description of the Claim and the nature and amount of such Claim (to the extent that the nature and amount of such Claim is known at such time).

(b) **Control of Defense**. The Indemnifying Party shall have the right to assume the defense of any Claim by giving written notice to the Indemnified Party within **[*****]** days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Claim any legal counsel selected by the Indemnifying Party; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). In the event the Indemnifying Party assumes the defense of a Claim, upon the Indemnifying Party's relevant notice the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Claim. Should the Indemnifying Party assume the defense of a Claim, except as provided in Section 13.3(c) (Right to Participate in Defense), the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Claim unless specifically requested and approved in writing by the Indemnifying Party. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all reasonable and verifiable out-of-pocket costs and expenses (including attorneys' fees and costs of suit) incurred by the Indemnifying Party in accordance with this ARTICLE 13 (Indemnification; Liability) in its defense of the Claim.

(c) **Right to Participate in Defense**. Any Indemnified Party shall be entitled to participate in the defense of such Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's sole cost and expense unless (i) the employment thereof has been specifically authorized in writing in advance by the Indemnifying Party (in which case, the defense shall be controlled as provided in Section 13.3(b) (Control of Defense), with such provisions applying mutatis mutandis; (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.3(b) (Control of Defense) (in which case the Indemnified Party shall control the defense, with the reasonable out-of-pocket expense with respect thereto borne by the Indemnifying Party); or (iii) the interests of the indemnitee and the Indemnifying Party with respect to such Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Laws, ethical rules or equitable principles (in which case, the Indemnified Party shall control its defense, with the reasonable out-of-pocket expense with respect thereto borne by the indemnifying Party).

(d) **Settlement**. With respect to any Claims relating solely to the payment of money damages in connection with a Claim that shall not result in the applicable indemnitee(s) becoming subject to injunctive or other relief or otherwise adversely affect the business or interests of the Indemnified Party in any manner and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable indemnitee hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Claim, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Claims in connection with Claims, where the Indemnifying Party has assumed the defense of the Claim in accordance with Section 13.3(b) (Control of Defense), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Claim; provided, it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the Indemnifying Party does not assume and conduct the defense of a Claim as provided above, the Indemnified Party may defend against such Claim; provided, that the Indemnified Party shall not settle any Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

(e) **Cooperation**. If the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party shall and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested by the indemnifying Party in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim and making the Indemnified Party, the indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the Indemnifying Party shall reimburse the Indemnified Party for all of its, its Affiliates' and its and their sublicensees' or their respective directors', officers', employees' and agents', as applicable, reasonable and verifiable out-of-pocket expenses in connection therewith.

(f) **Expenses**. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party and its Affiliates and its and their sublicensees and their respective directors, officers, employees and agents, as applicable, in connection with any Claim shall be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

13.4 **Mitigation of Loss**. Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and actions as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this ARTICLE 13 (Indemnification; Liability). Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

13.5 **Special, Indirect and Other Losses**. EXCEPT IN THE EVENT OF A BREACH OF SECTION 2.7 (NON-DIVERSION), SECTION 2.8 (NON-COMPETE) OR ARTICLE 10 (CONFIDENTIALITY; PUBLICATION), NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section 13.5 shall not be construed to limit either Party's indemnification obligations under Section 13.1 (Indemnification by VistaGen) or Section 13.2 (Indemnification by EverInsight), as applicable.

13.6 **Insurance**. Each Party, at its own expense, shall maintain product liability and other appropriate insurance in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon request.

ARTICLE 14 GENERAL PROVISIONS

14.1 **Governing Law**. This Agreement shall be governed by and construed in accordance with the law of Hong Kong without reference to its conflicts of laws principles.

14.2 **Assignment**.

(a) Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent: (a) in connection with the transfer or sale of all or substantially all of the business or assets of such Party to which this Agreement relates to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets or otherwise; provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) and its Affiliates existing prior to the transaction shall not be included in the technology licensed hereunder; or (b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate; and provided, further, that in any such case the assigning Party shall provide written notice to the other Party within five (5) calendar days after such assignment or transfer. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Section 14.2 (Assignment) shall be null and void.

(b) The rights to Information, materials and intellectual property, shall, in each of cases (1) and (2) below, be automatically excluded from the rights licensed or granted to the other Party under this Agreement:

(1) Rights to Information, materials and intellectual property controlled by a Third Party permitted assignee of a Party that immediately prior to such assignment (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its Affiliates to, or for the benefit of, such Third Party); or

(2) Rights to Information, materials and intellectual property controlled by an Affiliate of a Party that becomes an Affiliate through any Change of Control of such Party that was Controlled by such Affiliate (and not such Party) immediately prior to such Change of Control (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its other Affiliates to, or for the benefit of, such Affiliate).

14.3 **Entire Agreement; Modification**. This Agreement is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. No amendment, modification, release or discharge shall be binding on the Parties unless in writing and duly executed by authorized representatives of each of VistaGen and EverInsight; provided that, pursuant to the definition of "Licensed Trademarks" herein, VistaGen may designate in a writing to EverInsight from time to time such other Trademarks, names and logos as VistaGen may reasonably determine. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

14.4 **Relationship among the Parties**. The Parties' relationship with one another, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party. Neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

14.5 **Non-Waiver**. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

14.6 **Force Majeure**. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments unless the force majeure event affects the payment process itself, such as bank closure or government closure that affects the review and approval of the payment) when such failure or delay is caused by or results from events beyond the reasonable control of the non- performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (including expropriation, seizure of works, requisition, nationalization, exercise of march-in rights or compulsory licensing, except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement) and any material change in the Applicable Laws of a Regulatory Authority that results in a development, clinical or regulatory delay **[*****]**. The non-performing Party shall notify the other Party of such force majeure within thirty (30) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform.

14.7 **Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Laws. VistaGen hereby undertakes to use Commercially Reasonable Efforts to obtain necessary licenses (if required) for exporting the Compound, the Licensed Product and the Licensed Technology from the United States or other countries.

14.8 **Severability**. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby: (a) such provision shall be fully severable; (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom; and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Laws, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

14.9 **Notices.** Any notice to be given under this Agreement must be in writing and delivered either (a) in person or (b) by overnight courier, to the Party to be notified at its address(es) given below for convenience, or at any address such Party may designate by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the date of actual receipt.

If to VistaGen:

VistaGen Therapeutics, Inc.
343 Allerton Avenue
South San Francisco, CA 94080
United States of America

Attention: CEO

with a mandatory copy (which shall not constitute notice) to:

Reid Adler, J.D.
Capital Technology Law Group
5335 Wisconsin Ave., N.W., Suite 440
Washington, DC 20015
United States of America

If to EverInsight:

EverInsight Therapeutics Inc.
Vistra Corporate Services Centre
Wickhams Cay II, Road Town
Tortola, VG1110
British Virgin Islands
ATTN: CEO / General Counsel

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

with a mandatory copy to (which shall not constitute notice) to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
ATTN: Lila Hope, Ph.D.

14.10 **Dispute Resolution**.

(a) Except as provided in Section 3.3(b)(i), (b)(ii), (c) or Excluded Claims as set forth in subsection 14.10(g) below, if a dispute arises within the JSC with respect to any decision under the jurisdiction of the JSC that remains unresolved pursuant to Section 3.3 (JSC Decision-Making) or otherwise between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (collectively, a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Executive Officers for attempted resolution by good faith negotiations during a period of forty-five (45) days. Any final decision mutually agreed to in writing by the Executive Officers shall be conclusive and binding on the Parties.

(b) The Executive Officers shall negotiate in good faith and use reasonable efforts to settle any Dispute arising from or related to this Agreement or the breach thereof within such forty-five (45) day period. Subject to Section 14.10(h) (Dispute Resolution - subsection (h)), in the event the Executive Officers cannot fully resolve or settle such Dispute within such period, and a Party wishes to pursue the matter further, each such Dispute that is not an Excluded Claim (defined in Section 14.10(g) (Dispute Resolution - subsection (g)) below) shall be finally resolved by binding arbitration administered by the Hong Kong International Arbitration Centre ("**HKIAC**") in accordance with its arbitration rules then in effect.

(c) The arbitration shall be conducted by a panel of three (3) neutral arbitrators experienced in the pharmaceutical business, none of whom shall be a current or former employee or director, or a current stockholder, of either Party or any of their respective Affiliates or any Sublicensee. Within thirty (30) days after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the HKIAC (or its successor entity) in accordance with the then-current HKIAC arbitration rules, except as modified in this Agreement. The place of arbitration shall be in Hong Kong, and all proceedings and communications shall be in English. The procedures for the taking of evidence shall be governed by the HKIAC. The decision or award rendered by the arbitrators shall be final, binding, conclusive and non-appealable, and judgment may be entered upon it in accordance with Applicable Laws in the Hong Kong or any other court of competent jurisdiction.

(d) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. The arbitrators' authority to award punitive or any other type of damages not measured by a Party's compensatory damages shall be subject to the limitation set forth in Section 13.5 (Special, Indirect and Other Losses). Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

(e) Except to the extent necessary to confirm or enforce an award or as may be required by law, neither Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable Hong Kong statute of limitations.

(f) The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

(g) As used in this Section, the term "Excluded Claim" means a dispute, controversy or claim that concerns the construction, scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright.

(h) Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the construction, scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright, and no such claim shall be subject to arbitration pursuant to subsections (b) and (c) of this Section 14.10 (Dispute Resolution). Both Parties agree to waive any requirement that the other (i) post a bond or other security as a condition for obtaining any such relief; or (ii) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy.

14.11 **Performance by Affiliates**. Each Party may discharge any obligations and exercise any rights hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.12 **Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

14.13 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

14.14 **Business Day Requirements**. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to require to be taken on the next occurring Business Day.

14.15 **English Language**. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language

14.16 **No Benefit to Third Parties**. Except as provided in ARTICLE 13 (Indemnification; Liability), the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

14.17 **Further Assurances**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

14.18 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License Agreement to be executed by their duly authorized representatives.

EverInsight Therapeutics Inc.		**VistaGen Therapeutics, Inc.**	
By:	/s/ Wei Fu	By:	/s/ Shawn K. Singh
Name:	Wei Fu	Name:	Shawn K. Singh, J.D.
Title:	Director of EverInsight Therapeutics Inc.	Title	Chief Executive Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

LIST OF EXHIBITS

Exhibit A: Licensed Patents Existing as of the Effective Date

Exhibit B: Licensed Trademarks

Exhibit C: PH94B Chemical Structure

Exhibit D: Initial Development Plan

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

[*****]

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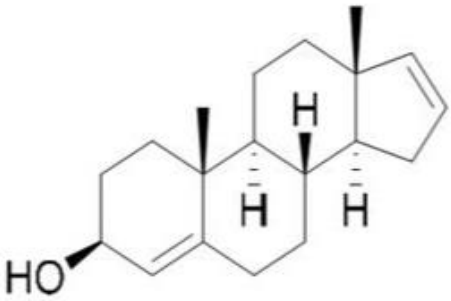
Exhibit B: Licensed Trademarks as of the Effective Date

VISTAGEN®, United States Registration # 2787886 and international counterparts in the Territory to be obtained in due course

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

Exhibit C: PH94B Chemical Structure

(3b)-androsta-4,16-dien-3-ol



CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

Exhibit D
Initial Development Plan for Acute Treatment of SAD in the Territory

[*****]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*****], HAS BEEN OMITTED BECAUSE VISTAGEN THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VISTAGEN THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

EXHIBIT 31.1

CERTIFICATION

I, Shawn K. Singh, certify that;

1. I have reviewed this quarterly report on Form 10-Q of VistaGen Therapeutics, Inc.;

2. Based on my knowledge, this report, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 13, 2020

/s/ Shawn K. Singh
Shawn K. Singh
Principal Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Jerrold D. Dotson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VistaGen Therapeutics, Inc.;

2. Based on my knowledge, this report, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 13, 2020

/s/ Jerrold D. Dotson
Jerrold D. Dotson
Principal Financial Officer

EXHIBIT 32

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of VistaGen Therapeutics, Inc. (the "*Company*") for the quarter ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "*Report*"), Shawn K. Singh, JD, the Company's Principal Executive Officer, and Jerrold D. Dotson, the Company's Principal Financial Officer, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

1. The Report fully complies with the requirement of Section 13(a) or Section 15 (d) of the Securities Exchange Act of 1934, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 13, 2020

/s/ Shawn K. Singh
Shawn K. Singh
Principal Executive Officer

/s/ Jerrold D. Dotson
Jerrold D. Dotson
Principal Financial Officer