# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q	_

(Mark One)

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

For the quarterly period ended June 30, 2022

Or

o 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: 001-37524

# vTv Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware47-3916571(State or other jurisdiction of incorporation or organization)(I.R.S. Employer Identification No.)

3980 Premier Dr, Suite 310
High Point, NC
(Address of principal executive offices)

27265 (Zip Code)

(336) 841-0300

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value \$0.01 per share	VTVT	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 x No o

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 x No.0

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

Large accelerated filer 0 Accelerated filer 0
Non-accelerated filer 0 Smaller reporting company x
Emerging growth company 0

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. 0

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

Class of Stock	Shares Outstanding as of August 15, 2022
Class A common stock, par value \$0.01 per share	81,483,600
Class B common stock, par value \$0.01 per share	23,093,860

# vTv THERAPEUTICS INC. AND SUBSIDIARIES

# INDEX TO FORM 10-Q

# FOR THE QUARTER ENDED JUNE 30, 2022

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#### PART I – FINANCIAL INFORMATION

The financial statements and other disclosures contained in this report include those of vTv Therapeutics Inc. ("we", the "Company" or the "Registrant"), which is the registrant, and those of vTv Therapeutics LLC ("vTv LLC"), which is the principal operating subsidiary of the Registrant. Unless the context suggests otherwise, references in this Quarterly Report on Form 10-Q to the "Company", "we", "us" and "our" refer to vTv Therapeutics Inc. and its consolidated subsidiaries.

# **Condensed Consolidated Balance Sheets**

# (in thousands, except number of shares and per share data)

		June 30, 2022		December 31, 2021
		(Unaudited)		
Assets				
Current assets:				
Cash and cash equivalents	\$	17,863	\$	13,415
Accounts receivable		77		57
Promissory note receivable		11,941		_
Prepaid expenses and other current assets		643		2,049
Current deposits		85		100
Total current assets		30,609		15,621
Property and equipment, net		254		278
Operating lease right-of-use assets		354		402
Long-term investments		5,772		9,173
Total assets	\$	36,989	\$	25,474
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit				
Current liabilities:				
Accounts payable and accrued expenses	\$	9,600	\$	8,023
Current portion of operating lease liabilities		199		184
Current portion of contract liabilities		26		35
Current portion of notes payable		_		256
Total current liabilities		9,825		8,498
Contract liabilities, net of current portion		18,669		_
Operating lease liabilities, net of current portion		388		492
Warrant liability, related party		717		1,262
Total liabilities		29,599		10,252
Commitments and contingencies				
Redeemable noncontrolling interest		15,916		24,962
Stockholders' deficit:				
Class A common stock, \$0.01 par value; 200,000,000 shares authorized, 77,329,051 and 66,942,777 shares outstanding as of June 30, 2022, and December 31, 2021	3	773		669
Class B common stock, \$0.01 par value; 100,000,000 shares authorized, and 23,093,860 outstanding as of June 30, 2022, and December 31, 2021		232		232
Additional paid-in capital		243,772		238,193
Accumulated deficit		(253,303)		(248,834)
Total stockholders' deficit attributable to vTv Therapeutics Inc.		(8,526)		(9,740)
•	\$	36,989	\$	25,474
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	Ψ	30,789	Ψ	23,474

# vTv Therapeutics Inc. Condensed Consolidated Statements of Operations - Unaudited (in thousands, except number of shares and per share data)

	Three Mor June		Six Mont Jun	 
	2022	2021	2022	2021
Revenue	\$ 9	\$ 9	\$ 2,009	\$ 996
Operating expenses:				
Research and development	2,205	2,437	5,338	5,540
General and administrative	1,831	2,242	7,179	4,406
Total operating expenses	4,036	4,679	12,517	9,946
Operating loss	(4,027)	(4,670)	(10,508)	(8,950)
Other income (expense)	(167)	2,898	(3,401)	2,898
Other income (expense) – related party	53	931	545	(717)
Interest income	50	_	50	1
Interest expense	_	_	(1)	_
Loss before income taxes and noncontrolling interest	(4,091)	(841)	(13,315)	(6,768)
Income tax provision	_	_	200	15
Net loss before noncontrolling interest	(4,091)	(841)	(13,515)	(6,783)
Less: net loss attributable to noncontrolling interest	(940)	(233)	(3,357)	(1,934)
Net loss attributable to vTv Therapeutics Inc.	\$ (3,151)	\$ (608)	\$ (10,158)	\$ (4,849)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (3,151)	\$ (608)	\$ (10,158)	\$ (4,849)
Net loss per share of vTv Therapeutics Inc. Class A common stock, basic and diluted	\$ (0.04)	\$ (0.01)	\$ (0.15)	\$ (0.08)
Weighted average number of vTv Therapeutics Inc. Class A common stock, basic and diluted	70,366,823	58,615,137	68,664,259	57,549,755

# Condensed Consolidated Statement of Changes in Redeemable Noncontrolling Interest and Stockholders' Deficit - Unaudited (in thousands, except number of shares)

For the three months ended June 30, 2022

_				Class A Cor	mmo	n Stock	Class B Common Stock																																																																											
		Redeemable Noncontrolling Interest		Shares Amount		Amount	Shares		Amount	A	Additional Paid-in Capital	l-in Accumulated		Total Stockholders' Deficit																																																																				
В	alances at March 31, 2022	\$	14,367	66,942,777	\$	669	23,093,860	\$	232	\$	238,669	\$	(247,663)	\$ (8,093)																																																																				
	Net loss		(940)	_		_	_		_		_		(3,151)	(3,151)																																																																				
	Share-based compensation		_	_		_	_		_		167		_	167																																																																				
	Issuance of Class A common stock to collaboration partner		_	10,386,274		104	_		_		4,936		_	5,040																																																																				
	Change in redemption value of noncontrolling interest		2,489	_		_					_		_		_		_		_		_		_		- –		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_		_						_		(2,489)	(2,489)
В	alances at June 30, 2022	\$	15,916	77,329,051	\$	773	23,093,860	\$	232	\$	243,772	\$	(253,303)	\$ (8,526)																																																																				

For the three months ended June 30, 2021

_				10	1 111	c three months	s chucu sunc 50, 2	202						
				Class A Cor	mme	on Stock	Class B Cor	mn	non Stock					
			edeemable controlling Interest	Shares	Shares Amount		Shares	Shares Amount		Additional Paid-in Accumulated Capital Deficit		Accumulated		otal Stockholders' Deficit
B	nlances at March 31, 2021	\$	62,647	57,571,904	\$	576	23,093,860	S	232	\$ 217,647	\$	(274,730)	\$	(56,275)
	Net loss		(233)	_		_	_		_	_		(608)		(608)
	Share-based compensation		_	_		_	_		_	452		_		452
	Issuance of Class A common stock under ATM offering		_	2,180,337		22	_		_	5,313		_		5,335
	Issuance of Class A common stock under LPC Agreement		_	441,726		4	_		_	1,045		_		1,049
	Change in redemption value of noncontrolling interest		(2,224)	_		_	_		_	_		2,224		2,224
B	alances at June 30, 2021	\$	60,190	60,193,967	\$	602	23,093,860	\$	232	\$ 224,457	\$	(273,114)	\$	(47,823)

# Condensed Consolidated Statement of Changes in Redeemable Noncontrolling Interest and Stockholders' Deficit - Unaudited (in thousands, except number of shares)

For the six months ended June 30, 2022

				Class A Cor	mmoi	n Stock	Class B Common Stock									
		Redeemable Noncontrolling Interest		Shares Amount		Shares Amount			Additional Paid-in Capital			Accumulated Deficit	1	Total Stockholders' Deficit		
В	salances at December 31, 2021	\$	24,962	66,942,777	\$	669	23,093,860	\$	232	\$	238,193	\$	(248,834)	\$	(9,740)	
	Net loss		(3,357)	_		_	_		_		_		(10,158)		(10,158)	
	Share-based compensation		_	_		_	_		_		643		_		643	
	Issuance of Class A common stock to collaboration partner		_	10,386,274		104	_		_		4,936		_		5,040	
	Change in redemption value of noncontrolling interest		(5,689)	_		_	_		_		_		5,689		5,689	
В	alances at June 30, 2022	\$	15,916	77,329,051	\$	773	23,093,860	\$	232	\$	243,772	\$	(253,303)	53,303) \$		

For the six months ended June 30, 2021

				chaca sanc 50, 20				
		Class A Co	mmon Stock	Class B Con	ımon Stock			
	Redeemable Noncontrolling Interest	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balances at December 31, 2020	\$ 83,895	54,050,710	\$ 541	23,094,221	S 232	\$ 209,161	\$ (290,036)	\$ (80,102)
Net loss	(1,934)	_	_	_	_	_	(4,849)	(4,849)
Share-based compensation	_	_	_	_	_	888	_	888
Issuance of Class A common stock under ATM offering	_	2,180,337	22	_	_	5,313	_	5,335
Exchange of Class B common stock for Class A common stock	_	361	_	(361)	_	_	_	_
Exercise of stock options	_	20,833	_	_	_	47	_	47
Issuance of Class A common stock under LPC Agreement	_	3,941,726	39	_	_	9,048	_	9,087
Change in redemption value of noncontrolling interest	(21,771)	_	_	_	_	_	21,771	21,771
Balances at June 30, 2021	\$ 60,190	60,193,967	\$ 602	23,093,860	\$ 232	\$ 224,457	\$ (273,114)	\$ (47,823)

# Condensed Consolidated Statements of Cash Flows - Unaudited (in thousands)

	Six Months E 2022	nded	June 30, 2021
Cash flows from operating activities:	 		
Net loss before noncontrolling interest	\$ (13,515)	\$	(6,783)
Adjustments to reconcile net loss before noncontrolling interest to net cash used in operating activities:			
Depreciation expense	45		45
Non-cash interest income	(50)		_
Share-based compensation expense	643		888
Change in fair value of investments	3,401		(2,897)
Change in fair value of warrants, related party	(545)		717
Changes in assets and liabilities:			
Accounts receivable	(20)		158
Prepaid expenses and other assets	1,421		873
Accounts payable and accrued expenses	1,536		(1,302)
Contract liabilities	6,769		(996)
Net cash used in operating activities	(315)		(9,297)
Cash flows from investing activities:			
Purchases of property and equipment	(21)		_
Net cash used in investing activities	 (21)		_
Cash flows from financing activities:			
Proceeds from sale of Class A common stock to collaboration partner, net of offering costs	5,040		_
Proceeds from issuance of Class A common stock, net of offering costs	_		14,422
Proceeds from exercise of stock options	_		47
Repayment of notes payable	(256)		(84)
Net cash provided by financing activities	 4,784		14,385
Net increase in cash, cash equivalents and restricted cash and cash equivalents	4,448		5,088
Total cash, cash equivalents and restricted cash and cash equivalents, beginning of period	13,415		5,747
Total cash, cash equivalents and restricted cash and cash equivalents, end of period	\$ 17,863	\$	10,835
Non-cash activities:			
Change in redemption value of noncontrolling interest	\$ (5,689)		(21,771)
Notes receivable recorded at fair value from collaboration partner	\$ 11,891	\$	_

# Notes to Condensed Consolidated Financial Statements – Unaudited (dollar amounts are in thousands, unless otherwise noted)

#### Note 1: Description of Business, Basis of Presentation and Going Concern

#### **Description of Business**

vTv Therapeutics Inc. (the "Company," the "Registrant," "we" or "us") was incorporated in the state of Delaware in April 2015. The Company is a clinical stage pharmaceutical company focused on treating metabolic diseases to minimize their long-term complications through end-organ protection.

#### Principles of Consolidation

vTv Therapeutics Inc. is a holding company, and its principal asset is a controlling equity interest in vTv Therapeutics LLC ("vTv LLC"), the Company's principal operating subsidiary, which is a clinical stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates to fill significant unmet medical needs.

The Company has determined that vTv LLC is a variable-interest entity ("VIE") for accounting purposes and that vTv Therapeutics Inc. is the primary beneficiary of vTv LLC because (through its managing member interest in vTv LLC and the fact that the senior management of vTv Therapeutics Inc. is also the senior management of vTv LLC) it has the power and benefits to direct all of the activities of vTv LLC, which include those that most significantly impact vTv LLC's economic performance. vTv Therapeutics Inc. has therefore consolidated vTv LLC's results pursuant to Accounting Standards Codification Topic 810, "Consolidation" in its Condensed Consolidated Financial Statements. As of June 30, 2022, various holders own nonvoting interests in vTv LLC, representing a 23.0% economic interest in vTv LLC, effectively restricting vTv Therapeutics Inc.'s interest to 77.0% of vTv LLC's economic results, subject to increase in the future, should vTv Therapeutics Inc. purchase additional non-voting common units ("vTv Units") of vTv LLC, or should the holders of vTv Units decide to exchange such units (together with shares of Class B common stock) for shares of Class A common stock (or cash) pursuant to the Exchange Agreement (as defined in Note 9). vTv Therapeutics Inc. has provided financial and other support to vTv LLC in the form of its purchase of vTv Units with the net proceeds of the Company's initial public offering ("IPO") in 2015, its registered direct offering in March 2019, and its agreeing to be a co-borrower under the Venture Loan and Security Agreement (the "Loan Agreement") with Horizon Technology Finance Corporation and Silicon Valley Bank (together, the "Lenders") which was entered into in 2016. vTv Therapeutics Inc. entered into the letter agreements with MacAndrews and Forbes Group LLC ("M&F Group"), a related party and an affiliate of MacAndrews & Forbes Incorporated (together with its affiliates "MacAndrews"), in December 2017, July 2018, December 2018, March 2019, September 2019, and December 2019 (the "Letter Agreements"). In addition, vTv Therapeutics Inc. also entered into the Controlled Equity Offering SM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") (the "ATM Offering"), the purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") (the "LPC Purchase Agreement"), and the common stock purchase agreement with G42 Investments AI Holding RSC Ltd ("G42 Investments") (the "G42 Purchase Agreement"). vTv Therapeutics Inc. will not be required to provide financial or other support for vTv LLC. However, vTv Therapeutics Inc. will control its business and other activities through its managing member interest in vTv LLC, and its management is the management of vTv LLC. Nevertheless, because vTv Therapeutics Inc. will have no material assets other than its interests in vTv LLC, any financial difficulties at vTv LLC could result in vTv Therapeutics Inc. recognizing a loss.

#### Going Concern and Liquidity

To date, the Company has not generated any product revenue and has not achieved profitable operations. The continuing development of our drug candidates will require additional financing. From its inception through June 30, 2022, the Company has funded its operations primarily through a combination of private placements of common and preferred equity, research collaboration agreements, upfront and milestone payments for license agreements, debt and equity financings and the completion of its IPO in August 2015. As of June 30, 2022, the Company had an accumulated deficit of \$253.3 million and has generated net losses in each year of its existence.

As of June 30, 2022, the Company's liquidity sources included cash and cash equivalents of \$17.9 million. To meet our future funding requirements into the third quarter of 2023, including funding the on-going and future clinical trials of *TTP399*, we are evaluating several financing strategies, including direct equity investments and the potential licensing and monetization of other Company programs such as *HPP737*. The Company also has a promissory note of \$12.5 million under

the G42 Purchase Agreement payable to the Company on or before May 31, 2023 (see Note 9) and on July 25, 2022, announced a \$10.0 million investment by CinPax, LLC (see Note 14).

The Company may also use its remaining availability of \$37.3 million under our Sales Agreement with Cantor Fitzgerald pursuant to which the Company may offer and sell, from time to time shares of the Company's Class A common stock (the "ATM Offering") and the ability to sell an additional 9,437,376 shares of Class A common stock under the LPC Purchase Agreement based on the remaining number of registered shares. However, the ability to use these sources of capital is dependent on a number of factors, including the prevailing market price of and the volume of trading in the Company's Class A common stock. See Note 9 for further details.

These conditions raise substantial doubt about the Company's ability to continue as a going concern. If we are unable to raise additional capital as and when needed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition.

The Company's financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Condensed Consolidated Financial Statements do not include adjustments to reflect the possible future effects on the recoverability and classification of recorded assets or the amounts of liabilities that might be necessary should the Company be unable to continue as a going concern.

#### **Note 2: Summary of Significant Accounting Policies**

#### Unaudited Interim Financial Information

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying Condensed Consolidated Balance Sheet as of June 30, 2022, Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2022, and 2021, Condensed Consolidated Statement of Changes in Redeemable Noncontrolling Interest and Stockholders' Deficit for the three and six months ended June 30, 2022, and 2021 and Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022, and 2021 are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These financial statements should be read in conjunction with the audited financial statements and the accompanying notes for the year ended December 31, 2021, contained in the Company's Annual Report on Form 10-K. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of June 30, 2022, the results of operations for the three and six months ended June 30, 2022, and 2021 and cash flows for the six months ended June 30, 2022, and 2021. The December 31, 2021 Condensed Consolidated Balance Sheet included herein was derived from the audited financial statements but does not include all disclosures or notes required by GAAP for complete financial statements.

The financial data and other information disclosed in these notes to the financial statements related to the three and six months ended June 30, 2022, and 2021 are unaudited. Interim results are not necessarily indicative of results for an entire year.

The Company does not have any components of other comprehensive income recorded within its Condensed Consolidated Financial Statements, and, therefore, does not separately present a statement of comprehensive income in its Condensed Consolidated Financial Statements.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of 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

On an ongoing basis, the Company evaluates its estimates, including those related to the grant date fair value of equity awards, the fair value of warrants to purchase shares of its Class A common stock, the fair value of the Class B common stock, the useful lives of property and equipment, the fair value of derivative liabilities, the fair value of the promissory note receivable, and the fair value of the Company's debt, among others. The Company bases its estimates on historical

experience and on various other assumptions that it believes to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities.

#### Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash on deposit with one financial institution. The balances of these cash accounts frequently exceed insured limits.

One customer represented 100% of the revenue earned during the three and six months ended June 30, 2022, and 2021, respectively.

#### Cash and Cash Equivalents

The Company considers any highly liquid investments with an original maturity of three months or less to be cash and cash equivalents.

#### Investments

Investments in entities in which the Company has no control or significant influence, is not the primary beneficiary, and have a readily determinable fair value are classified as equity investments with readily determinable fair value. The investments are measured at fair value based on a quoted market price per unit in active markets multiplied by the number of units held without consideration of transaction costs (Level 1). Gains and losses are recorded in other income (expense), net on the Consolidated Statements of Operations.

Equity investments without readily determinable fair value include ownership rights that do not provide the Company with control or significant influence and these investments do not have readily determinable fair values. The Company has elected to measure its equity investments without readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment.

#### Revenue Recognition

The Company uses the revenue recognition guidance established by ASC Topic 606, *Revenue From Contracts With Customers* ("ASC 606"). When an agreement falls under the scope of other standards, such as ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), the Company will apply the recognition, measurement, presentation, and disclosure guidance in ASC 606 to the performance obligations in the agreements if those performance obligations are with a customer. Revenue recognized by analogizing to ASC 606, is recorded as collaboration revenue on the statements of operations.

The majority of the Company's revenue results from its license and collaboration agreements associated with the development of investigational drug products. The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. For each contract meeting these criteria, the Company identifies the performance obligations included within the contract. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. The Company then recognizes revenue under each contract as the related performance obligations are satisfied.

The transaction price under the contract is determined based on the value of the consideration expected to be received in exchange for the transferred assets or services. Development, regulatory and sales milestones included in the Company's collaboration agreements are considered to be variable consideration. The amount of variable consideration expected to be received is included in the transaction price when it becomes probable that the milestone will be met. For contracts with multiple performance obligations, the contract's transaction price is allocated to each performance obligation using the Company's best estimate of the standalone selling price of each distinct good or service in the contract. The primary method used to estimate standalone selling price is the expected cost-plus margin approach.

# Research and Development

Major components of research and development costs include cash and share-based compensation, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, regulatory and compliance costs, fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf, facilities costs, and overhead costs. Research and development costs are expensed as incurred.

The Company records accruals based on estimates of the services received, efforts expended, and amounts owed pursuant to contracts with numerous contract research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical study activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events and the completion of portions of the clinical study or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical studies are recognized based on the Company's estimate of the degree of completion of the event or events specified in the specific clinical study.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the Condensed Consolidated Statements of Operations as the Company receives the related goods or services.

Research and development costs that are reimbursed under a cost-sharing arrangement are reflected as a reduction of research and development expense.

#### Recently Issued Accounting Pronouncements

Fair Value Measurements: In June 2022, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2022-03 "Fair Value Measurements (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions." These amendments clarify that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. This guidance is effective for public business entities for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted. The Company has assessed ASU 2022-03 and early adopted the guidance during the second quarter of 2022. The adoption did not have a material impact on the Company's Condensed Consolidated Financial Statements.

#### **Note 3: Collaboration Agreements**

#### G42 Purchase Agreement and Cogna Collaborative and License Agreement

The Company and G42 Investments AI Holding RSC Ltd, a private limited company ("G42 Investments"), entered into a Common Stock Purchase Agreement (the "G42 Purchase Agreement"), pursuant to which the Company sold to G42 Investments 10,386,274 shares of the Company's Class A common stock, par value \$0.01 per share (the "G42 Common Stock) at a price per share of approximately \$2.41, for an aggregate purchase price of \$25.0 million, which was paid (i) \$12.5 million in cash at the closing and (ii) \$12.5 million in the form of a promissory note of G42 Investments to be paid at the one-year anniversary of the execution of the G42 Purchase Agreement. As part of the G42 Purchase Agreement, G42 Investments put forward a director as appointee and the Company's board of directors approved appointing the new director to the Company's board.

G42 Investments has agreed to certain transfer restrictions (including restrictions on short sales or similar transactions) and restrictions on further acquisitions of shares, in each case subject to specified exceptions. Following the expiration of a lock up period, from the period May 31, 2022 until December 31, 2024 (or if earlier, the date of receipt of U.S. Food and Drug Administration ("FDA") approval in the U.S. for *TTP399* (the "FDA Approval") of *TTP399*), the Company has granted to G42 Investments certain shelf and piggyback registration rights with respect to those shares of Class A common stock issued to G42 Investments pursuant to the G42 Purchase Agreement, including the ability to conduct an underwritten offering to resell such shares under certain circumstances. The registration rights include customary cooperation, cut-back, expense reimbursement, and indemnification provisions.

Contemporaneously with the G42 Purchase Agreement, effective on May 31, 2022, the Company entered into a collaboration and license agreement (the "Cogna Agreement") with Cogna Technology Solutions LLC, an affiliate of G42 Investments ("Cogna") ("Collaboration Partner"), which requires Cogna to work with the Company in performing Phase 3 clinical trials for the Company's *TTP399* compound (the "Licensed Product") as well as jointly creating a global development plan to develop, market, and commercialize *TTP399* in certain countries in the Middle East, Africa, and Central Asia (the "Partner Territory"). Under the terms of the Cogna Agreement, Cogna will obtain rights to the Company's license of *TTP399*, for purposes of performing Phase 3 clinical trials in the Partner Territory, but will not have access to the various intellectual property ("IP") related to the license and *TTP399*. Specifically, the Company will share various protocols with Cogna related to conducting the clinical trials and will provide the patient dosages and placebo of *TTP399* needed to conduct the trials. Separately, the Company will conduct its Phase 3 clinical trials for *TTP399* in the U.S. at its own cost that similarly

will not be reimbursed. The results of each party's Phase 3 clinical trials will be combined by the Company to seek FDA approval in the U.S. for TTP399.

Under the Cogna Agreement, Cogna has the right to develop and commercialize the Licensed Product in the Partner Territory at its own cost once restrictions on the use of the IP have been lifted by the Company. The Cogna Agreement determined which specific countries in the Partner Territory that Cogna may pursue development and commercialization and provides the Company with the ability to determine when Cogna can benefit from this IP through the powers granted to the Company to approve the global development plan. Further, the Company may supply at cost, or Cogna may manufacture, *TTP399* for commercial sale under terms to be agreed upon by the parties at a later date.

The G42 Purchase Agreement also provides for, following the receipt of FDA approval of the Licensed Product, at the option of G42 Investments, either (a) the issuance of the Company's Class A common stock (the "Milestone Shares") having an aggregate value equal to \$30.0 million or (b) the payment by the Company of \$30.0 million in cash (the "Milestone Cash Payment"). The issuance of the Milestone Shares or the payment of the Milestone Cash Payment, as applicable, are conditioned upon receipt of the FDA Approval and subject to certain limitations and conditions set forth in the G42 Purchase Agreement. There can be no assurance that the FDA Approval will be granted or as to the timing thereof.

Once commercialization takes place in the Partner Territories, the Company will receive royalties of 8% from Cogna on the sale of the Licensed Product for ten years after the first commercial sale of the Licensed Product.

Common stock is generally recorded at fair value at the date of issuance. In determining the fair value of the Class A common stock issued to G42 Investments, the Company considered the closing price of the common stock on the effective date. The Company did not make an adjustment to the fair value for sale restrictions on the stock in accordance with guidance recently adopted in ASU 2022-03. See the "Recently Issued Accounting Guidance" in this 10-Q for details of the ASU. Accordingly, the Company determined that cash consideration of \$5.7 million should be recorded as fair value of the Class A common stock at the effective date, utilizing the Class A common stock closing price of \$0.55 at the effective date.

A premium was paid on the Class A common stock by G42 Investments of \$18.7 million, net of a note receivable discount of \$0.6 million. This premium is determined to be the transaction price for all remaining obligations under the agreements, which will be accounted for under ASC 808 or ASC 606 based on determination of the unit of account.

The Company determined that certain commitments under the agreements are in the scope of ASC 808 as both the Company and Cogna are active participants in the clinical trials of the Licensed Product, and both are exposed to significant risks and rewards based on the success of the clinical trials and subsequent FDA approval. Cogna is determined to be a vendor of the Company during the clinical trial phase, working on the Company's behalf to complete R&D activities, and not in a customer capacity. The Company accounted for the commitments related to the clinical trials, which includes transfer of trial protocols, supply of clinical trial dosages, and collaboration on the joint development committee ("JDC") as an ASC 808 unit of account, applying the recognition and measurement principles of ASC 606 by analogy. The Company will recognize collaboration revenue for its development activities under ASC 808 over time based on the estimated period of performance.

By applying the principals in ASC 606 by analogy, the Company identified the performance obligation and considered the timing of satisfaction of the obligation to account for the pattern of revenue recognition. In order to recognize collaboration revenue, generally, the Company would have to complete its performance obligation and Cogna would need to be able to use and benefit from delivery of the assets or services. The performance obligation under the agreements that fall within the 808 unit of account are concentrated in the Phase 3 clinical trials. As of June 30, 2022, the Phase 3 clinical trials had not commenced. Accordingly, no collaboration revenue was recognized for the ASC 808 unit of account during the three and six months ended June 30, 2022.

The Company identified certain commitments that are in the scope of ASC 606 as Cogna's relationship is that of a customer for these commitments. The significant performance obligations that are in the scope of ASC 606 are (1) the development, commercialization and manufacturing license of the IP once restrictions on the use of the IP have been lifted by the Company and (2) a potential material right to a commercial supply agreement. The material right is predicated upon FDA approval. The Company will recognize revenue from the development, commercial and manufacturing license at a point in time when the Company releases the restrictions on the use of the IP, which is expected to be after the Licensed Product is approved by the FDA. As a result, the Company has not recognized any revenue under the ASC 606 unit of account during the three and six months ended June 30, 2022.

As of June 30, 2022, the Company has recognized the cash and a non-interest bearing promissory note receivable of with a principal balance of \$12.5 million. The promissory note receivable was classified and accounted for under ASC 310 and was measured at its fair value of and will be subsequently remeasured at its amortized cost thru its maturity date. The

Company also recorded the \$18.7 million as deferred revenue in the Consolidated Balance Sheets, as none of the underlying performance obligations had been satisfied as of and for the three and six months ended June 30, 2022.

#### Reneo License Agreement

The Company is party to a license agreement with Reneo Pharmaceuticals, Inc. ("Reneo") (the "Reneo License Agreement"), under which Reneo obtained an exclusive, worldwide, sublicensable license to develop and commercialize the Company's peroxisome proliferation activated receptor delta (PPAR-δ) agonist program, including the compound *HPP593*, for therapeutic, prophylactic or diagnostic application in humans.

The Company has fully allocated the transaction price to the license and the technology transfer services, which represents a single combined performance obligation because they were not capable of being distinct on their own. The revenue related to this performance obligation was recognized on a straight-line basis over the technology transfer service period.

The revenue related to this performance obligation has been fully recognized and no revenue related to this performance obligation was recognized for the three and six months ended June 30, 2022, and 2021. There have been no adjustments to the transaction price for the performance obligations under the Reneo License Agreement during the three and six months ended June 30, 2022, and 2021.

#### **Huadong License Agreement**

The Company is party to a License Agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong") (the "Huadong License Agreement"), under which Huadong obtained an exclusive and sublicensable license to develop and commercialize the Company's glucagon-like peptide-1 receptor agonist ("GLP-1r") program, including the compound *TTP273*, for therapeutic uses in humans or animals, in China and certain other pacific rim countries, including Australia and South Korea (collectively, the "Huadong License Territory"). Additionally, under the Huadong License Agreement, the Company obtained a non-exclusive, sublicensable, royalty-free license to develop and commercialize certain Huadong patent rights and know-how related to the Company's GLP-1r program for therapeutic uses in humans or animals outside of the Huadong License Territory.

On January 14, 2021, the Company entered into the First Huadong Amendment which eliminated the Company's obligation to sponsor a multiregion clinical trial (the "Phase 2 MRCT"), and corresponding obligation to contribute up to \$3.0 million in support of such trial. The amendment also reduced the total potential development and regulatory milestone payments by \$3.0 million.

Prior to the First Amendment, the Company had allocated a portion of the transaction price to the obligation to sponsor and conduct a portion of the Phase 2 MRCT. Upon the removal of this performance obligation, the Company evaluated the impact of the modification under the provisions of ASC Topic 606 and performed a reallocation of the transaction price among the remaining performance obligations. This resulted in the recognition of approximately \$1.0 million of revenue on a cumulative catch-up basis during the six months ended June 30, 2021. The majority of the transaction price originally allocated to the Phase 2 MRCT performance obligation was reallocated to the license and technology transfer services combined performance obligation discussed below, which had already been completed. The reallocation of the purchase price in connection with the First Huadong Amendment was made based on the relative estimated selling prices of the remaining performance obligations.

The significant performance obligations under this license agreement, as amended, were determined to be (i) the exclusive license to develop and commercialize the Company's GLP-1r program, (ii) technology transfer services related to the chemistry and manufacturing know-how for a defined period after the effective date, (iii) the Company's obligation to participate on a joint development committee (the "JDC"), and (iv) other obligations considered to be de minimis in nature.

The Company has determined that the license and technology transfer services related to the chemistry and manufacturing know-how represent a combined performance obligation because they were not capable of being distinct on their own. The Company also determined that there was no discernible pattern in which the technology transfer services would be provided during the transfer service period. As such, the Company recognized the revenue related to this combined performance obligation using the straight-line method over the transfer service period. This combined performance obligation was considered complete as of June 30, 2021. The Company recognized \$1.0 million of revenue related to this combined performance obligation during the six months ended June 30, 2021. During the six months ended June 30, 2022, the transaction price for this performance obligation was increased by \$2.0 million due to the satisfaction of a development milestone under the license agreement. This amount was fully recognized as revenue during the six months ended June 30, 2022, as the related performance obligation was fully satisfied.

A portion of the transaction price allocated to the obligation to participate in the JDC to oversee the development of products and the Phase 2 MRCT in accordance with the development plan remained deferred as of June 30, 2022, and revenue will be recognized using the proportional performance model over the period of the Company's participation on the JDC. The unrecognized amount of the transaction price allocated to this performance obligation as of June 30, 2022, was de minimis. An immaterial amount of revenue for this performance obligation has been recognized during six months ended June 30, 2022, and 2021.

#### Newsoara License Agreement-

The Company is party to a license agreement with Newsoara Biopharma Co., Ltd., ("Newsoara") (the "Newsoara License Agreement") under which Newsoara obtained an exclusive and sublicensable license to develop and commercialize the Company's phosphodiesterase type 4 inhibitors ("PDE4") program, including the compound *HPP737*, in China, Hong Kong, Macau, Taiwan and other pacific rim countries (collectively, the "Newsoara License Territory"). Additionally, under the Newsoara License Agreement, the Company obtained a non-exclusive, sublicensable, royalty-free license to develop and commercialize certain Newsoara patent rights and know-how related to the Company's PDE4 program for therapeutic uses in humans outside of the Newsoara License Territory.

The Company has fully allocated the transaction price to the license and the technology transfer services which represents a single performance obligation because they were not capable of being distinct on their own. The Company recognized revenue for this performance obligation using the straight-line method over the transfer service period. The revenue for this performance obligation has been fully recognized as of June 30, 2022. No revenue related to this performance obligation was recognized and there have been no changes to the transaction price during the three and six months ended June 30, 2022, and 2021.

#### Anteris License Agreement

On December 11, 2020, the Company entered into a license agreement with Anteris Bio, Inc. ("Anteris") (the "Anteris License Agreement"), under which Anteris obtained a worldwide, exclusive and sublicensable license to develop and commercialize the Company's Nrf2 activator, *HPP971*.

Under the terms of the Anteris License Agreement, Anteris paid the Company an initial license fee of \$2.0 million. The Company is eligible to receive additional potential development, regulatory, and sales-based milestone payments totaling up to \$151.0 million. Anteris is also obligated to pay the Company royalty payments at a double-digit rate based on annual net sales of licensed products. Such royalties will be payable on a licensed product-by-licensed product basis until the latest of expiration of the licensed patents covering a licensed product in a country, expiration of data exclusivity rights for a licensed product in a country, or a specified number of years after the first commercial sale of a licensed product in a country. As additional consideration, the Company received preferred stock representing a minority ownership interest in Anteris.

Pursuant to the terms of the Anteris License Agreement, the Company was required to provide technology transfer services for a 30-day period after the effective date. In accordance with ASC Topic 606, the Company identified all the performance obligations at the inception of the Anteris License Agreement. The significant obligations were determined to be the license and the technology transfer services. The Company has determined that the license and technology transfer services represent a single performance obligation because they were not capable of being distinct on their own. The transaction price has been fully allocated to this combined performance obligation and consisted of the \$2.0 million initial license payment, as well as the fair value of the equity interest received in Anteris of \$4.2 million. The revenue related to this performance obligation was fully recognized during the year ended December 31, 2020, as the technology transfer services were considered complete as of that date. No revenue related to this performance obligation was recognized and there have been no changes to the transaction price during the three and six months ended June 30, 2022, and 2021.

#### JDRF Agreement

In August 2017, the Company entered into a research and collaboration agreement with JDRF International (the "JDRF Agreement") to support the funding of the Simplici-T1 Study, a Phase 2 study to explore the effects of *TTP399* in patients with type 1 diabetes. The JDRF Agreement was amended in June 2021 to provide additional funding for the Company's mechanistic study exploring the effects of *TTP399* on ketone body formation during a period of insulin withdrawal in people with type 1 diabetes. According to the terms of the JDRF Agreement, JDRF will provide research funding of up to \$3.4 million based on the achievement of research and development milestones, with the total funding provided by JDRF not to exceed approximately one-half of the total cost of the project. Additionally, the Company has the obligation to make certain milestone payments to JDRF upon the commercialization, licensing, sale or transfer of *TTP399* as a treatment for type 1 diabetes.

Payments that the Company receives from JDRF under this agreement will be recorded as restricted cash and current liabilities and recognized as an offset to research and development expense, based on the progress of the project, and only to the extent that the restricted cash is utilized to fund such development activities. As of June 30, 2022, the Company had received funding under this agreement of \$3.4 million. Research and development costs have been offset by a total of \$3.4 million over the course of this agreement.

#### **Contract Liabilities**

Contract liabilities related to the Company's collaboration agreements consisted of the following (in thousands):

	J	June 30,	2022	Dece	mber	31, 2021
Current portion of contract liabilities	\$		26	\$		35
Contract liabilities, net of current portion			18,669			
Total contract liabilities	\$		18,695	\$		35
Changes in short-term and long-term contract liabilities for the six months ended	June	30,	2022,	were	as	follows:
			Cor	ntract Li	abiliti	ies
Balance on January 1, 2022			\$			35
Reclassification of the beginning contract liabilities to revenue, as the result of performance obligations satisfi	ed					(9)
Consideration received in advance and not recognized as revenue						18,669
Balance on June 30, 2022			\$			18,695

### **Note 4: Share-Based Compensation**

The Company has issued non-qualified stock option awards to management, other key employees, consultants, and non-employee directors. These option awards generally vest ratably over a three-year period and the option awards expire after a term of ten years from the date of grant. As of June 30, 2022, the Company had total unrecognized stock-based compensation expense for its outstanding stock option awards of approximately \$1.7 million, which is expected to be recognized over a weighted average period of 2.3 years. The weighted average grant date fair value of options granted during the six months ended June 30, 2022, and 2021 was \$0.65 and \$2.21 per option, respectively. The aggregate intrinsic value of the in-the-money awards outstanding at June 30, 2022, was de minimis.

On February 27, 2022, Ms. Deepa Prasad notified the Board of Directors (the "Board") of the Company of her decision to resign from her positions as Chief Executive Officer, President, and Board member, effective as of March 29, 2022, and served in these roles through March 29, 2022 (the "Effective Date"). Ms. Prasad agreed to serve as a Strategic Advisor to the Company for six months after the Effective Date. Ms. Prasad will retain 624,659 of the outstanding options previously granted to her, which will vest at the end of the 15-month period following the Effective Date. As a result of the separation agreement, these options were modified to accelerate vesting at the Effective Date. These options will remain exercisable for the original ten-year period and the remaining 1,873,976 of her options were cancelled. The additional stock compensation expense for the modification during the six months ended June 30, 2022, was de minimis.

The following table summarizes the activity related to the stock option awards for the six months ended June 30, 2022:

	Number of Shares	Weighted Average Exercise Price	
Awards outstanding at December 31, 2021	7,056,035	\$	3.19
Granted	1,200,000		0.76
Forfeited	(2,871,508)		2.29
Awards outstanding at June 30, 2022	5,384,527	\$	3.12
Options exercisable at June 30, 2022	2,496,888	\$	5.19
Weighted average remaining contractual term	6.1 Years		
Options vested and expected to vest at June 30, 2022	4,858,805	\$	3.33
Weighted average remaining contractual term	7.6 Years		

Compensation expense related to the grants of stock options is included in research and development and general and administrative expense as follows (in thousands):

	Three Months Ended June 30,				June 30,			
		2022		2021		2022		2021
Research and development	\$	88	\$	180	\$	180	\$	356
General and administrative		79		272		463		532
Total share-based compensation expense	\$	167	\$	452	\$	643	\$	888

#### **Note 5: Investments**

In connection with the Reneo and Anteris License Agreements, the Company has received equity ownership interests of less than 20% of the voting equity of the investee. Further, the Company does not have the ability to exercise significant influence over the investees. The investments are classified as long-term investments in the Company's Consolidated Balance Sheets.

Reneo completed its initial public offering in April 2021. Prior to Reneo becoming a publicly traded company, the Company's investment in Reneo did not have a readily determinable fair value and was measured at cost less impairment, adjusted for any changes in observable prices, under the measurement alternative. Subsequent to Reneo's initial public offering, the Company's investment in Reneo is considered to have a readily determinable fair value and, as such, is adjusted to its fair value each period with changes in fair value recognized as a component of net loss.

The Company's investment in Anteris does not have a readily determinable fair value and is measured at cost less impairment, adjusted for any changes in observable prices.

The Company's investments consist of the following:

	Jun	ne 30, 2022	Dece	ember 31, 2021
Equity investment with readily determinable fair value:	·			
Reneo common stock	\$	1,527	\$	4,928
Equity investment without readily determinable fair values assessed under the measurement alternative:				
Anteris preferred stock		4,245		4,245
Total	\$	5,772	\$	9,173

No adjustments have been made to the value of the Company's investment in Anteris since its initial measurement either due to impairment or based on observable price changes. The Company recognized an unrealized loss on its investment in Reneo of \$0.2 million and \$3.4 million for the three and six months ended June 30, 2022, respectively. During the three and six months ended June 30, 2021, the Company recognized an unrealized gain on its investment in Reneo of \$2.9 million. These adjustments were recognized as a component of other income/(expense) in the Company's Condensed Consolidated Statements of Operations.

#### Note 6: Commitments and Contingencies

#### Legal Matters

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. If a specific contingent liability is determined to be probable and can be reasonably estimated, the Company accrues and discloses the amount. The Company is not currently a party to any material legal proceedings.

#### Novo Nordisk

In February 2007, the Company entered into an Agreement Concerning Glucokinase Activator Project with Novo Nordisk A/S (the "Novo License Agreement") whereby the Company obtained an exclusive, worldwide, sublicensable license under certain Novo Nordisk intellectual property rights to discover, develop, manufacture, have manufactured, use and commercialize products for the prevention, treatment, control, mitigation or palliation of human or animal diseases or conditions. As part of this license grant, the Company obtained certain worldwide rights to Novo Nordisk's GKA program, including rights to preclinical and clinical compounds such as *TTP399*. This agreement was amended in May 2019 to create

milestone payments applicable to certain specific and non-specific areas of therapeutic use. Under the terms of the amended Novo License Agreement, the Company has potential developmental and regulatory milestone payments totaling up to \$9.0 million for approval of a product for the treatment of type 1 diabetes, \$50.5 million for approval of a product for the treatment of type 2 diabetes, or \$115.0 million for approval of a product in any other indication. The Company may also be obligated to pay an additional \$75.0 million in potential sales-based milestones, as well as royalty payments, at mid-single digit royalty rates, based on tiered sales of commercialized licensed products. During the fourth quarter of 2021, the Company made a payment of \$2.0 million related to the satisfaction of the milestone to complete the phase 2 trials for *TTP399* under this agreement.

#### Note 7: Leases

The Company leases office space for its headquarters location under an operating lease. This lease commenced in November 2019 after the completion of certain tenant improvements made by the lessor. The lease includes an option to renew for a five-year term as well as an option to terminate after three years, neither of which have been recognized as part of its related right of use assets or lease liabilities as their election was not considered reasonably certain. The Company has notified the lessor that it intends to exercise the early termination option and is negotiating an amendment to the lease. Further, this lease does not include any material residual value guarantee or restrictive covenants.

At each of June 30, 2022, and December 31, 2021, the weighted average incremental borrowing rate for the operating leases held by the Company was 13.1%. At June 30, 2022, and December 31, 2021, the weighted average remaining lease terms for the operating leases held by the Company were 2.6 years and 3.1 years, respectively.

Maturities of lease liabilities for the Company's operating leases as of June 30, 2022, were as follows (in thousands):

2022 (remaining six months)	\$ 131
2023	268
2024	275
2025	23
2026	_
Thereafter	
Total lease payments	697
Less: imputed interest	(110)
Present value of lease liabilities	\$ 587

Operating lease cost and the related operating cash flows for the six months ended June 30, 2022, and 2021 were immaterial amounts.

#### **Note 8: Redeemable Noncontrolling Interest**

The Company is subject to the Exchange Agreement with respect to the vTv Units representing the 23.0% noncontrolling interest in vTv LLC outstanding as of June 30, 2022 (see Note 9). The Exchange Agreement requires the surrender of an equal number of vTv Units and Class B common stock for (i) shares of Class A common stock on a one-for-one basis or (ii) cash (based on the fair market value of the Class A common stock as determined pursuant to the Exchange Agreement), at the Company's option (as the managing member of vTv LLC), subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications. The exchange value is determined based on a 20-day volume weighted average price of the Class A common stock as defined in the Exchange Agreement, subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications.

The redeemable noncontrolling interest is recognized at the higher of (1) its initial fair value plus accumulated earnings/losses associated with the noncontrolling interest or (2) the redemption value as of the balance sheet date. At June 30, 2022, and December 31, 2021, the redeemable noncontrolling interest was recorded based on the redemption value as of the balance sheet date of \$15.9 million and \$25.0 million, respectively.

Changes in the Company's ownership interest in vTv LLC while the Company retains its controlling interest in vTv LLC are accounted for as equity transactions, and the Company is required to adjust noncontrolling interest and equity for

such changes. The following is a summary of net income attributable to vTv Therapeutics Inc. and transfers to noncontrolling interest:

	For the Three Mor	nths Ended June 30,	For the Six Months Ended June 30,			
	2022	2021	2022	2021		
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (3,151)	\$ (608)	\$ (10,158)	\$ (4,849)		
(Increase)/Decrease in vTv Therapeutics Inc. accumulated deficit for purchase of LLC Units as a result of common stock issuances	(1,361)	(115)	1,071	(2,525)		
Change from net loss attributable to vTv Therapeutics Inc. common shareholders and transfers to noncontrolling interest	\$ (4,512)	\$ (723)	\$ (9,087)	\$ (7,374)		

#### Note 9: Stockholders' Deficit

#### Amendment to Certificate of Incorporation

On May 4, 2021, the Company filed an amendment to its Amended and Restated Certificate of Incorporation (the "Charter Amendment") to increase the number of shares of Class A common stock that the Company is authorized to issue from 100,000,000 shares of Class A common stock to 200,000,000 shares of Class A common stock, representing an increase of 100,000,000 shares of authorized Class A common stock, with a corresponding increase in the total authorized common stock, which includes Class A common stock and Class B common stock, from 200,000,000 to 300,000,000, and a corresponding increase in the total authorized capital stock, which includes common stock and preferred stock, from 250,000,000 shares to 350,000,000 shares.

#### **G42 Investments Transaction**

On May 31, 2022, the Company and G42 Investments entered in to the G42 Purchase Agreement (see Note 3), pursuant to which the Company agreed to sell to G42 Investments 10,386,274 shares of the Company's Class A common stock, par value \$0.01 per share at a price per share of approximately \$2.41, for an aggregate purchase price of \$25.0 million, consisting of (i) \$12.5 million in cash at the closing of the transaction and (ii) \$12.5 million in the form of a promissory note of G42 Investments to be paid at the one-year anniversary of the execution of the G42 Purchase Agreement.

#### ATM Offering

In April 2020, the Company entered into the Sales Agreement with Cantor Fitzgerald as the sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of its Class A common stock, par value \$0.01 per share, having an aggregate offering price of up to \$13.0 million by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act (the "ATM Offering"). The shares are offered and sold pursuant to the Company's shelf registration statement on Form S-3. In no event will we sell Class A common stock under this registration statement with a value exceeding more than one-third of the "public float" (the market value of our Class A common stock and any other equity securities that we may issue in the future that are held by non-affiliates) in any 12-calendar month period so long as our public float remains below \$75 million.

On January 14, 2021, and June 25, 2021, the Company filed a prospectus supplement in connection with the ATM Offering to increase the size of the at-the-market offering pursuant to which the Company may offer and sell, from time to time, through or to Cantor, as sales agent or principal, shares of the Company's Class A common stock, by an aggregate offering price of \$5.5 million and \$50.0 million, respectively.

During the three and six months ended June 30, 2021, the Company sold 2,180,337 shares of its Class A common stock under the ATM Offering for net proceeds of \$5.3 million.

During the three and six months ended June 30, 2022, the Company did not sell any shares under the ATM Offering.

#### Lincoln Park Capital Transaction

On November 24, 2020, the Company entered into the LPC Purchase Agreement and a registration rights agreement (the "Registration Rights Agreement"), pursuant to which the Company has the right to sell to Lincoln Park shares of the Company's Class A common stock having an aggregate value of up to \$47.0 million, subject to certain limitations and conditions set forth in the LPC Purchase Agreement. The Company will control the timing and amount of any sales of shares

to Lincoln Park. pursuant to the LPC Purchase Agreement. During the three and six months ended June 30, 2021, the Company sold 441,726 and 3,941,726 shares under the LPC Purchase Agreement for total proceeds of \$1.0 million and \$9.1 million, respectively.

During the three and six months June 30, 2022, the Company did not sell any shares under the LPC Purchase Agreement.

#### **Note 10: Related-Party Transactions**

#### MacAndrews & Forbes Incorporated

As of June 30, 2022, subsidiaries and affiliates of MacAndrews & Forbes Incorporated (collectively "MacAndrews") indirectly controlled 23,084,267 shares of the Company's Class B common stock and 36,519,212 shares of the Company's Class A common stock. As a result, MacAndrews' holdings represent approximately 59.4% of the combined voting power of the Company's outstanding common stock.

The Company has entered into several agreements with MacAndrews or its affiliates as further detailed below:

### Letter Agreements

The Company has previously entered into the Letter Agreements with MacAndrews. Under the terms of the Letter Agreements, the Company had the right to sell to MacAndrews shares of its Class A common stock at a specified price per share, and MacAndrews has the right (exercisable up to three times) to require the Company to sell to it shares of Class A common stock at the same price. In addition, in connection with and as a commitment fee for the entrance into certain of these Letter Agreements, the Company also issued MacAndrews warrants (the "Letter Agreement Warrants") to purchase additional shares of the Company's Class A common stock.

The Letter Agreement Warrants have been recorded as warrant liability, related party within the Company's Condensed Consolidated Balance Sheets based on their fair value. The issuance of the Letter Agreement Warrants was considered to be a cost of equity recorded as a reduction to additional paid-in capital.

#### Exchange Agreement

The Company and MacAndrews are party to an exchange agreement (the "Exchange Agreement") pursuant to which the vTv Units (along with a corresponding number of shares of the Class B common stock) are exchangeable for (i) shares of the Company's Class A common stock on a one-for-one basis or (ii) cash (based on the fair market value of the Class A common stock as determined pursuant to the Exchange Agreement), at the Company's option (as the managing member of vTv LLC), subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications. Any decision to require an exchange for cash rather than shares of Class A common stock will ultimately be determined by the entire board of directors of vTv Therapeutics Inc. (the "Board of Directors"). As of June 30, 2022, MacAndrews had not exchanged any shares under the provisions of the Exchange Agreement.

### Tax Receivable Agreement

The Company and MacAndrews are party to a tax receivable agreement (the "Tax Receivable Agreement"), which provides for the payment by the Company to M&F TTP Holdings Two LLC ("M&F"), as successor in interest to vTv Therapeutics Holdings, LLC ("vTv Therapeutics Holdings"), and M&F TTP Holdings LLC (or certain of its transferees or other assignees) of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that the Company actually realizes (or, in some circumstances, the Company is deemed to realize) as a result of (a) the exchange of Class B commons stock, together with the corresponding number of vTv Units, for shares of the Company's Class A common stock (or for cash), (b) tax benefits related to imputed interest deemed to be paid by the Company as a result of the Tax Receivable Agreement and (c) certain tax benefits attributable to payments under the Tax Receivable Agreement.

As no shares have been exchanged by MacAndrews pursuant to the Exchange Agreement (discussed above), the Company has not recognized any liability, nor has it made any payments pursuant to the Tax Receivable Agreement as of June 30, 2022.

#### Investor Rights Agreement

The Company is party to an investor rights agreement with M&F, as successor in interest to vTv Therapeutics Holdings (the "Investor Rights Agreement"). The Investor Rights Agreement provides M&F with certain demand, shelf, and piggyback registration rights with respect to its shares of Class A common stock and also provides M&F with certain

governance rights, depending on the size of its holdings of Class A common stock. Under the Investor Rights Agreement, M&F was initially entitled to nominate a majority of the members of the Board of Directors and designate the members of the committees of the Board of Directors.

#### **Note 11: Income Taxes**

The Company is subject to U.S. federal income taxes as well as state taxes. The Company did not record an income tax provision for the three months ended June 30, 2022. The Company's income tax provision for the six months ended June 30, 2022, was \$0.2 million related to foreign withholding taxes. The Company did not record an income tax provision for the three months ended June 30, 2021. The Company's income tax provision for the six months ended June 30, 2021, was a de minimis amount related to foreign withholding taxes.

Management has evaluated the positive and negative evidence surrounding the realization of its deferred tax assets, including the Company's history of losses, and under the applicable accounting standards determined that it is more-likely-than-not that the deferred tax assets will not be realized. The difference between the effective tax rate of the Company and the U.S. statutory tax rate of 21% on June 30, 2022, is due to the valuation allowance against the Company's expected net operating losses.

As discussed in Note 10, the Company is party to a tax receivable agreement with a related party which provides for the payment by the Company to M&F (or certain of its transferees or other assignees) of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that the Company actually realizes (or, in some circumstances, the Company is deemed to realize) as a result of certain transactions. As no transactions have occurred which would trigger a liability under this agreement, the Company has not recognized any liability related to this agreement as of June 30, 2022.

#### Note 12: Net Loss per Share

Basic loss per share is computed by dividing net loss attributable to vTv Therapeutics Inc. by the weighted-average number of shares of Class A common stock outstanding during the period. Diluted loss per share is computed giving effect to all potentially dilutive shares. Diluted loss per share for all periods presented is the same as basic loss per share as the inclusion of potentially issuable shares would be antidilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share of Class A common stock is as follows (in thousands, except share and per share amounts):

		For the Three Months Ended June 30,			For the Six Months Ended June 30,			
		2022		2021		2022		2021
Numerator:								
Net loss	\$	(4,091)	\$	(841)	\$	(13,515)	\$	(6,783)
Less: Net loss attributable to noncontrolling interests		(940)		(233)		(3,357)		(1,934)
Net loss attributable to common shareholders of vTv Therapeutics Inc., basic and diluted	S	(3,151)		(608)		(10,158)		(4,849)
Denominator:								
Weighted average vTv Therapeutics Inc. Class A common stock, basic and diluted		70,366,823		58,615,137		68,664,259		57,549,755
Net loss per share of vTv Therapeutics Inc. Class A common stock, basic and diluted	\$	(0.04)	\$	(0.01)	\$	(0.15)	\$	(0.08)

Potentially dilutive securities not included in the calculation of diluted net loss per share are as follows:

	June 30, 2022	June 30, 2021
Class B common stock (1)	23,093,860	23,093,860
Common stock options granted under the Plan	5,384,527	4,474,403
Common stock warrants	2,014,503	2,014,503
Total	30,492,890	29,582,766

(1) Shares of Class B common stock do not share in the Company's earnings and are not participating securities. Accordingly, separate presentation of loss per share of Class B common stock under the two-class method has not been provided. Each share of Class B common stock (together with a corresponding vTv Unit) is exchangeable for one share of Class A common stock.

#### **Note 13: Fair Value of Financial Instruments**

The carrying amount of certain of the Company's financial instruments, including cash and cash equivalents, net accounts receivable, note receivable, accounts payable, and other accrued liabilities, approximate fair value due to their short-term nature.

#### Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments. The Company determined that the promissory note receivable was level 2 and the fair value measurement was based on the market yield curves. The following table summarizes the conclusions reached regarding fair value measurements as of June 30, 2022, and December 31, 2021 (in thousands):

		ee at June 30, 2022	Marke	Prices in Active ets for Identical Assets (Level 1)	S	ignificant C Observabl Inputs (Level 2)	le	Unobse	gnificant rvable Inputs Level 3)
Assets:		,							
Equity securities with readily determinable fair value	\$	1,527	\$	1,527	\$		_	\$	_
Total	\$	1,527	\$	1,527	\$			\$	_
Liabilities:									
Warrant liability, related party (1)	\$	717	\$	_	\$		_	\$	717
Total	•	717	\$		\$			\$	717
iotai	Ψ	, 1,			_				
Total		alance at ther 31, 2021	Marke	Prices in Active ets for Identical Assets (Level 1)	s	ignificant C Observabl Inputs (Level 2)	le	Unobse	gnificant rvable Inputs Level 3)
Assets:		nlance at	Marke	ets for Identical Assets	s	Observabl Inputs	le	Unobse	gnificant rvable Inputs
		nlance at	Marke	ets for Identical Assets	\$	Observabl Inputs	le	Unobse	gnificant rvable Inputs
Assets:		alance at aber 31, 2021	Marke	ets for Identical Assets (Level 1)		Observabl Inputs	le	Unobse	gnificant rvable Inputs
Assets:  Equity securities with readily determinable fair value		alance at ther 31, 2021	Marke	ets for Identical Assets (Level 1) 4,928		Observabl Inputs	le	Unobse	gnificant rvable Inputs
Assets:  Equity securities with readily determinable fair value		alance at ther 31, 2021	Marke	ets for Identical Assets (Level 1) 4,928		Observabl Inputs	le	Unobse	gnificant rvable Inputs
Assets:  Equity securities with readily determinable fair value  Total		alance at ther 31, 2021	Marke	ets for Identical Assets (Level 1) 4,928		Observabl Inputs	le	Unobse	gnificant rvable Inputs

<sup>(1)</sup> Fair value determined using the Black-Scholes option pricing model. Expected volatility is based on the historical volatility of the Company's common stock over the most recent period. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of valuation.

	Balance	e at January 1	Net Change in value included in earnings	Purchases / Issuance	Sales / Repurchases	Balance at June 30,
2022						
Warrant liability, related party	\$	1,262	\$ (545)	\$ 	\$ 	\$ 717
Total	\$	1,262	\$ (545)	\$ 	\$ 	\$ 717
2021						
Warrant liability, related party	\$	2,871	\$ 717	\$ 	\$ <u> </u>	\$ 3,588
Total	\$	2,871	\$ 717	\$ 	\$ 	\$ 3,588

During the three and six months ended June 30, 2021, Reneo completed its initial public offering. As a result, the fair value of the Company's investment in Reneo's common stock now has a readily determinable market value and is no longer eligible for the practical expedient for investments without readily determinable fair market values. As such, the Company's investment in Reneo is adjusted each reporting period to its fair value based on its most recent closing price, which is considered a Level 1 fair value measurement under the fair value hierarchy.

There were no transfers into or out of level 3 instruments and/or between level 1 and level 2 instruments during the three and six months ended June 30, 2022. Gains and losses recognized due to the change in fair value of the warrant liability, related party are recognized as a component of other (expense) income, related party in the Condensed Consolidated Statements of Operations.

The fair value of the Letter Agreement Warrants was determined using the Black-Scholes option pricing model or option pricing models based on the Company's current capitalization. Expected volatility is based on the historical volatility of the Company's common stock over the most recent period. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of valuation. Significant inputs utilized in the valuation of the Letter Agreement Warrants as of June 30, 2022, and December 31, 2021, were:

	June 30	, 2022	December	31, 2021
	Range	Weighted Average	Range	Weighted Average
Expected volatility	83.47% - 138.02%	117.64%	82.68% - 142.86%	128.13%
Risk-free interest rate	2.95% - 3.00%	3.00%	0.95% - 1.26%	1.15%

The weighted average expected volatility and risk-free interest rate was based on the relative fair values of the warrants.

Changes in the unobservable inputs noted above would impact the amount of the liability for the Letter Agreement Warrants. Increases (decreases) in the estimates of the Company's annual volatility would increase (decrease) the liability and an increase (decrease) in the annual risk-free rate would increase (decrease) the liability.

#### **Note 14: Subsequent Events**

### CinPax Partnership

On July 25, 2022, the Company and CinPax, LLC ("CinPax"), a subsidiary of CinRx Pharma, LLC ("CinRx") entered into a Common Stock and Warrant Purchase Agreement (the "CinRx Purchase Agreement"). Under the terms of the CinRx Purchase Agreement, CinPax acquired 4,154,549 shares of Class A common stock at an issue price of approximately \$2.41 per share, for an aggregate purchase price of \$10.0 million, consisting of (i) \$6.0 million in cash at the closing of the transaction and (ii) \$4.0 million in the form of a promissory note of CinPax payable on November 22, 2022. The CinRx Purchase Agreement also provides CinRx a warrant to purchase up to 1,200,000 shares of Class A common stock at an initial exercise price of approximately \$0.72 per share, that become exercisable upon agreed vesting triggers (including FDA Approval of *TTP399*). In addition to the investment, the CinRx Purchase Agreement sets forth the terms under which the Company will leverage the CinRx team's industry experience to collaborate on the oversight of the clinical trials for pharmaceutical products that contain *TTP399*.

#### Leadership

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On July 25, 2022, the Company entered into an employment agreement with Paul Sekhri, who was appointed President and Chief Executive Officer and a member of the Board (the "Sekhri Employment Agreement"). In addition to outlining the terms of Mr. Sekhri's compensation, it also provides for the grant of stock options (the "Options") to purchase 2,200,000 shares of Class A common stock at an exercise price of \$0.79 per share pursuant to an inducement award agreement (the "Inducement Award Agreement"). Subject to potential acceleration upon the achievement of certain performance metrics as set forth in the Inducement Award Agreement, 25% of the Options will vest on the first anniversary of the grant date and the remaining 75% of the Options will vest quarterly over three years thereafter. Upon certain terminations of employment, a portion of the Options will vest on a pro rata basis based on the number of days employed during the four-year term.

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

As used in this Quarterly Report on Form 10-Q, the "Company", the "Registrant", "we" or "us" refer to vTv Therapeutics Inc. and "vTv LLC" refers to vTv Therapeutics LLC. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes that appear elsewhere in this report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, assumptions and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report under "Part II, Other Information—Item 1A, Risk Factors." Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies and operations, financing plans, potential growth opportunities, potential market opportunities, potential results of our drug development efforts or trials, and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions and the negatives of those terms. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's plans, estimates, assumptions and beliefs only as of the date of this report. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

#### **Company Overview**

We are a clinical stage pharmaceutical company focused on treating metabolic and inflammatory diseases to minimize their long-term complications and improve the lives of patients. We have an innovative pipeline of first-in-class small molecule clinical and preclinical drug candidates. Our lead program is *TTP399*, an orally administered, small molecule, liver-selective glucokinase activator ("GKA") for the treatment of type 1 diabetes.

#### **Recent Developments**

On July 27, 2022, the Company appointed Paul Sekhri as President, Chief Executive Officer (CEO) effective August 1, 2022, and was confirmed as a member of the board of directors on August 9, 2022. Mr. Sekhri brings nearly 30 years of healthcare experience, including serving as President and CEO of several healthcare companies, experience in several senior business development and strategy roles and he has been a director on more than 30 private, public company and non-profit boards.

Based upon the positive results of our Simplici-T1 Study, we requested Breakthrough Therapy Designation ("BTD") with the FDA which was granted in April 2021. In October 2021, we began to implement a strategy to focus our efforts on the continued development of *TTP399* as a potential treatment for patients with type 1 diabetes ("T1D").

After several meetings with the FDA BTD-team, the Company is planning two pivotal, placebo-controlled clinical trials of *TTP399* in subjects with T1D. The studies will recruit a total of approximately 1,000 patients and at least one of the studies will be one year of treatment. The FDA confirmed that the effect size of *TTP399* on events of hypoglycemia as demonstrated in the Phase 2 SimpliciT-1 Study is clinically meaningful and has agreed on the primary endpoint for the studies as the difference between placebo and *TTP399*-treated group in number of hypoglycemia events.

The results of the mechanistic study provided additional evidence to support the idea that treatment with *TTP399* will not increase the risk of diabetic ketoacidosis ("DKA") in patients with T1D. The data demonstrate that in contrast to agents such as SGLT2 inhibitors and GLP-1RAs, *TTP399* does not increase the risk of ketoacidosis when used as an adjunctive therapy to insulin in individuals with T1D. Moreover, these findings support prior studies that demonstrate that *TTP399* improves glucose control and reduces hypoglycemia and suggests a protective effect of *TTP399* against acidosis in people with T1D. Thus, accumulating data suggest that *TTP399* has robust potential as an adjunctive therapy for T1D. Full study results were published in the *Diabetes Obesity and Metabolism* journal in conjunction with the 82nd American Diabetes Association Scientific Sessions on June 6, 2022.

The following table summarizes our drug candidates, their partnership status, and their respective stages of development:

PRODUCT	PRECLINICAL	PHASE I	PHASE II	PHASE III	PARTNERS
TTP399 GK activator	Type 1 Diabetes				
TTP273	Cystic Fibrosis Related Diabetes				
Oral GLP-1R agonist	Type 2 Diabetes				HUADONG MEDICINE
	SAD/MAD Completed				
HPP737	Psoriasis				
PDE4 inhibitor	COPD *				NEWSOAR
	Atopic Dermatitis				
HPP593 PPAR-5 activator	Primary Mitochondrial M	yopathy			Ø Renec
Azeliragon RAGE antagonist	Pancreatic Cancer				CANTEX
HPP971 Nrf2/Bach1 modulator	Renal Diseases				Anteris Bio
HPP3033 Nrf2/Bach1 modulator	Undisclosed				
TTP-RA RAGE antagonist	T10 Prevention				

<sup>\*</sup> Chronic obstructive pulmonary disease

#### Our Type 1 Diabetes Program - TTP399

The Company is planning two pivotal, placebo-controlled clinical trials of *TTP399* in subjects with T1D and has engaged with FDA on the optimal clinical trial designs for these studies. The studies will recruit a total of approximately 1000 patients and at least one of the studies will be one year of treatment. The FDA and the company have agreed on the primary endpoint for the studies as the difference between placebo and *TTP399*-treated group in number of hypoglycemia events. These pivotal studies are expected to start in 4Q 2022.

In October 2021, we announced positive results of a mechanistic study of *TTP399* in patients with T1D. The study demonstrated that patients with T1D taking *TTP399* experienced no increase in ketone levels relative to placebo during a period of acute insulin withdrawal, indicating no increased risk of ketoacidosis. Consistent with previous clinical studies, improved fasting plasma glucose levels and fewer hypoglycemic events were observed in the *TTP399* treated group during the week of treatment prior to the insulin withdrawal test. The FDA has declined to approve SGLT2 inhibitors as an adjunctive therapy in T1D, with concerns over the potential risks of diabetic ketoacidosis ("DKA") in focus. DKA can lead to hospitalization and, if untreated, death. To address these concerns, vTv, following the FDA's recommendation, conducted this mechanistic study to demonstrate that treatment with *TTP399*, a liver-selective glucokinase activator, will not result in increased production of ketones, a precursor to ketoacidosis.

In April 2021, we announced that the FDA granted BTD for *TTP399* as an adjunctive therapy to insulin for the treatment of T1D. This designation provides a sponsor with added support and the potential to expedite development and review timelines for a promising new investigational medicine.

#### **G42 Investments**

On May 31, 2022, the Company announced entry into agreements that include a \$25.0 million investment by G42 Investments. Under the terms of the agreements, the Company agreed to sell G42 Investments 10,386,274 shares of the Company's Class A common stock at an issue price of \$2.407 per share, with \$12.5 million paid in cash at closing, and the remaining amount of \$12.5 million payable on May 31, 2023. The agreements also provide for the potential issuance of \$30.0 million in additional shares of Class A common stock to G42 Investments (or cash in lieu of such issuance at the option of

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G42 Investments) if the FDA approves the marketing and sale of a pharmaceutical product containing *TTP399*, a liver selective glucokinase activator, as the active ingredient for treatment of T1D in the United States. The agreements set forth the terms under which the Company and Cogna, an affiliate of G42 Investments, plan to collaborate on clinical trials for pharmaceutical products that contain *TTP399*, including Cogna funding a portion of the Phase 3 clinical trials for *TTP399*, and the Company granting Cogna an exclusive license to develop and commercialize pharmaceutical products containing *TTP399* in a specified territory, principally consisting of the Middle East, Africa and Central Asia.

#### **Holding Company Structure**

vTv Therapeutics Inc. is a holding company, and its principal asset is a controlling equity interest in vTv Therapeutics LLC, the principal operating subsidiary. We have determined that vTv LLC is a variable-interest entity ("VIE") for accounting purposes and that vTv Therapeutics Inc. is the primary beneficiary of vTv LLC because (through its managing member interest in vTv LLC and the fact that the senior management of vTv Therapeutics Inc. is also the senior management of vTv LLC) it has the power to direct all of the activities of vTv LLC, which include those that most significantly impact vTv LLC's economic performance. vTv Therapeutics Inc. has therefore consolidated vTv LLC's results under the VIE accounting model in its consolidated financial statements.

#### **Financial Overview**

#### Revenue

To date, we have not generated any revenue from drug sales. Our revenue has been primarily derived from up-front proceeds, milestones and research fees under collaboration and license agreements.

In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and royalties from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, milestone and other payments, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue and our results of operations and financial position will be materially adversely affected.

#### Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts, and activities related to regulatory filings for our drug candidates. We recognize research and development expenses as they are incurred. Our direct research and development expenses consist primarily of external costs such as fees paid to investigators, consultants, central laboratories, and clinical research organizations ("CRO(s)") in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. Our indirect research and development costs consist primarily of cash and share-based compensation costs, the cost of employee benefits, and related overhead expenses for personnel in research and development functions. Since we typically use our employee and infrastructure resources across multiple research and development programs such costs are not allocated to the individual projects.

From our inception, including our predecessor companies, through June 30, 2022, we have incurred approximately \$605.4 million in research and development expenses.

Our research and development expenses by project for the three and six months ended June 30, 2022, and 2021 were as follows (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,			
	2022		2021		2022		2021
Direct research and development expense:							
Azeliragon	\$ (92)	\$	175	\$	(52)	\$	887
TTP399	1,633		368		4,129		636
HPP737	(8)		712		45		1,767
Other projects	238		157		251		232
Indirect research and development expense	434		1,025		965		2,018
Total research and development expense	\$ 2,205	\$	2,437	\$	5,338	\$	5,540

We plan to continue to incur significant research and development expenses for the foreseeable future as we continue the development of *TTP399* and further advance the development of our other drug candidates, subject to the availability of additional funding.

The successful development of our clinical and preclinical drug candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing, or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical drug candidates or the period, if any, in which material net cash inflows from these drug candidates may commence. This is due to the numerous risks and uncertainties associated with the development of our drug candidates, including:

- the uncertainty of the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- the potential benefits of our candidates over other therapies;
- our ability to market, commercialize, and achieve market acceptance for any of our drug candidates that we are developing or may develop in the future;
- future clinical trial results:
- our ability to enroll patients in our clinical trials;
- the timing and receipt of any regulatory approvals; and
- the filing, prosecuting, defending, and enforcing of patent claims and other intellectual property rights, and the expense of doing so.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a drug candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time with respect to the development of that drug candidate.

### General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits, and related costs for employees in executive, finance, corporate development, human resources, and administrative support functions. Other significant general and administrative expenses include accounting and legal services, expenses associated with obtaining and maintaining patents, cost of various consultants, occupancy costs, and information systems.

#### Interest Income

Interest income represents non-cash interest income related to the imputed interest from our promissory note receivable, all of which are recognized in our Condensed Statement of Operations using the effective interest method.

#### Interest Expense

The Company's interest expense is immaterial.

#### Other Income (Expense), Net

Other income/expense primarily consists of unrealized gains or losses attributable to the changes in fair value of the equity investments held by our licensees, as well as the recognition of changes in fair value of the warrants to purchase shares of our Class A common stock held by a related party.

#### **Results of Operations**

#### Comparison of the three months ended June 30, 2022, and 2021

The following table sets forth certain information concerning our results of operations for the periods shown:

(dollars in thousands) Three Months Ended June			ıe 30,		
Statement of operations data:	2022 2021		Change		
Revenue	\$	9	\$ 9	\$	_
Operating expenses:					
Research and development		2,205	2,437		(232)
General and administrative		1,831	2,242		(411)
Total operating expenses		4,036	4,679		(643)
Operating loss		(4,027)	(4,670)		643
Interest income		50	_		50
Interest expense		_	_		_
Other (expense) income, net		(114)	3,829		(3,943)
Loss before income taxes		(4,091)	(841)		(3,250)
Income tax provision		_	_		_
Net loss before noncontrolling interest		(4,091)	(841)		(3,250)
Less: Net loss attributable to noncontrolling interest		(940)	(233)		(707)
Net loss attributable to vTv Therapeutics Inc.	\$	(3,151)	\$ (608)	\$	(2,543)

#### Revenue

Revenue for the three months ended June 30, 2022, and 2021 were insignificant.

#### Research and Development Expenses

Research and development expenses were \$2.2 million and \$2.4 million for the three months ended June 30, 2022, and 2021, respectively. The decrease in research and development expenses during this period of \$0.2 million or 9.5%, was primarily driven by i) a decrease in clinical trial costs of \$0.3 million for *azeliragon*, driven by the discontinuance of its development as a potential treatment of Alzheimer's disease in patients with type 2 diabetes, ii) decreased spending of \$0.7 million related to the multiple ascending dose study for *HPP737*, due to its completion in 2021, iii) decreases in indirect costs of \$0.6 million offset by iv) higher spending on *TTP399* of \$1.3 million, due to trial preparation costs, and v) higher spending on other projects costs of \$0.1 million.

### General and Administrative Expenses

General and administrative expenses were \$1.8 million and \$2.2 million for the three months ended June 30, 2022, and 2021, respectively. The decrease in general and administrative expenses during this period of \$0.4 million, or 18.3%, was primarily driven by i) decreases in payroll costs of \$0.9 million due to the reduction in workforce in connection with the Company's restructuring plan that occurred in December 2021, ii) decreases in share-based expense of \$0.2 million, offset by iii) increases of \$0.4 million in legal expense, and iv) increases of \$0.3 million other general and administrative costs.

#### Interest income

Interest income for the three months ended June 30, 2022, and 2021, was insignificant.

#### Interest Expense

Interest expense for the three months ended June 30, 2022, and 2021, was insignificant.

#### Other (Expense) / Income

Other expense was \$0.1 million for the three months ended June 30, 2022, and was driven by an unrealized loss related to our investment in Reneo as well as the gains related to the change in the fair value of the outstanding warrants to purchase shares of our own stock issued to a related party ("Related Party Warrants"). Other income was \$3.8 million for the three months ended June 30, 2021, and was related to the unrealized gain recognized related to our investment in Reneo as well as gains related to the change in the fair value of the outstanding warrants in our own stock held by a related party.

#### Comparison of the six months ended June 30, 2022, and 2021

The following table sets forth certain information concerning our results of operations for the periods shown:

(dollars in thousands)	Six Months Ended June 30,			
Statement of operations data:	2022 2021		Change	
Revenue	\$ 2,009	\$ 996	\$ 1,013	
Operating expenses:				
Research and development	5,338	5,540	(202)	
General and administrative	7,179	4,406	2,773	
Total operating expenses	12,517	9,946	2,571	
Operating loss	(10,508)	(8,950)	(1,558)	
Interest income	50	1	49	
Interest expense	(1)	_	(1)	
Other (expense) income, net	(2,856)	2,181	(5,037)	
Loss before income taxes	(13,315)	(6,768)	(6,547)	
Income tax provision	200	15	185	
Net loss before noncontrolling interest	(13,515)	(6,783)	(6,732)	
Less: Net loss attributable to noncontrolling interest	(3,357)	(1,934)	(1,423)	
Net loss attributable to vTv Therapeutics Inc.	\$ (10,158)	\$ (4,849)	\$ (5,309)	

#### Revenue

Revenue for the six months ended June 30, 2022, includes a \$2.0 million increase to the transaction price for the license performance obligations under the amended license agreement with Huadong due to the satisfaction of a development milestone. Revenue for the six months ended June 30, 2021, relates to the reallocation of revenue to the license and technology transfer performance obligation made in connection with the First Huadong Amendment.

#### Research and Development Expenses

Research and development expenses were \$5.3 million and \$5.5 million for the six months ended June 30, 2022, and 2021, respectively. The decrease in research and development expenses during the period of \$0.2 million, or 3.6%, was primarily driven by i) a decrease in clinical trial costs of \$0.9 million for *azeliragon* which was mainly driven by discontinuance of its development as a potential treatment of Alzheimer's disease in patients with type 2 diabetes, ii) decreased spending of \$1.7 million related to the multiple ascending dose study for *HPP737*, due to its completion in 2021, iii) decreases in indirect costs of \$1.1 million offset by iv) higher spending on *TTP399*, due to trial preparation costs of \$3.5 million.

#### General and Administrative Expenses

General and administrative expenses were \$7.2 million and \$4.4 million for the six months ended June 30, 2022, and 2021, respectively. The increase of \$2.8 million has been primarily driven by i) increases of \$2.6 million in legal expense, ii) increases of \$0.8 million in severance costs, iii) increases of \$0.7 million in other general and administrative costs, offset by iv) decreases of \$0.1 million in shared based expense, and v) decreases of \$1.2 million in payroll costs due to the reduction in workforce in connection with the Company's restructuring plan that occurred in December 2021.

#### Interest income

Interest income for the six months ended June 30, 2022, and 2021, was insignificant.

#### Interest Expense

Interest expense for the six months ended June 30, 2022, and 2021, was insignificant.

#### Other Income / (Expense)

Other expense was \$2.9 million for the six months ended June 30, 2022 and is driven by an unrealized loss recognized related to the Company's investment in Reneo as well as the gains related to the change in the fair value of the outstanding warrants to purchase shares of our own stock issued to a related party. Other income was \$2.2 million for the six months ended June 30, 2021, and was driven by an unrealized gain recognized related to the Company's investment in Reneo as well as losses related to the change in fair value of the outstanding warrants in our own stock held by a related party.

#### **Liquidity and Capital Resources**

#### Liquidity and Going Concern

As of June 30, 2022, we have an accumulated deficit of \$253.3 million as well as a history of negative cash flows from operating activities. We anticipate that we will continue to incur losses for the foreseeable future as we continue our clinical trials. Further, we expect that we will need additional capital to continue to fund our operations. As of June 30, 2022, our liquidity sources included cash and cash equivalents of \$17.9 million. In addition to available cash and cash equivalents discussed above, we are evaluating several financing strategies to fund the on-going and future clinical trials of *TTP399*, including direct equity investments and the potential licensing and monetization of other Company programs such as *HPP737*. The Company also has a promissory note of \$12.5 million under the G42 Purchase Agreement payable to the Company on or before May 31, 2023 (see Note 9) and on July 25, 2022 announced a \$10.0 million Class A common stock investment by CinPax, LLC, consisting of \$6.0 million in cash and \$4.0 million payable on November 22, 2022 (see Note 14).

Based on our current operating plan, we may use the remaining availability of \$37.3 million under our Sales Agreement with Cantor Fitzgerald pursuant to which we could offer and sell, from time to time, shares of our Class A common stock under the ATM Offering and our ability to sell approximately 9.4 million shares of Class A common stock to Lincoln Park pursuant and subject to the limitations of the LPC Purchase Agreement. However, the ability to use these sources of capital is dependent on a number of factors, including the prevailing market price of and the volume of trading in our Class A common stock. These factors raise substantial doubt about our ability to continue as a going concern.

#### ATM Offering

We have entered into the Sales Agreement with Cantor Fitzgerald pursuant to which we may offer and sell, from time to time, through or to Cantor Fitzgerald, as sales agent or principal, shares of our Class A common stock having an aggregate offering price of up to \$68.5 million. We are not obligated to sell any shares under the Sales Agreement. Under the terms of the Sales Agreement, we will pay Cantor Fitzgerald a commission of up to 3% of the aggregate proceeds from the sale of shares and reimburse certain legal fees or other disbursements. As of June 30, 2022, we have sold \$31.2 million worth of Class A common stock under the ATM Offering for net proceeds of \$30.3 million, leaving \$37.3 million available to be sold. The shares are offered and sold pursuant to the Company's shelf registration statement on Form S-3. In no event will we sell Class A common stock under this registration statement with a value exceeding more than one-third of the "public float" (the market value of our Class A common stock and any other equity securities that we may issue in the future that are held by non-affiliates) in any 12-calendar month period so long as our public float remains below \$75 million.

#### Lincoln Park Purchase Agreement

We have entered into the LPC Purchase Agreement, pursuant to which we have the right to sell to Lincoln Park shares of the Company's Class A common stock having an aggregate value of up to \$47.0 million. As of June 30, 2022, we have issued 5,331,306 of these shares for gross proceeds of approximately \$11.1 million, leaving \$35.9 million available to be sold.

Over the 36-month term of the LPC Purchase Agreement, we have the right, but not the obligation, from time to time, in our sole discretion, to direct Lincoln Park to purchase up to 250,000 shares per day (the "Regular Purchase Share Limit") of the Class A common stock (each such purchase, a "Regular Purchase"). The Regular Purchase Share Limit will increase to 275,000 shares per day if the closing price of the Class A common stock on the applicable purchase date is not below \$4.00 per share and will further increase to 300,000 shares per day if the closing price of the Class A common stock on the applicable purchase date is not below \$5.00 per share. In any case, Lincoln Park's maximum obligation under any single Regular Purchase will not exceed \$2,000,000. The purchase price for shares of Class A common stock to be purchased by

Lincoln Park under a Regular Purchase will be equal to the lower of (in each case, subject to the adjustments described in the LPC Purchase Agreement): (i) the lowest sale price for the Class A common stock on the applicable purchase date and (ii) the arithmetic average of the three lowest closing sales prices for the Class A common stock during the 10 consecutive trading days prior to the purchase date.

If we direct Lincoln Park to purchase the maximum number of shares of Class A common stock that we may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the LPC Purchase Agreement, we may direct Lincoln Park to make an "accelerated purchase" and an "additional accelerated purchase", each of an additional number of shares of Class A common stock which may not exceed the lesser of: (i) 300% of the number of shares purchased pursuant to the corresponding Regular Purchase and (ii) 30% of the total number of shares of the common stock traded during a specified period on the applicable purchase date as set forth in the LPC Purchase Agreement. The purchase price for such shares will be the lesser of (i) 97% of the volume weighted average price of the Class A common stock over a certain portion of the date of sale as set forth in the LPC Purchase Agreement and (ii) the closing sale price of the Class A common stock on the date of sale (an "Accelerated Purchase"). Under certain circumstances and in accordance with the LPC Purchase Agreement, we may direct Lincoln Park to purchase shares in multiple Accelerated Purchases on the same trading day.

The LPC Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of its Class A common stock if those shares, when aggregated with all other shares of Class A common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of Class A common stock as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder.

#### Cash Flows

	Six Months Ended June 30,			
	 2022	2021		
(dollars in thousands)				
Net cash used in operating activities	\$ (315) \$	(9,297)		
Net cash used in investing activities	(21)	_		
Net cash provided by financing activities	4,784	14,385		
Net increase in cash and cash equivalents	\$ 4,448 \$	5,088		

#### Operating Activities

For the six months ended June 30, 2022, our net cash used in operating activities decreased by \$9.0 million from the six months ended June 30, 2021. The significant contributor to the change in cash used during the year was driven by working capital changes offset by cash received of \$6.8 million in excess of the fair value of the Class A common stock issued to G42 investments.

#### Investing Activities

For the six months ended June 30, 2022, net cash used in investing activities was insignificant. There were no cash flows from investing activities for the six months ended June 30, 2021.

# Financing Activities

For the six months ended June 30, 2022, net cash provided by financing activities was driven by sales of our Class A common stock to a collaboration partner. For the six months ended June 30, 2021, net cash provided by financing activities was driven by sales of shares of our Class A common stock during the six months ended June 30, 2021.

#### **Future Funding Requirements**

To date, we have not generated any revenue from drug product sales. We do not know when, or if, we will generate any revenue from drug product sales. We do not expect to generate revenue from drug sales unless and until we obtain regulatory approval of and commercialize any of our drug candidates. At the same time, we expect our expenses to continue or to increase in connection with our ongoing development activities, particularly as we continue the research, development, and clinical trials of, and seek regulatory approval for, our drug candidates. In addition, subject to obtaining regulatory approval of any of our drug candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing, and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We plan to finance our operations into the third quarter of 2023 through the use of our cash and cash equivalents and based on current operating plans, we are evaluating several financing strategies to fund the on-going and future clinical trials of *TTP399*, including direct equity investments and the potential licensing and monetization of other Company programs such as *HPP737*. The Company also has a promissory note of \$12.5 million under the G42 Purchase Agreement payable to the Company on or before May 31, 2023. The timing of any such transactions is not certain, and we may not be able to complete such transactions on acceptable terms, or at all. Even if we are able to complete such transactions, it may contain restrictions on our operations or cause substantial dilution to our stockholders. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our drug candidates. Additionally, we may rely on our ability to sell shares of our Class A common stock pursuant to the ATM Offering and LPC Purchase Agreement. However, the ability to use these sources of capital is dependent on a number of factors, including the prevailing market price of and the volume of trading in the Company's Class A common stock, and we may use our available capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- The progress, costs, results, and timing of our planned trials to evaluate TTP399 as a potential treatment of T1D;
- the willingness of the FDA to rely upon our completed and planned clinical and preclinical studies and other work, as the basis for review and approval of our drug candidates;
- the outcome, costs, and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue, including our drug candidates in preclinical development;
- the ability of our drug candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing, establishing, and maintaining commercialization capabilities;
- the costs of acquiring, licensing, or investing in businesses, products, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing, or other arrangements into which we may enter in the future;
- the amount of any payments we are required to make to M&F TTP Holdings Two LLC in the future under the Tax Receivable Agreement; and
- the impact and duration of the COVID-19 outbreak / pandemic.

Until such time, if ever, as we can generate substantial revenue from drug sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements. We currently have committed external source of funds available through the ATM Offering, LPC Purchase Agreement and a Promissory Note under the G42 Purchase Agreement for \$12.5 million payable to the Company on or before May 31, 2023.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants that will further limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may be required

to relinquish valuable rights to our technologies, future revenue streams or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional funding, we could be forced to delay, reduce, or eliminate our research and development programs or commercialization efforts, or pursue one or more alternative strategies, such as restructuring, any of which could adversely affect our business prospects.

#### **Off-Balance Sheet Arrangements**

As of June 30, 2022, we did not have outstanding any off-balance sheet arrangements as defined under SEC rules.

#### **Discussion of Critical Accounting Policies**

For a discussion of our critical accounting policies and estimates, please refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to our critical accounting policies and estimates in 2022.

#### **Forward-Looking Statements**

This quarterly report includes certain forward-looking statements within the meaning of the federal securities laws regarding, among other things, our management's intentions, plans, beliefs, expectations, or predictions of future events, which are considered forward-looking statements. You should not place undue reliance on those statements because they are subject to numerous uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Forward-looking statements include information concerning our possible or assumed future results of operations, including descriptions of our business strategy. These statements often include words such as "may," "will," "should," "believe," "expect," "outlook", "anticipate," "intend," "plan," "estimate" or similar expressions. These statements are based upon assumptions that we have made in light of our experience in the industry, as well as our perceptions of historical trends, current conditions, expected future developments and other factors that we believe are appropriate under the circumstances. As you read this quarterly report, you should understand that these statements are not guarantees of performance or results. They involve known and unknown risks, uncertainties, and assumptions, including those described under the heading "Risk Factors" under Item 1A of Part I in our Annual Report on Form 10-K and under Item 1A of Part II of this Quarterly Report on Form 10-Q. Although we believe that these forward-looking statements are based upon reasonable assumptions, you should be aware that many factors, including those described under the heading "Risk Factors" under Item 1A of Part II in our Annual Report on Form 10-K and under Item 1A of Part II of this Quarterly Report on Form 10-Q, could affect our actual financial results or results of operations and could cause actual results to differ materially from those in the forward-looking statements.

Our forward-looking statements made herein are made only as of the date of this quarterly report. We expressly disclaim any intent, obligation or undertaking to update or revise any forward-looking statements made herein to reflect any change in our expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained in this quarterly report.

#### **Effect of Recent Accounting Pronouncements**

See discussion of recent accounting pronouncements in Note 2, "Summary of Significant Accounting Policies", to the Condensed Consolidated Financial Statements in this Form 10-Q.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### **Interest Rate Risk**

We do not currently have any material interest rate exposure.

#### Market Risk

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of one year or less. The goals of our investment strategy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents in a financial institution that management believes to be of high credit quality. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the value of our investment portfolio.

#### Foreign Currency Risk

We do not have any material foreign currency exposure.

#### ITEM 4. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our Chief Executive Officer and Chief Accounting Officer, management has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2022. Based upon that evaluation, our Chief Executive Officer and Chief Accounting Officer concluded that, as of June 30, 2022, our disclosure controls and procedures were effective in causing material information relating to us (including our consolidated subsidiaries) to be recorded, processed, summarized, and reported by management on a timely basis and to ensure the quality and timeliness of our public disclosures pursuant to SEC disclosure obligations.

Our management, including our Chief Executive Officer and Chief Accounting Officer, does not expect that our disclosure controls and procedures will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, with the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error and mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or because the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

#### **Changes to Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Website Availability of Reports and other Corporate Governance Information

The Company maintains a comprehensive corporate governance program, including Corporate Governance Guidelines for its Board of Directors, Board Guidelines for Assessing Director Independence, and charters for its Audit Committee, Nominating and Corporate Governance Committee and Compensation Committee. The Company maintains a corporate investor relations website, www.vtvtherapeutics.com, where stockholders and other interested persons may review, without charge, among other things, corporate governance materials and certain SEC filings, which are generally available on the same business day as the filing date with the SEC on the SEC's website http://www.sec.gov. The contents of our website are not made a part of this Quarterly Report on Form 10-Q.

#### PART II – OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

# ITEM 1A. RISK FACTORS

Our risk factors are set forth under the heading "Risk Factors" under Item 1A of Part I in our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to our risk factors from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the three months ended June 30, 2022, the Company issued the following unregistered securities:

In May 2022, the Company sold 10,386,274 shares of the Company's Class A common stock at a price per share of approximately \$2.41, for an aggregate purchase price of \$25.0 million.

# ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

# ITEM 4. MINE SAFETY DISCLOSURES

None.

#### ITEM 5. OTHER INFORMATION

None.

# ITEM 6. EXHIBITS

Exhibit Number	Description
10.1*	Cogna Technology Solutions LLC, Collaboration and License Agreement
31.1*	Certification of President and Chief Executive Officer required by Rule 13a-14(a)/15d-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 Chief Accounting Officer required by Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	<u>Certification of Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

<sup>††</sup> Confidential treatment received with respect to portions of this exhibit.

<sup>\*</sup> Filed herewith

## **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.

Date: August 15, 2022

VTV THERAPEUTICS INC. (Registrant)

By: /s/ Paul J. Sekhri

Paul J. Sekhri

President and Chief Executive Officer

By: /s/ Barry Brown

Barry Brown

Chief Accounting Officer

#### COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the "<u>Agreement</u>") is entered into as of May 31, 2022 (the "<u>Effective Date</u>"), by and between vTv Therapeutics LLC, a Delaware limited liability company having an address at 3980 Premier Dr. Suite 310, High Point, North Carolina 27265 ("<u>Company</u>") and Cogna Technology Solutions LLC, an Abu Dhabi limited liability company having an address at Abu Dhabi 624, Plot C18, E48 RG Building, Al Salam, Abu Dhabi, United Arab Emirates ("<u>Partner</u>"). Company and Partner may be referred to herein individually as a "<u>Party</u>" or collectively as the "<u>Parties</u>."

#### **RECITALS**

WHEREAS, Company, a biopharmaceutical company, is developing a proprietary candidate known as TTP399 and owns or controls certain Patents, Know-How and other Intellectual Property relating to such candidate;

WHEREAS, Partner possesses substantial resources and expertise in clinical development and commercialization of pharmaceutical products; and

WHEREAS, Company and Partner desire to collaborate on certain Development of the Product and to grant Partner certain rights to Commercialize the Product within the Partner Territory, in each case, as further described in, and subject to, the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Company and Partner hereby agree as follows:

#### Section 1. Definitions.

Capitalized terms used in this Agreement shall have the meanings ascribed to such terms in this Agreement, including as specified in this <u>Section 1</u>. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Purchase Agreement; *provided* that any use of the term "Purchaser" therein shall mean "Partner" for the purposes hereof.

"Affiliate" means, as to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with such Person, as such terms are used in and construed under Rule 405 under the Securities Act; *provided* that for purposes of this Agreement (a) Company, its Subsidiaries, MAF and its Subsidiaries will not be deemed an Affiliate of Partner or its Subsidiaries, (b) Partner and its Subsidiaries will not be deemed an Affiliate of Company, its Subsidiaries, MAF or its Subsidiaries and (c) notwithstanding the foregoing other than in the case of Section 12 and 13, "Affiliate," as to Company, shall be deemed to mean Subsidiary.

"Anti-Corruption Laws" means, as applicable, the FCPA, the U.S. Travel Act, 18 U.S.C. § 1952, the U.K. Bribery Act 2010, any Law enacted to implement the OECD Convention on

Combating Bribery of Foreign Officials in International Business Transactions, and any other anti- corruption or anti-bribery Laws of similar effect in other countries or jurisdictions in which products, payments or services will be provided under this Agreement.

"Applicable Laws" means any and all applicable national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, and permits of or from any Regulatory Authority or other Governmental Authority having jurisdiction over or related to the subject item. For clarity, the Parties acknowledge and agree that, with respect to Partner's and any Partner Member's conduct of any Partner-Conducted Clinical Trials, and related activities hereunder, "compliance with Applicable Laws" shall be deemed to require compliance with the Laws of the applicable country or jurisdiction in which the Partner-Conducted Clinical Trial takes place or the IND is filed, as well as compliance with the FD&C Act, 21 CFR Parts 11, 50, 54, 56, 58 and 312 that are applicable as a result of Partner's assumption of responsibilities as a CRO for a Sponsor with its principal place of business in the United States.

"<u>Calendar Quarter</u>" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31, or the applicable part thereof during the first or last quarter of the Term.

"<u>Calendar Year</u>" means each respective period of twelve (12) consecutive months ending on December 31, or the applicable part thereof during the first or last year of the Term.

"cGCP" means the current clinical practice requirements set out in (a) ICH Harmonized Guidance on current Good Clinical Practice (CPMP/ICH/135/95), (b) U.S. Code of Federal Regulations, Title 21, Chapters 50, 54, 56, 58 and 312, (c) EU Directive 2001/20/EC and related guidelines, and (d) any foreign equivalents of any of the foregoing.

"<u>cGLP</u>" means current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58, and such other comparable regulatory standards in jurisdictions outside the U.S.

"cGMP" means the current minimum standards for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, distribution or holding of a drug as specified by Applicable Laws of the relevant jurisdictions at the time of manufacturing conducted in accordance with this Agreement, including (a) 21 C.F.R. Part 210 and 211, (b) Directive 2003/94/EC, (c) Volume 4, Rules Governing Medicinal Products in the EU, Part I and II, and (d) any foreign equivalents thereof.

"Clinical Hold" means that (a) the FDA has issued an order to a Party pursuant to 21 CFR § 312.42 to delay a proposed Clinical Trial or to suspend an ongoing Clinical Trial of the Compound or Product in the United States or (b) a Regulatory Authority other than the FDA has issued an equivalent order to that set forth in (a) in any other country or group of countries.

"Clinical Investigator" means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.

"Clinical Trial" means any clinical trial, which is any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects, including any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or Phase 4 Clinical Trial.

"Collaboration Clinical Trial" means any Clinical Trial that is set forth in, and conducted under, the Global Development Plan.

"Commercialization" means with respect to a pharmaceutical product, any and all activities directed to the marketing, promotion, importation, distribution, pricing and reimbursement approval, offering for sale, and sale of such pharmaceutical product, and interacting with Regulatory Authorities regarding the foregoing, but excluding, Development and Manufacturing. "Commercialize" and "Commercializing" have a correlative meaning.

"Commercially Reasonable Efforts" means, with respect to a Party and its obligations to Develop, Manufacture or Commercialize (as applicable) the Product under this Agreement, those efforts and resources commonly used in the pharmaceutical industry (which shall be no less than those efforts used by the applicable Party) for the development and commercialization of a pharmaceutical product which is at a similar stage of development or commercialization, taking into account product profile, efficacy and safety, proprietary position, including patent and regulatory exclusivity, regulatory status, including anticipated or approved labeling and anticipated or approved post-approval requirements and present and future market and commercial potential, including competitive market conditions (but not taking into account any payment owed to the other Party under this Agreement). Without limiting the foregoing, Commercially Reasonable Efforts requires that a Party: (a) establish a plan to achieve objectives and assign specific responsibilities for the achievement of that plan and (b) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

"Company Background IP" means any Intellectual Property, owned by or licensed to Company or any of its Affiliates that is: (a) (i) owned by or licensed to Company or any of its Affiliates as of the Effective Date or (ii) created or developed by a Company Member during the Term of this Agreement but outside of Company's performance of activities contemplated under this Agreement, including improvements thereto, without using or referencing any Partner IP, and (b) that is provided or otherwise made available to Partner under or in connection with this Agreement.

"Company IP" means the Company Know-How, Company Patents and Company Developed IP.

"Company Know-How" means any and all Know-How to the extent Controlled by Company or any of its Subsidiaries as of the Effective Date or any time during the Term that is incorporated into, or otherwise necessary for the Partner to Develop, Commercialize or Manufacture, the Product for use in the Partner Territory, excluding any Patents filed thereon or with respect thereto. Notwithstanding the foregoing, Company Know-How shall not include any Know-How to the extent related to any components, compounds or agents that are not the Compound, or products that are not the Product.

"Company Member" means Company, its Subsidiaries or its or their Sublicensees or subcontractors (including, for clarity, any of its CROs).

"Company Patents" means, to the extent Controlled by Company or any of its Subsidiaries as of the Effective Date or any time during the Term, any and all Patents (a) to the extent set forth on Schedule 1; (b) to the extent Covering any Company Know-How; (c) continuations, divisionals, renewals, continuations-in-part, and patents of addition claiming priority to any Patents described in the foregoing (a) or (b) and all foreign equivalents thereof; and (d) restorations, extensions, supplementary protection certificates, reissues and re-examinations of the Patents described in the foregoing (a), (b) or (c), each of the foregoing subsections (c) and (d), to the extent the claims of such Patents are fully supported by any Patent described in the foregoing subsections (a) or (b). Notwithstanding the foregoing, Company Patents shall not include any Patents to the extent related to any components, compounds or agents that are not the Compound, or products that are not the Product.

"Company Territory" means worldwide, other than the Partner Territory.

"Completion Date" means, as to a particular Clinical Trial, the earlier of (a) the date on which the last subject in such Clinical Trial completes the last visit as described in the protocol for such Clinical Trial and (b) the date such Clinical Trial or this Agreement is terminated.

"Compound" means TTP399, an oral, small molecule liver selective glucokinase activator. "Confidential Information"

means any and all Know-How and other information or data

that is generated or collected by or on behalf of a Party Member or which one Party Member provides or otherwise makes available to any other Party Member in connection with this Agreement, whether orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, Data, designs or formulae; *provided* that all confidential Company IP will be deemed Company's Confidential Information and all confidential Partner IP will be deemed Partner's Confidential Information.

"Controlled" means, with respect to any Intellectual Property, the legal authority or right (whether by ownership, license or otherwise, but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant the applicable access to, or license or sublicense under, such Intellectual Property to the other Party pursuant to this Agreement, without breaching the terms of any agreement or other arrangement with a Third Party, or violating any Applicable Laws.

"Co-Sponsor" means, with respect to any applicable Clinical Trial under this Agreement, such Clinical Trial is being "co-sponsored" by each of Partner and Company (each, a "Co-Sponsor"), which for purposes of this Agreement shall mean that (a) Company is the Sponsor (as defined below), and (b) subject to and in accordance with 21 CFR 312.52, and any corresponding Applicable Laws in any other countries or regulatory jurisdictions, Company has transferred to Partner, and following such transfer Partner is responsible for, certain of Company's responsibilities (and corresponding liabilities therefor) as the Sponsor of such Clinical Trial (i.e., Partner-Conducted Clinical Trials) in accordance with, and subject to, Section 4.2(e) (ii).

"Cover(ed)(ing)" means, with respect to any Patent and the subject matter at issue, that, but for a license granted under a Valid Claim of such Patent, the Development, Manufacture, use, sale, offer for sale, importation or other Commercialization of the subject matter at issue would infringe such Valid Claim, or, in the case of a Patent that is a patent application, would infringe a Valid Claim in such patent application if it were to issue as a patent.

"CRF" or "Case Report Form" means the collection of documents designed specifically for recording Data pursuant to the protocol for a Clinical Trial. For clarity, a CRF is completed for each subject and will be in electronic form, validated and in compliance with all Applicable Laws.

"CRO" means a contract research organization.

"CSR" means, with respect to a Clinical Trial, a clinical study report, or other equivalent document or series of materials, constituting a summary report of the clinical and medical data resulting from such Clinical Trial and prepared for incorporation into submissions seeking Regulatory Approval for the Product, and includes all statistical analyses of such data per the Statistical Analysis Plan.

"<u>Data</u>" means any and all scientific, technical, test, marketing or sales data pertaining to the Product that is generated by or on behalf of any Party Member, including research data, clinical pharmacology data, pre-clinical data and clinical data.

"Development" means any and all development activities with respect to a compound or product that are directed to obtaining Regulatory Approval, including all non-clinical, preclinical and clinical testing and studies; toxicology, pharmacokinetic and pharmacological studies; statistical analyses; assay development; protocol design and development; the preparation, filing and submission of any NDA therefor; and all regulatory affairs related to any of the foregoing. "Develop" and "Developing" have correlative meanings.

"EMA" means the European Medicines Agency or any successor thereof. "EU" means the European

Economic Area and Switzerland.

"Executive Officers" means the Chief Executive Officer of Company (or any other executive officer as appointed by Company) and the Chief Executive Officer of Partner (or any other executive officer as appointed by Partner).

"Exploit(ation)" means to make, have made, import, export, use, sell or offer for sale, including to research, Develop, Manufacture, export, transport, and distribute, promote, market, or have sold or otherwise dispose of and otherwise Commercialize.

"Export Control Laws" means all Applicable Laws governing the export or re-export of commodities, software, technologies, or services, including the Export Control Reform Act of 2018, 50 U.S.C. §§ 4801-4852; the Export Administration Act of 1979, 24 U.S.C. §§ 4601 et seq.; the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701 et seq.; the Trading with the Enemy Act, 50 U.S.C. §§ 1 et seq.; sections 38 and 39 of the Arms Export Control Act, 22

U.S.C. §§ 2778 and 2779; and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

"FCPA" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et seq.). "FD&C Act" means the U.S.

Federal Food, Drug and Cosmetic Act.

"FDA" means the U.S. Food and Drug Administration or any successor thereof.

"<u>First Commercial Sale</u>" means, on a country-by-country basis, the first sale by a Partner Member to a Third Party for end use in such country after Regulatory Approval has been granted for the Product in such country.

"Force Majeure Event" means external acts beyond the reasonable control of the affected Party, including acts of God, fires, floods, storms, wars, earthquakes, acts of terrorism, riots or civil commotions, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, legal or government restrictions or government acts or orders (even if caused by the Sars-Cov-2 pandemic), epidemics or pandemics (excluding the current Sars-Cov-2 pandemic in and of itself).

"GAAP" means generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity, as they exist from time to time, consistently applied.

"Government Official" means (a) any elected or appointed official of any Governmental Authority (e.g., a legislator or a member of a ministry of health), (b) any employee or other Person acting for or on behalf of a Governmental Authority, a Governmental Authority department or agency, an institution or entity owned or controlled by a Governmental Authority (e.g., an HCP employed by a Governmental Authority-owned or -controlled hospital, or a Person serving on a healthcare committee that advises a Governmental Authority), or an enterprise or instrumentality performing a governmental function, (c) any candidate for public office, or officer, employee, or other Person acting for or on behalf of a political party or candidate for public office, (d) an employee or other Person acting for or on behalf of a public international organization (e.g., the United Nations, the Red Cross, or the World Bank), (e) any member of a military or a royal or ruling family or (f) any Person otherwise categorized as an official of a Governmental Authority under Law.

"HCP" or "Healthcare Professional" includes any physician, nurse, pharmacist, or other person who may administer, prescribe, purchase, or recommend pharmaceutical products or other healthcare products.

"ICH" means the International Conference on Harmonization (of Technical Requirements for Pharmaceuticals for Human Use).

"IDMC" means the independent data monitoring committee, which shall be established pursuant to the terms hereof.

"<u>IFRS</u>" means International Financial Reporting Standards of the International Accounting Standards Board or any successor entity, as they exist from time to time, consistently applied.

"IND" means (a) an Investigational New Drug Application as defined in the FD&C Act or 21 C.F.R. Part 312, or any successor application or procedure required to initiate a Clinical Trial in the United States, (b) any counterpart in any country other than the United States and (c) all supplements and amendments to any of the foregoing.

"Initial Clinical Trials" means those Collaboration Clinical Trials for Development of the Initial Product.

"<u>Initial Product</u>" means that certain pharmaceutical product that is formulated as a tablet for oral administration and contains either four hundred (400) or eight hundred (800) milligrams of the Compound as the sole active pharmaceutical ingredient to the extent administered in a Clinical Trial, or approved, for treatment of Type 1 diabetes.

"Intellectual Property" means all Patents, Trademarks, Know-How, registered designs, design rights, copyrights (including rights in computer software), domain names, rights in databases and any and all other intellectual property and proprietary rights in any country or regulatory jurisdiction throughout the world, whether registered or not, together with all applications and registrations therefor.

"Investigator's Brochure" means the written document containing a brief description of the drug substance and formulation of the Product, a summary of the pharmacological and toxicological effects of the Product in animals and human nonclinical models, a summary of the pharmacokinetics and biological disposition of the Product in animals and humans, a summary of information relating to safety and effectiveness of the Product in humans obtained from prior clinical studies, and a description of possible risks and side effects to be anticipated on the basis of prior experience with the Product under investigation or with related drugs.

"IPR Claim" means any Third Party Claim alleging Development or Commercialization of the Product by or on behalf of any Partner Member infringes, misappropriates or otherwise violates any Patent or Know-How owned by any Third Party.

"IRB" means institutional review board, or its equivalent.

"Know-How" means all technical, scientific, regulatory and other information, results, knowledge, techniques and data, in whatever form and whether or not confidential, patented or patentable, including inventions, invention disclosures, discoveries, plans, processes, practices, methods, knowledge, trade secrets, know-how, instructions, skill, experience, ideas, concepts, data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, quality control, and preclinical and clinical data), formulae, formulations, compositions, specifications, marketing, pricing, distribution, cost, sales and manufacturing data or descriptions. Know-How does not include Patents claiming any of the foregoing.

" $\underline{Knowledge}$ " means the actual knowledge of the executive officers of Company or Partner, as applicable, as listed on Schedule 2.

"Losses" means liabilities, expenses and losses, including personal injury or death of any person, property damage, including reasonable legal expenses and attorneys' fees.

"Manufacture" means all activities related to making, having made, production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of any compound or product, including process development, testing method development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control. "Manufactured" and "Manufacturing" have correlative meanings.

"Material Safety Issue" means a Party's good faith belief that there is an unacceptable risk for harm in humans based upon (a) preclinical safety data, including data from animal toxicology studies or (b) the observation of serious adverse effects in humans after dosing the Product.

"NDA" means a New Drug Application, as defined in the FD&C Act or 21 C.F.R. Part 314 or any foreign equivalent thereof.

"Net Sales" means the gross amounts billed or invoiced by any Partner Member for sale of the Product, less the following deductions, without duplication, to the extent allocable to the Product and invoiced or otherwise directly incurred in accordance with IFRS and Partner's usual and customary accounting practices:

- (a) trade discounts, returns, credits or allowances,
- (b) credits or allowances additionally granted on account of rejections, returns, recalls (unless caused by its gross negligence or willful misconduct) or billing errors, commissions,
- (c) import/export or other custom duties, reasonable prepaid outbound freight expenses, insurance and other transportation costs incurred in transporting the applicable Product,
  - (d) sale taxes, VAT, and other governmental charges (other than taxes on the income or capital of Partner),
  - (e) government mandated rebates,
- (f) refunds and rebates for spoiled, damaged, outdated, rejected or returned Product or as otherwise required by Applicable Laws, and
- (g) amounts that are actually written off as non-collectible for the sale of the Product after Partner Members' commercially reasonable best efforts to collect such amounts.

In the case of any sale of the Product for non-cash consideration, Net Sales shall be calculated as the fair market price of the Product in the applicable country of sale or disposal. Sales of the Product between Partner and other Partner Members for resale shall be excluded from

the computation of Net Sales, but the subsequent resale of the Product to a Third Party shall be included within the computation of Net Sales.

The supply of the Product as samples, for use in nonclinical, preclinical, or clinical trials, or for use in any test or studies reasonably necessary to comply with any Applicable Laws, or as is otherwise normal and customary in the industry, shall not be included in the computation of Net Sales, so long as Partner Members do not receive consideration of monetary value for the Product.

"Novo Agreement" means that certain Agreement Concerning Glucokinase Activator Project, by and between Novo Nordisk A/S ("Novo") and vTv Therapeutics, Inc. (f/k/a TransTech Pharma, Inc., "vTv Inc."), dated as of February 20, 2007, as amended from time to time.

"Partner Background IP" means any Intellectual Property, owned by or licensed to any Partner Member that is: (a) (i) owned by or licensed to Partner or any Partner Member as of the Effective Date or (ii) created or developed by Partner or a Partner Member during the Term of this Agreement but outside of Partner's performance of activities contemplated under this Agreement, in both cases including any improvements thereto, without using or referencing any Company IP, and (b) that is provided or otherwise made available to Company under or in connection with this Agreement.

"Partner-Conducted Clinical Trial" means any Collaboration Clinical Trial to be conducted by Partner pursuant to this Agreement.

"Partner-Conducted Initial Clinical Trial" means the Initial Clinical Trial to be conducted by Partner pursuant to this Agreement.

"Partner IP" means the Partner Know-How, Partner Patents and Partner Developed IP, including Partner Background IP.

"<u>Partner Know-How</u>" means any and all Know-How to the extent Controlled by Partner or any of its Affiliates as of the Effective Date or any time during the Term that is necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Product.

"Partner Member" means Partner, its Affiliates or its or their Sublicensees or subcontractors (including, for clarity, any of its CROs).

"<u>Partner Patents</u>" means any and all Patents to the extent Controlled by Partner or any of its Affiliates as of the Effective Date or any time during the Term that is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Product.

"Partner Territory" means those countries set forth on Schedule 3.

"Party Member" means, in the case of Partner, any Partner Party Member, and in the case of Company, any Company Member.

"<u>Patents</u>" means patents, patent applications, and all related continuations, continuations- in-part, divisionals, reissues, re-examinations, substitutions, and extensions thereof.

- "Phase 1 Clinical Trial" means a Clinical Trial that is designed in a manner that is generally consistent with 21 CFR § 312.21(a).
- "Phase 2 Clinical Trial" means a Clinical Trial that is designed in a manner that is generally consistent with 21 CFR § 312.21(b).
- "Phase 3 Clinical Trial" means a Clinical Trial that is designed in a manner that is generally consistent with 21 CFR § 312.21(c).
- "Phase 4 Clinical Trial" means any post-marketing approval clinical study, whether initiated by a Party or at the request of any Governmental Authority, to delineate additional information about the Product's risks, benefits, and optimal use.
- "Product" means any pharmaceutical product containing the Compound as an active ingredient, alone or in combination with other active ingredients, in any formulation or dosage form and for any mode of administration for treatment of any and all indications and uses in humans and animals.
- "<u>Purchase Agreement</u>" means that certain Common Stock Purchase Agreement, dated as of the Effective Date, by and among vTv Inc., G42 Investments AI Holding RSC Ltd and, solely for purposes of Sections 5.3, 5.11 and Section 6 thereof, Group 42 Holding Limited.
- "Regulatory Approval" means any and all approvals of any applicable Regulatory Authority required to commence commercial sale of the applicable product in the applicable country or regulatory jurisdiction, including approval of an NDA in the United States and pricing and reimbursement approval where required.
- "Regulatory Authority" means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a given country or regulatory jurisdiction, including the FDA and EMA.
- "Regulatory Exclusivity" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to the Product other than Patents, including rights similar to those conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity) and in the EU under Directive 2001/83/EC.
- "Regulatory Filing" means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications and authorizations (or waivers) with respect to the testing, Development, Manufacture or Commercialization of a compound or product made to or received from any Regulatory Authority in a given country or regulatory jurisdiction, including any INDs, NDAs and labels.
- "Right of Reference" shall have the meaning set forth in 21 C.F.R. § 314.3(b) or equivalents thereto under Applicable Laws in jurisdictions outside the United States.

"Sponsor" has the meaning set forth in Title 21 CFR Part 312, Subpart D, and any corresponding Applicable Laws in any other countries or regulatory jurisdictions.

"Sublicensee" means any permitted sublicensee of Partner under Section 2.2 or Company under Section 2.6.

"Subsequent Clinical Trial" means any Collaboration Clinical Trial set forth in the Global Development Plan that is not an Initial Clinical Trial.

"Subsidiary" means, with respect to a specified Person, any corporation or other Person of which securities or other interests having the power to elect a majority of that corporation's or other Person's board of directors or similar governing body, or otherwise having the power to direct the business and policies of that corporation or other Person (other than securities or other interests having such power only upon the happening of a contingency that has not occurred) are held by the specified Person or one or more of its Subsidiaries.

"Third Party" means any Person other than (a) in the case of Company, any Subsidiary of Company and (b) in the case of Partner, any Affiliate of a Party.

"Third Party Claim" means any claim, demand, action or other proceeding brought by any Third Party.

"<u>Trademarks</u>" means trade names, brand names, trade dress, logos, slogans, trademarks and service marks and all other indicia of origin (whether registered or unregistered), and registrations, applications for registration, renewals and extensions thereof, together with all translations, adaptations, combinations and derivations thereof and all goodwill associated therewith.

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

"<u>Valid Claim</u>" means (a) a claim of an issued and unexpired Patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal or (b) a claim of a pending patent application that has not been revoked, cancelled, withdrawn, or abandoned or finally disallowed without the possibility of appeal or refiling of such application.

# 1.1 <u>Additional Definitions</u>. The following table identifies the location of definitions set forth in various Sections of the Agreement:

Acquiror	Section 15.5(b)
Acquisition Transaction	Section 15.5(b)
Agreement	Preamble
Alliance Manager	Section 3.1
Annual Limitation	Section 4.6(b)
Arbitral Tribunal	Section 15.11(d)

Auditor	Section 9.4
Clinical Investigator Meeting	Section 4.3(c)(i)
Clinical Trial Agreement	Section 4.3(b)(i)
Clinical Trials Database	Section 4.5(c)(i)
Clinical Trials Master File	Section 4.5(d)
СМО	Section 7.2(a)
Collaboration Protocol	Section 4.2(d)(ii)
Commercial Supply Agreement	Section 7.3(a)
Company	Preamble
Company Abandoned Patent	Section 10.2(b)(iii)
Company Developed IP	Section 10.1(b)(i)(3)
Company Indemnifiable IPR Claim	Section 12.1(b)
Company Indemnitee	Section 12.2
Company-Conducted Clinical Trials	Section 4.2(e)(i)
Compliance Policies	Section 11.1(h)
Data Management Plan	Section 4.5(b)(i)
Database Lock	Section 4.10(a)
Delivery	Section 7.2(c)
Disclosing Party	Section 13.1
Dispute	Section 15.11(b)
Effective Date	Preamble
Election Notice	Section 10.2(b)(iii)
Final Partner-Conducted Clinical Trial CSR	Section 4.11(c)
Financial Disclosure Form	Section 4.3(b)(ii)
Finished Product	Section 7.2(a)
FTO Analysis	Section 10.4
Global Development Plan	Section 4.2(a)
Global Trademarks	Section 6.6(c)(i)
IDMC Charter	Section 4.8(c)(i)
Indemnifying Party	Section 12.3(a)
Indemnitee	Section 12.3(a)
Indemnity Notice	Section 12.3(a)
Informed Consent	Section 4.3(e)(i)
Insights	Section 2.2(b)
JDC	Section 3.2
LCIA	Section 15.11(b)
Local Trademark	Section 6.6(c)(ii)
Manufacturing Agreement	Section 7.3(c)
Material Breach by Company	Section 12.1(a)
Material Breach by Partner	Section 12.2
Monitoring Plan	Section 4.7
New York Courts	Section 15.11(j)
Non-Conforming Product	Section 7.2(d)(i)
Parties	Preamble
Partner	Preamble

Partner Commercialization Plan	Section 6.2
Partner Developed IP	Section 10.1(b)(ii)
Partner Indemnitee	Section 12.1(a)
Partner Site	Section 4.3(b)(i)
Partner Territory Infringement	Section 10.3(a)
Party	Preamble
Pharmacovigilance Agreement	Section 5.8
Prosecuting Party	Section 10.2(a)
Prosecution Activities	Section 10.2(a)
Quality Agreement	Section 7.2(a)
Recipient	Section 13.1
Regulatory Meeting	Section 5.2(a)
Rejection Period	Section 7.2(d)(i)
Royalty Rate	Section 8.1(a)
Royalty Term	Section 8.1(b)
Site	Section 4.3(b)(i)
Statistical Analysis Plan	Section 4.5(f)
Subject Recruitment Plan	Section 4.3(d)
Sunshine Reporting Laws	Section 11.1(d)
Term	Section 14.1(a)
Third Party Infringement	Section 10.3(b)
Trademark Infringement Claim	Section 10.6(a)(i)
Trademark Searches	Section 6.6(c)(i)
Transfer of Responsibilities	Section 4.2(e)(ii)
UNCITRAL Rules	Section 15.11(b)

1.2 Construction. Any reference in this Agreement to a "Section," "Exhibit" or "Schedule" refers to the corresponding Section, Exhibit or Schedule of or to this Agreement, unless the context indicates otherwise. The table of contents and the headings of Sections are provided for convenience only and are not intended to affect the construction or interpretation of this Agreement. All words used in this Agreement are to be construed to be of such gender or number as the circumstances require. The words "including," "includes" or "include" are to be read as listing nonexclusive examples of the matters referred to, whether or not words such as "without limitation" or "but not limited to" are used in each instance. Where this Agreement states that a party "shall," "will" or "must" perform in some manner or otherwise act or omit to act, it means that the party is legally obligated to do so in accordance with this Agreement. Any reference to a statute is deemed also to refer to any amendments or successor legislation as in effect at the relevant time. Any reference to a contract or other document as of a given date means the contract or other document as amended, supplemented and modified from time to time through such date. Any words (including capitalized terms defined herein) in the singular will be held to include the plural and vice versa and words (including capitalized terms defined herein) of one gender will be held to include the other gender as the context requires. The terms "hereof," "herein" and "herewith" and words of similar import will, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement. All references herein to "\$" or dollars will be deemed to be to the relevant number of calendar days unless otherwise specified. All references herein to "\$" or dollars will refer to United States dollars, unless

otherwise specified. All accounting terms not otherwise defined herein have the meanings given to them in accordance with GAAP.

## Section 2. Grant of Licenses.

- 2.1 <u>Licenses Granted to Partner</u>. Subject to the terms and conditions of this Agreement, during the Term, Company hereby grants to Partner:
- (a) an exclusive (even as to Company, except to the extent expressly set forth herein), sublicensable (provided that each such sublicense is consistent with the terms of this Agreement and solely to the extent permitted under Sections 2.2 and 4.17), non-assignable (except to the extent permitted in Section 15.5) license under the Company IP to use, promote, market, sell, offer for sale, import into, distribute and otherwise Commercialize (but not to Develop or Manufacture) the Product for use for those indications for which Partner is granted Regulatory Approval in the Partner Territory in accordance with the terms hereof, solely within the Partner Territory;
- (b) a non-exclusive, sublicensable (*provided* that each such sublicense is consistent with the terms of this Agreement and solely to the extent permitted under <u>Sections 2.2</u> and <u>4.17</u>), non-assignable (except to the extent permitted in <u>Section 15.5</u>) license under the Company IP to Develop (but not to Manufacture or Commercialize) the Product in the Company Territory solely in accordance with, and subject to, the Global Development Plan;
- (c) an exclusive (even as to Company), sublicensable (*provided* that each such sublicense is consistent with the terms of this Agreement and solely to the extent permitted under <u>Sections 2.2</u> and <u>4.17</u>), non-assignable (except to the extent permitted in <u>Section 15.5</u>) license under the Company IP to Develop (but not to Manufacture or Commercialize) the Product in the Partner Territory solely in accordance with, and subject to, the Global Development Plan; and
- (d) an exclusive (even as to Company, except to the extent expressly set forth herein), sublicensable (provided that each such sublicense is consistent with the terms of this Agreement and solely to the extent permitted under Sections 2.2 and 4.17), non-assignable (except to the extent permitted in Section 15.5) license under the Company IP to Manufacture (but not to Develop or Commercialize) the Product in the Partner Territory solely for commercial sale of such Product in the Partner Territory (such commercial sale, for clarity, solely in accordance with, and subject to, Section 2.1(a)).

#### 2.2 <u>Sublicenses</u>.

(a) Partner shall have the right to grant sublicenses under the licenses granted in <u>Sections 2.1(a)</u> and <u>2.1(d)</u> to its Affiliates and Third Parties, in each case, without Company's consent; *provided* that Partner shall not have the right to grant sublicenses to any Affiliate or Third Party, in each case, that is a Sanctioned Person or is owned or controlled (for purposes of this <u>Section 2.2</u>, as such term is used in and construed under Rule 405 under the Securities Act) by a Sanctioned Person.

- (b) Partner shall have the right to grant sublicenses under the licenses granted in Sections 2.1(b) and 2.1(c) to its Affiliates and Third Parties, subject to prior written consent of the Company (such consent not to be unreasonably withheld, conditioned, or delayed and if Company fails to grant or deny such consent within seven (7) days of receipt of Partner's request for such consent, such consent shall be deemed to be granted); provided that Partner shall not have the right to grant any sublicense to any Affiliate or Third Party that is a Sanctioned Person or owned or controlled by a Sanctioned Person. Notwithstanding the foregoing, Company hereby consents to Partner granting (i) its Affiliate, Insights Pharmaceutical Research LLC ("Insights"), a sublicense in the rights granted to Partner under Sections 2.1(b) and 2.1(c) to serve as a CRO for the purpose of the conduct of the Partner-Conducted Clinical Trials and (ii) to the extent necessary, the Sites and Clinical Investigators, appointed by either Partner or Insights, and in each case, selected in accordance with the terms of this Agreement, for the Partner-Conducted Clinical Trials; provided, in each case (in respect of the foregoing (i) and (ii)), that the sublicense agreement therefor is in writing.
- (c) As soon as reasonably practicable following the Effective Date, Company shall, or shall cause vTv Inc. to, use commercially reasonable efforts to obtain a waiver from Novo with respect to the obligation set forth in Section 2.1(c) of the Novo Agreement to provide Novo with notice of sublicenses granted under the Novo Agreement; provided that, for clarity, in no event shall the foregoing require Company to agree to or make any payments or other concessions. Notwithstanding anything to the contrary herein, in the event Company is unable to obtain such waiver from Novo despite its use of commercially reasonable efforts in accordance with the foregoing, Partner must provide Company with forty-five (45) days advance written notice of each sublicense granted with respect to any licenses granted to Partner hereunder in order to ensure that Company complies with its obligations with respect thereto under the Novo Agreement.
- (d) For clarity, granting a sublicense shall not relieve Partner of any obligations hereunder and Partner shall cause each of its Sublicensees to comply, and shall remain responsible for its Sublicensees' compliance, with the terms of this Agreement that are applicable to Partner and all Applicable Laws. Sublicenses granted hereunder shall be subject to, and consistent with, the terms of this Agreement.

## 2.3 <u>Reserved Rights of Company.</u>

- (a) Company hereby expressly reserves: (i) rights under Company IP to exercise its rights and perform its obligations under this Agreement and (ii) all rights to practice, and to grant licenses under, the Company IP outside of the scope of the licenses granted in <u>Section 2.1</u>, including the right to Manufacture the Compound and Product anywhere in the world (except in the Partner Territory for commercial sale by or on behalf of Partner within the Partner Territory), Develop the Product outside the scope of the Global Development Plan in the Company Territory, and Exploit compounds and products (other than the Product within the scope of Partner's exclusive licenses granted under Section 2.1).
- (b) Partner acknowledges and agrees that nothing herein shall preclude Company from conducting research, or Development activities not set forth in the Global Development Plan, with respect to the Product in the Company Territory; *provided* that, during

the Term, Partner shall be granted rights to Data (if any) generated in connection with any such research or Development activities, solely for Partner to conduct Development in accordance with the Global Development Plan within the scope of the licenses granted in <u>Sections 2.1(b)</u> and <u>2.1(c)</u>, and Commercialize the Product for use in the Partner Territory within the scope of the license granted in <u>Section 2.1(a)</u>.

- 2.4 <u>Licenses Granted to Company</u>. Subject to the terms and conditions of this Agreement, Partner hereby grants to Company in partial consideration for the issue of certain shares in vTv Inc. to Sparkly Holdings SPV Ltd pursuant to the Purchase Agreement:
- (a) an exclusive (even as to Partner), fully paid-up, royalty-free, sublicensable (*provided* that each such sublicense is consistent with the terms of this Agreement and solely to the extent permitted under <u>Sections 2.6</u> and <u>4.17</u>), non-transferable (except to the extent permitted in <u>Section 15.5</u>) license under the Partner IP, to the extent necessary to use, promote, market, sell, offer for sale, import, distribute and otherwise Commercialize (but not Develop or Manufacture) the Product for use in the Company Territory;
- (b) an exclusive (even as to Partner, except to the extent expressly set forth herein), fully paid-up, royalty-free, sublicensable (*provided* that each such sublicense is consistent with the terms of this Agreement and solely to the extent permitted under <u>Sections 2.6</u> and <u>4.17</u>), non-transferable (except to the extent permitted in <u>Section 15.5</u>), license under the Partner IP, to the extent necessary to Develop the Product in the Company Territory; and
- (c) an exclusive (even as to Partner, except to the extent expressly set forth herein), fully paid-up, royalty-free, sublicensable (*provided* that each such sublicense is consistent with the terms of this Agreement and solely to the extent permitted under <u>Sections 2.6</u> and <u>4.17</u>), non-transferable (except to the extent permitted in <u>Section 15.5</u>), worldwide license under the Partner IP, to the extent necessary to Manufacture the Product; *provided* that Company may not Manufacture the Product in the Partner Territory for commercial sale in the Partner Territory.
- 2.5 <u>Reserved Rights of Partner</u>. Partner hereby expressly reserves: (a) rights under Partner IP to exercise its rights and perform its obligations under this Agreement and (b) all rights to practice, and to grant licenses under, the Partner IP outside of the scope of the licenses granted in <u>Section 2.4</u>, including the right to develop, commercialize and/or manufacture any product other than the Product, anywhere in the world.
- 2.6 <u>Sublicenses</u>. Company shall have the right to grant sublicenses under the licenses granted in <u>Section 2.4</u> to its Affiliates and Third Parties, in each case, without Partner's consent; *provided* that Company shall not have the right to grant sublicenses to any Affiliate or Third Party, in each case, that is a Sanctioned Person or is owned or controlled (for purposes of this <u>Section 2.6</u>, as such term is used in and construed under Rule 405 under the Securities Act) by a Sanctioned Person. For clarity, granting a sublicense shall not relieve Company of any obligations hereunder and Company shall cause each of its Sublicensees to comply, and shall remain responsible for its Sublicensees' compliance, with the terms of this Agreement that are applicable to Company. Sublicenses granted hereunder shall be subject to, and consistent with, the terms of this Agreement.

- 2.7 <u>No Implied Licenses</u>. Except to the extent expressly set forth in this Agreement, neither Party is granted any license or other right, title or interest, by implication or otherwise, in, to or under any Intellectual Property of the other Party. Each Party shall ensure that neither it, nor any of its Party Members, practices any Intellectual Property licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.
- 2.8 <u>Disclosure of Know-How.</u> During the Term, Partner shall, and shall cause the Partner Members to, without additional compensation, disclose and make available to Company, in electronic form or such other form agreed upon by the Parties in writing, any Partner Know-How not previously provided to Company, promptly after the earlier of developing, making, conceiving or reducing to practice such Partner Know-How.

#### Section 3. Governance.

- 3.1 <u>Alliance Managers</u>. Promptly following the Effective Date, each Party shall appoint an employee with appropriate qualifications and experience to act as its alliance manager (each an "<u>Alliance Manager</u>"). Each Alliance Manager shall be responsible for facilitating communications between the Parties and shall act as a liaison between the Parties with respect to activities to be conducted pursuant to this Agreement. Each Alliance Manager shall be permitted to attend meetings of the JDC as a non-voting participant. Each Party may replace its Alliance Manager with another qualified employee at any time with prior notice to the other Party.
- 3.2 <u>Joint Development Committee</u>. The Parties shall establish a joint development committee (the "<u>JDC</u>"), composed of three (3) members for each Party, to coordinate and oversee Development of the Product under the Global Development Plan and Commercialization of the Product for use throughout the Partner Territory. The JDC shall in particular:
  - (a) coordinate, monitor and oversee implementation of the Global

Development Plan;

(b) provide a forum for and facilitate communications between the

Parties with respect to the activities conducted hereunder;

- (c) review and approve changes to the Global Development Plan and any Collaboration Protocols;
  - (d) monitor and coordinate the Parties' regulatory activities,

responsibilities and obligations hereunder, including with respect to pharmacovigilance and safety matters worldwide, as such activities, responsibilities and obligations are further set forth in the Pharmacovigilance Agreement;

(e) review and approve the Partner Commercialization Plan and any

changes thereto;

(f) oversee the exchange of information as required under the

Pharmacovigilance Agreement and all Applicable Laws;

- (g) monitor and oversee Commercialization of the Product by the Partner Members under this Agreement;
  - (h) provide a forum for dispute resolution as provided in <u>Section 3.4</u>;

and

(i) perform such other functions to the extent related to or in support of this Agreement or otherwise agreed upon by the Parties in writing.

## 3.3 <u>JDC Membership and Meetings</u>.

- (a) <u>JDC Members</u>. Each JDC member shall have sufficient expertise and seniority within the applicable Party to fulfill the JDC's responsibilities as set forth herein at the applicable time. The initial JDC members of each Party shall be appointed as soon as reasonably practicable following the Effective Date. Each Party may replace its JDC members upon written notice to the other Party; *provided* that each Party shall strive to maintain continuity in its JDC membership. Company shall appoint one of its JDC members to act as the JDC chairperson, which chairperson may be replaced with another Company JDC member or qualified employee in Company's sole discretion upon written notice to Partner.
- (b) Meetings. Prior to the First Commercial Sale of the Product in the Partner Territory, the JDC shall meet at least four (4) times per year (which meetings may be conducted via teleconference; provided that at least two (2) meetings per year shall be conducted by videoconference), spaced at regular intervals, unless the Parties agree otherwise. Following the First Commercial Sale of the Product in the Partner Territory, the JDC shall meet at least two (2) times per year, with such meetings spaced at regular intervals, unless the Parties agree otherwise. Either Party may call a special meeting of the JDC upon at least five (5) days' prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting. Each Party may invite individuals who are not JDC members to participate in JDC meetings in a non-voting capacity; provided that (i) the other Party is given prior written notice thereof and in the case of any Third Party participants, grants written consent and (ii) such non-member is subject to written confidentiality and non-use obligations consistent with the terms of this Agreement. In accordance with the foregoing, Partner hereby grants Company consent for MAF representatives to participate in JDC meetings. The JDC chairperson shall prepare and circulate agendas to JDC members at least five (5) Business Days prior to each JDC meeting. The chairperson of the JDC shall circulate minutes to the JDC members within thirty (30) days from the date of the relevant meeting. Each Party shall have ten (10) Business Days from receipt to comment on and approve such minutes (such approval to be in writing and not to be unreasonably withheld, conditioned or delayed) and if such Party fails to respond within such time period, the minutes shall be deemed to have been approved by such Party.

## 3.4 <u>Decision-Making</u>.

(a) All decisions of the JDC shall be made in good faith by unanimous vote, with each Party's JDC members collectively having one (1) vote. If the JDC cannot reach an agreement as to such matter within thirty (30) days after such matter was referred to the JDC

for resolution, then either Party at any time may refer such issue to the Executive Officers for resolution.

- (b) If the Executive Officers cannot resolve such matter within ten (10) Business Days of the date on which such matter was first referred to them by either Party's JDC members, then:
  - (i) Company shall have the deciding vote on any matter that Company reasonably believes could detrimentally and materially impact in any way:
    - (1) the ability to obtain or maintain any Regulatory

Approval for the Product;

(2) the Commercialization of the Product in the

Company Territory

(3) the Manufacture of the Compound or the Product

by or on behalf of any Company Member;

(4) the research or Development (including any

Collaboration Clinical Trials) of the Compound or the Product in the Company Territory or Partner Territory, including, for clarity, any revisions to the Global Development Plan and any decisions regarding (including with respect to any changes to) any Collaboration Protocol; and

(5) the scope, validity or enforceability of any

Company IP;

(ii) Partner shall have the deciding vote on any and all matters

solely related to the Development or Commercialization of the Product in the Partner Territory, or Manufacture by Partner of the Product for use in the Partner Territory to the extent permitted hereunder; *provided* in each case, that such matter does not fall under Company's final decision-making authority pursuant to Section 3.4(b)(i); and

- (iii) the status quo shall be maintained for all other matters.
- (c) Notwithstanding the foregoing Section 3.4(b), neither Party shall

have the deciding vote (as set forth in Sections 3.4(b)(i) and 3.4(b)(i)) on, and the JDC shall not have decision-making authority regarding: (i) the imposition of any additional material obligations on the other Party (1) other than those for which it is expressly responsible hereunder, (2) that would violate any Applicable Laws or otherwise impose liability on a Party or any of its Affiliates; or (3) that would cause such Party to forgo any of its rights under this Agreement; (ii) any decision that is expressly stated to require the Parties' mutual agreement; or (iii) any matters that would excuse the Party with the deciding vote from its obligations under this Agreement. For clarity, notwithstanding anything to the contrary herein, (x) in the event that the JDC fails to amend the Global Development Plan to include any Subsequent Clinical Trial, the Global Development Plan shall not be amended to include such Subsequent Clinical Trial and (y) in no event shall the JDC have decision-making authority with respect to the research, Development, or Commercialization

of the Compound or Product within the Company Territory (other than in respect of the Collaboration Clinical Trials as and to the extent expressly set forth herein) or the Manufacture of the Compound or Product in the Company Territory or Partner Territory (other than Manufacture of the Product by Partner for commercial sale in the Partner Territory).

3.5 <u>Limitations on Authority</u>. The JDC 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. Without limiting the generality of the foregoing, the JDC shall not have the power to amend this Agreement, and no decision of the JDC may be in contravention of any terms and conditions of this Agreement.

## Section 4. <u>Development</u>.

4.1 <u>Overview</u>. Subject to the terms and conditions of this Agreement, the Parties shall collaborate with respect to the Development of the Product as further described in this <u>Section 4</u>.

#### 4.2 Development Plan.

- (a) <u>General</u>. Development of the Product under this Agreement shall be conducted pursuant to a comprehensive written global development plan (the "<u>Global Development Plan</u>"), which, when approved in writing by the JDC shall be incorporated by reference into this Agreement and shall set forth the activities to be undertaken by each Party under this Agreement to Develop the Product for use throughout the Partner Territory and Company Territory. Except as expressly stated herein, to the extent any terms or conditions of the Global Development Plan expressly conflict with the terms or conditions of this Agreement, the terms and provisions of this Agreement shall control. For clarity and notwithstanding anything to the contrary herein, in no event shall Partner or any Partner Member conduct any Development activities with respect to the Compound or the Product that are not expressly set forth in, or otherwise in compliance with, the Global Development Plan.
- (b) <u>Development Responsibilities</u>. Subject to the terms hereof, the Global Development Plan shall allocate Development responsibilities under this Agreement for the Product between the Parties, including that Partner shall provide data management and services related to its genomic capabilities for the Partner-Conducted Clinical Trials.
- (c) <u>Initial Global Development Plan</u>. The initial Global Development Plan shall be developed jointly by the Parties and shall set forth the Parties' responsibilities for the Initial Clinical Trials. The JDC shall meet and agree upon such Global Development Plan as soon as reasonably practicable following the Effective Date. During the Term, any changes to the Global Development Plan, including any changes required by Applicable Laws and changes made in response to any communications with any Regulatory Authority, shall be developed jointly by the Parties and shall require the JDC's written approval.

## (d) <u>Clinical Trial Protocols</u>.

- (i) <u>Protocols</u>. The Parties acknowledge and agree that the protocols for the Collaboration Clinical Trials shall require approval by the JDC and following such approval, shall be incorporated into the Global Development Plan.
- (ii) <u>Changes to the Protocols</u>. Any changes to the protocol for any Collaboration Clinical Trial set forth in the then-current Global Development Plan (each, a "<u>Collaboration Protocol</u>"), including any country-specific appendices required by Applicable Laws and changes made in response to any communications with any Regulatory Authorities, shall require the JDC's written approval.

## (e) Sponsorship and Responsibilities.

- (i) <u>Company-Conducted Clinical Trials</u>. As between the Parties, Company shall be the Sponsor of all Collaboration Clinical Trials that are not Partner- Conducted Clinical Trials (the "<u>Company-Conducted Clinical Trials</u>"). Except to the extent expressly set forth herein, as between the Parties, Company shall have sole discretion and control over the conduct of the Company-Conducted Clinical Trials.
- Partner-Conducted Clinical Trials. As between the Parties, Company and Partner shall be Co-Sponsors of the Partner-Conducted Clinical Trials, and in furtherance of the foregoing, in accordance with 21 CFR 312.52, and any corresponding Applicable Laws in any other countries or regulatory jurisdictions, Company hereby transfers the responsibilities (and all corresponding liabilities therefor) of a Sponsor to Partner for the Partner-Conducted Clinical Trials as set forth in Schedule 4 (such transfer, the "Transfer of Responsibilities"); provided, that, if designating Company as the Sponsor in furtherance of the foregoing would violate any Applicable Laws (including, by way of example, local Laws that require the Sponsor to have a presence in the applicable jurisdiction in order to be the Sponsor of a Clinical Trial with subjects in such jurisdiction), Partner shall notify Company and the Parties shall meet to discuss whether any amendments hereto are required (provided that any such amendments shall be subject to Section 15.4) to ensure that no such violation occurs. In the event required by any Regulatory Authority under 21 CFR 312.52. or any other corresponding Applicable Laws in any other countries or regulatory jurisdictions, the Parties shall prepare a separate written document documenting the Transfer of Responsibilities. In connection with the Partner- Conducted Clinical Trials, Partner shall provide Company with any information and assistance requested by Company to fulfill its obligations as a Co-Sponsor hereunder, and Partner agrees that time is of the essence with regard to the foregoing and shall take all steps necessary to comply with any such requests. Partner acknowledges and agrees that, in order to comply with its obligations as a Co-Sponsor hereunder, Company shall have the right to terminate or pause any Partner-Conducted Clinical Trial hereunder. Without limiting the foregoing, Partner shall ensure that any portion of any Partner-Conducted Clinical Trial that is conducted outside the United States complies with all Applicable Laws that are necessary or useful to obtain Regulatory Approval of the Product within the United States and the EU.

## 4.3 <u>Sites and Clinical Investigators</u>.

(a) <u>Selection</u>. As between the Parties, each Party shall be responsible for selecting the study sites for the Collaboration Clinical Trials with respect to which it has responsibility under the Global Development Plan (which, for clarity, in the case of Partner, such Clinical Trials are the Partner-Conducted Clinical Trials, and in the case of Company, such Clinical Trials are Company-Conducted Clinical Trials), and will inform the JDC of each such study site; *provided* that, within seven (7) days of submission of such sites to the JDC, the JDC will have the right to reject any such sites proposed by Partner that the JDC determines in its reasonable judgment are not appropriate.

## (b) <u>Clinical Trial Agreement</u>.

- (i) For any Partner-Conducted Clinical Trials, Partner (or Partner Member, as applicable) shall enter into an agreement with each such study site, which agreement will be substantially in the form(s) provided by Company and consented to by Partner in writing (such consent not to be withheld except to the extent that such form violates any Applicable Laws) (the "Clinical Trial Agreement"). If a Partner Site requires any material changes to such form Clinical Trial Agreement, Partner shall provide Company with written notice thereof and such changes shall require the Company's prior written approval. Upon execution of a Clinical Trial Agreement with any site for any Collaboration Clinical Trial, such study site shall be deemed a "Site" and any such Site for a Partner-Conducted Clinical Trial shall be deemed to be a "Partner Site." For clarity, each Clinical Trial Agreement shall be on commercially reasonable and customary terms, consistent with industry standards for similar agreements and sufficient to enable Partner to comply with its obligations hereunder with respect to the applicable Collaboration Clinical Trial, including Sections 4.2(e), 4.6 and 5.3, the terms pertaining to ownership of Intellectual Property and publications, and treatment of Confidential Information and to enable Company to exercise its rights under Section 4.6.
- (ii) The Clinical Trial Agreements for the Partner-Conducted Clinical Trials shall also require, to the extent required by Applicable Laws, that the Clinical Investigators, any Subinvestigators (including any research fellows, residents and associates) and any others required by Applicable Laws at each Partner Site, complete a financial disclosure document, which will be substantially in the form(s) provided by or on behalf of Company and consented to by Partner in writing (such consent not to be withheld except to the extent that such form violates any Applicable Laws) within seven (7) days following receipt of such form (the "Financial Disclosure Form"). For clarity, if any of the foregoing individuals that are required by Applicable Laws to complete such Financial Disclosure Form do not complete such Financial Disclosure Form, such individuals may not participate in, or do any work in connection with, the Partner-Conducted Clinical Trials.

# (c) <u>Meetings and Communications with Sites.</u>

(i) Partner (or Partner Member, as applicable) shall conduct meetings with the Clinical Investigators of the Partner-Conducted Clinical Trials (each, a

"Clinical Investigator Meeting"), of which the JDC will be provided with reasonable advance written notice and to which Company (or, at Company's option, any Company Members) shall have the right (but not the obligation) to attend and participate. Minutes of such Clinical Investigator Meetings shall promptly be made available to the JDC upon the JDC's request.

- (ii) Partner shall promptly provide the JDC with copies of all communications relevant to the Partner-Conducted Clinical Trials provided to Partner Sites and any other material communications between Partner and any individual Partner Sites.
- (d) <u>Subject Recruitment Plan</u>. In recruiting subjects for any Partner-Conducted Clinical Trial, Partner shall comply with the subject recruitment plan for such Clinical Trial, which plan Partner shall prepare, and communicate to the JDC, for the JDC's review and approval, within a reasonable period of time (which shall be no more than thirty (30) days) after the Effective Date (each, a "<u>Subject Recruitment Plan</u>"). For clarity, prior to engaging in any recruiting activities, Partner shall ensure that the applicable IRBs and/or other ethics committees approve any related materials and activities as required by the JDC and all Applicable Laws. Notwithstanding anything to the contrary herein, in the event that the JDC fails to approve such Subject Recruitment Plan in writing, the Global Development Plan shall automatically be amended to remove such Partner-Conducted Clinical Trial and for clarity, Company shall be permitted to conduct such Clinical Trial outside of the scope of this Agreement.

#### (e) Informed Consent.

- (i) Company, with support from Partner, shall prepare the informed consent documents for use in any Collaboration Clinical Trial. Partner shall ensure that the informed consent of each subject participating in each Partner-Conducted Clinical Trial is obtained in accordance with all Applicable Laws (including, for clarity, all Applicable Laws required to obtain Regulatory Approval for the Product within the United States), including completion of such informed consent document. Such informed consent document for a Collaboration Clinical Trial shall be substantially in the form to be approved by the JDC within thirty (30) days of the Effective Date (collectively, "Informed Consent"). If a Partner Site or subject requires any material changes to such form Informed Consent, Partner shall provide Company with written notice thereof and such changes shall require the Company's prior written approval. For clarity, the Informed Consent document that each subject executes shall expressly state that such subject understands that such Party is providing support for the Clinical Trial and shall authorize disclosure of Data and results related to such Clinical Trial to Company, Partner and each of their respective Party Members, as applicable, for any purpose, subject to all Applicable Laws; provided that (1) the Parties agree that neither Party shall provide the other Party any personally identifiable data of the subjects unless required for handling, investigating or reporting adverse events and in such case, such provision shall be subject to the terms of the Pharmacovigilance Agreement and (2) each Party's use of any such data and results shall be subject to and in accordance with the terms hereof.
- (ii) Partner shall ensure that the Informed Consent has been obtained from each subject participating in a Partner-Conducted Clinical Trial prior to

administration of the Product, or any placebo of the Product, to such subject in accordance with the applicable Collaboration Protocol.

(f) <u>Inclusion and Exclusion Criteria</u>. Partner shall not waive any exclusion or inclusion criteria specified in the Collaboration Protocol for any Partner-Conducted Clinical Trial without Company's prior written consent.

## 4.4 <u>Investigator's Brochure</u>.

- (a) As between the Parties, Company shall maintain the Investigator's Brochure for the Product. Partner shall, promptly following receipt of written notice from Company of the need for an Investigator's Brochure update, provide Company with all information regarding the Partner-Conducted Clinical Trials that is necessary to enable Company to update the Investigator's Brochure.
- (b) Promptly following the Effective Date, Company shall provide Partner with the most recent version of the Investigator's Brochure for the Initial Product. Company shall also promptly provide Partner with any updated versions of such Investigator's Brochure. Each Party shall ensure that each Site in such Party's respective territory, and all applicable IRBs and other ethics committees, receive a copy of, and promptly receive any updates to, the Investigator's Brochure for the applicable Product.

## 4.5 <u>Data Collection and Management.</u>

(a) <u>CRF</u>. Partner, in consultation with Company, shall be responsible for preparing the form of CRF for the Partner-Conducted Clinical Trials in accordance with the Collaboration Protocols and Company's CRF standards.

## (b) <u>Data Management Plan</u>.

- (i) Partner, in consultation with Company, shall be responsible for preparing the data management plan (the "<u>Data Management Plan</u>") for the Partner-Conducted Clinical Trials, and the Data Management Plan for the Partner-Conducted Initial Clinical Trial shall be submitted to the JDC for its review and approval promptly following the Effective Date. Partner shall use Commercially Reasonable Efforts to comply with the Data Management Plan. For clarity, the applicable Data Management Plan must be agreed upon by the JDC prior to recruitment of subjects for the applicable Partner-Conducted Clinical Trials.
- (ii) With respect to any data collected in connection with the Partner-Conducted Clinical Trials, Partner shall ensure that such data is held in one or more appropriate facilities with information security protections in accordance with all Applicable Laws, including (1) unique accounts for all operators; (2) cancellation of an account when an employee or other personnel terminates employment; (3) deactivation of an account when an employee or other personnel ceases working on the applicable Clinical Trials; (4) required password changes at frequent intervals; and (5) regular backups of electronic data.

#### (c) <u>Clinical Trials Database</u>.

- (i) Partner, in consultation with Company, shall establish a Clinical Trials database for the purpose of hosting the data collected from each Partner Site for the Partner-Conducted Clinical Trials (the "Clinical Trials Database"). Such Clinical Trials Database shall be established by Partner for the Partner-Conducted Initial Clinical Trial promptly following the Effective Date (but, for clarity, will not be populated until the Partner-Conducted Initial Clinical Trial is conducted in accordance with the terms hereof) and Company shall be provided with access to such database (including the information therein) beginning on the date of such Clinical Trials Database's establishment. Partner, in consultation with Company, shall promptly update the Clinical Trials Database upon any final amendments to the Collaboration Protocol, as necessary, and in accordance with this Section 4.5. Partner shall promptly update the Clinical Trials Database upon receiving data for the Partner-Conducted Clinical Trials from any Partner Site, and Partner shall use reasonable efforts to ensure that the Partner-Conducted Clinical Trials to Partner or its Affiliate, as applicable.
- (ii) Partner shall provide the JDC with electronic copies of any data related to the Partner-Conducted Clinical Trials requested by the JDC at JDC meetings and in accordance with Applicable Laws.
- (iii) Partner shall provide SAS datasets to Company in accordance with specifications as defined by Company (1) when fifty percent (50%) of subjects have been dosed for six (6) months (where the Collaboration Protocol provides for interim analysis); (2) when the data in the Clinical Trials Database is equivalent to one hundred percent (100%) of total data expected to be recorded in the Clinical Trials Database; (3) if a safety signal is identified; or (4) if a request is received from any applicable Regulatory Authorities, in relation to the Partner-Conducted Clinical Trials.
- (iv) Partner shall maintain the Clinical Trials Database for the Partner-Conducted Clinical Trials, including ensuring that information included in the Clinical Trials Database is accurate and up-to-date.
- (v) Company shall be responsible for registering, maintaining and updating any registries pertaining to the Initial Clinical Trials to the extent required by any Applicable Laws, including <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>, <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>, and the PHRMA Website Synopsis.
- (d) <u>Clinical Trials Master File</u>. Partner shall establish and maintain a Clinical Trials master file for each Partner-Conducted Clinical Trial in the format as agreed upon by the JDC (each, a "<u>Clinical Trials Master File</u>"), and the Clinical Trials Master File for the Partner-Conducted Initial Clinical Trial shall be established promptly following the Effective Date.
- (e) <u>Source Data Verification</u>. Partner shall be responsible for source verification of data records with respect to the Partner-Conducted Clinical Trials, as set forth in the Monitoring Plan. At Company's request, Partner shall provide Company with copies of any

reports relating to source data verification and other types of Partner-Conducted Clinical Trials audits.

(f) <u>Statistical Analysis</u>. The Parties shall collaborate to perform any statistical analysis required in accordance with the statistical analysis plan ("<u>Statistical Analysis Plan</u>") for the Collaboration Clinical Trials. The Statistical Analysis Plan for the Collaboration Clinical Trials shall be developed by Company in consultation with the JDC. The Parties shall cooperate in good faith in carrying out the Statistical Analysis Plans.

## 4.6 Audits; Inspection.

- (a) During the term of a Partner-Conducted Clinical Trial, Company (on its own or through a Third Party) shall have the right, at its expense, to conduct quality oversight inspections and audits of the facilities (including Partner Sites) and services utilized, and activities performed, by or on behalf of Partner in connection with any Partner-Conducted Clinical Trial in accordance with its standard operating procedures and shall provide Partner with copies of such audit reports upon request, subject to Company giving to Partner no less than two (2) Business Days' prior written notice of its intent to audit.
- (b) Upon thirty (30) days' prior written notice and during normal business hours, no more frequently than once per Calendar Year (the "Annual Limitation"), Company or any of its Affiliates, or a Third Party auditor appointed by Company and reasonably acceptable to Partner, may inspect and audit any and all records created by Partner Members in the conduct of the Partner-Conducted Clinical Trials solely for the purpose of confirming Partner's compliance with this Agreement and Applicable Laws in the conduct of such Clinical Trials; provided that the scope of such audit is reasonable in its intended purpose. Partner agrees to make available employees of Partner and its Affiliates, and cause applicable Partner Members to make their employees available, as reasonably requested by Company, to answer Company's reasonable questions in connection with such inspection or audit. Notwithstanding the foregoing, if Company has a reasonable, good faith belief that Partner has failed to materially comply with this Agreement or Applicable Laws in the conduct of the Partner-Conducted Clinical Trials and such reasonable, good faith belief is supported by reasonable evidence, Company shall have the right to conduct an audit and inspection described in this Section 4.6 upon thirty (30) days' prior written notice and without regard to the Annual Limitation. All expenses of any inspection or audit requested by Company pursuant to this Section 4.6 (including the fees and expenses of any Third Party auditor engaged by Company for such purpose) shall be borne by Company. All information obtained by Company as a result of such inspection or audit shall be Confidential Information in accordance with the terms hereof. Any Third Party auditor appointed by Company pursuant to this Section 4.6 shall be subject to confidentiality obligations no less restrictive than those set forth in Section 13 with respect to such Confidential Information.
- 4.7 <u>Monitoring</u>. (a) Partner shall monitor the Partner-Conducted Clinical Trials, and Company shall monitor the Collaboration Clinical Trials that it is conducting, in each case, in accordance with the monitoring plan (the "<u>Monitoring Plan</u>") to ensure compliance with this Agreement and all Applicable Laws, and (b) each Party shall share information with the JDC pertaining to such monitoring, in each case (with respect the foregoing (a) and (b)) in accordance

with the Monitoring Plan for the Collaboration Clinical Trials (which shall be prepared by Company, in consultation with Partner, and submitted to the JDC for its review and approval).

#### 4.8 <u>IRBs and Other Ethics Committees</u>.

- (a) Partner shall be responsible for obtaining the approval of the IRBs and other ethics committees required prior to commencing, and during, the Partner-Conducted Clinical Trials at every Partner Site. Partner shall ensure that such IRBs and such other relevant ethics committees have current registrations and accreditations as required by Applicable Laws and shall provide all ethics committees, including all IRBs, and Regulatory Authorities, with all necessary documentation prior to, and during the course of, the Partner-Conducted Clinical Trials as required by Applicable Laws.
- (b) Partner shall be responsible for responding to all queries from the IRBs and other ethics committees in respect of the Partner-Conducted Clinical Trials; *provided* that (i) following Partner's reasonable request, Company shall make itself reasonably available to assist with any such queries and (ii) if such query relates solely to the Company's responsibilities or activities hereunder, Company shall prepare the applicable response and provide Partner with a copy thereof.

#### (c) IDMC.

- (i) Company shall establish an IDMC, and the charter that governs such IDMC (the "<u>IDMC</u> <u>Charter</u>"), for the Collaboration Clinical Trials.
- (ii) The Parties, via the JDC, shall ensure that the IDMC is provided with all required information and data in a timely manner as specified in the IDMC Charter.

## 4.9 Environmental Health and Safety.

- (d) In conducting the Partner-Conducted Clinical Trials, Partner shall comply with all Applicable Laws relating to environmental, health and safety matters and shall be solely responsible for establishing material and specimen handling guidelines and for ensuring use of controls, including appropriate personal protective equipment, that minimize potential worker exposure, obtaining the material safety data sheets and providing the appropriate training for workers who will be potentially exposed to the Product.
- (e) Each Party shall promptly notify the JDC, in writing, of any worker claims of suspected occupational illnesses related to working with the Product, regardless of whether such claims are received during the Term or any time thereafter. After termination of this Agreement for whatever reasons, or expiration of this Agreement, each Party shall promptly notify the other Party in writing of any worker claims of suspected occupational illnesses related to working with the Product during the Term, of which it has Knowledge.

## 4.10 Completion of Partner-Conducted Clinical Trials.

- Efforts to keep the Partner Sites operational, including continuing to dose subjects with the Product in accordance with the Collaboration Protocol, and conducting any follow-up work required, until the Completion Date for such Partner-Conducted Clinical Trial. On and following the Completion Date for each Partner-Conducted Clinical Trial, Partner shall close out such Clinical Trial in accordance with the Collaboration Protocol for such Clinical Trial, including performing any and all subject follow-up, providing Company with any and all data not provided as of such date and undertaking all activities required to lock the database (which shall occur no later than sixty (60) calendar days after the date on which the last subject in such Clinical Trial completes the last visit as described in the Collaboration Protocol for such Clinical Trial) ("Database Lock"). For clarity, copies of documents, including any CRFs and the Clinical Trials Master File, shall be transferred to Company within sixty (60) days of the Completion Date of each Partner-Conducted Clinical Trial or, at Company's request, destroyed (provided that such destruction is in compliance with ICH guidelines and Applicable Laws). Notwithstanding the foregoing, neither Party shall provide the other Party (or its Party Members) with any personally identifiable information, unless as required under the Pharmacovigilance Agreement in relation to adverse events and as per Applicable Laws.
- (b) Upon the Completion Date of a Partner-Conducted Clinical Trial, unless otherwise agreed upon by the Parties in writing, Partner, at its expense, shall return to the location specified by Company at such time, or, at Company's option, destroy, any unused Product and placebo of Product from such Clinical Trial, and shall comply with all Applicable Laws in so returning or destroying such Product or placebo of Product.

#### 4.11 <u>Data Results and CSRs.</u>

- (a) Within ninety (90) days of Database Lock, or any interim Database Lock, in each case, for a Partner-Conducted Clinical Trial, Partner shall promptly provide to Company (i) the analysis report, including the information, tables and value added data set, set forth in the Statistical Analysis Plan or otherwise agreed upon (including with respect to the format) by the JDC and (ii) all raw data collected for such Clinical Trial.
- (b) Partner shall deliver to Company the top-line results from the Partner-Conducted Clinical Trials within ninety (90) days after Database Lock for such Clinical Trial. Such top-line results shall include the primary and secondary endpoints, as well as available safety and exposure data.
- (c) The CSR, and any interim CSRs, for each Partner-Conducted Clinical Trial shall be prepared by Partner, with support from Company, in compliance with all Applicable Laws, including ICH E3 guidelines. The final, signed CSR for each Partner-Conducted Clinical Trial (the "Final Partner-Conducted Clinical Trial CSR") shall be provided to Company promptly (but not more than ninety (90) days) following Database Lock of such Partner-Conducted Clinical Trial and any interim CSRs shall be provided to Company promptly (but no more than ninety (90) days) following the corresponding interim Database Lock for such Clinical Trial. In the event that there are any additional safety or efficacy data pertaining to a Partner-Conducted

Clinical Trial that come into the possession of a Partner Member after Partner has provided Company with the Final Partner-Conducted Clinical Trial CSR for such Partner-Conducted Clinical Trial, including as a result of any long-term safety monitoring which occurs or continues after the Database Lock, Partner shall promptly prepare and promptly provide Company with a supplement to such CSR.

## 4.12 <u>Development Reports</u>.

- (a) At each regularly scheduled JDC meeting, Partner shall provide the JDC with regular reports detailing its Development activities for the Product under the Global Development Plan, and a summary of the Data and results from such activities.
- (b) In addition to the reports and notices described in <u>Section 4.12(a)</u>, following Company's reasonable request and subject to reasonable notice, Partner shall make its and its applicable Affiliates' employees and any applicable Third Parties (to the extent permitted hereunder) available for an in-person, video or telephonic meeting with Company to discuss its progress with respect to its conduct of any Development activities under the Global Development Plan. Partner shall provide Company with access to the Data and results from the Partner- Conducted Clinical Trials upon Company's reasonable request.
- 4.13 <u>Development Costs</u>. Except to the extent otherwise expressly set forth herein, each Party shall bear its own costs and expenses incurred in performing Development activities under this Agreement.
- 4.14 <u>Diligence</u>. Partner shall use Commercially Reasonable Efforts to conduct those Development activities that it is assigned under the Global Development Plan and, seek Regulatory Approval for the Product in one or more countries or regulatory jurisdictions in the Partner Territory.
- 4.15 <u>Compliance</u>. Each Party shall Develop the Product under this Agreement in compliance with the applicable Collaboration Protocol and all Applicable Laws, including good scientific and clinical practices, cGCP, cGLP, and cGMP. For the avoidance of doubt, Partner shall ensure that the Partner-Conducted Clinical Trials are conducted in accordance with (a) 21 CFR 312.120 and 21 CFR 314.106 and shall provide Company with any and all supporting documentation required under such regulations in accordance with <u>Section 4.16</u> and (b) all Applicable Laws with respect to privacy and data protections.
- 4.16 <u>Development Records</u>. Partner shall maintain complete, current and accurate records of all Development activities conducted by it under this Agreement, including all Data and other information arising or otherwise resulting from such activities, including all records required under all Applicable Laws. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory (including, in the case of records maintained by Partner, as required to obtain and maintain Regulatory Approval in the Company Territory) and patent purposes and shall be made available to Company upon reasonable request.

#### 4.17 <u>Use of Subcontractors</u>.

- (a) Each Party may perform its activities under the Global Development Plan through one or more subcontractors; *provided* that each Party complies with Section 2.2 (in the case of subcontractors engaged by Partner) or 2.6 (in the case of subcontractors engaged by Company) as if such subcontractor was a Sublicensee hereunder; *provided* that (i) such Party will remain responsible for performance of the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself, (ii) each subcontractor is subject to confidentiality and non-use obligations consistent with the terms of this Agreement and (iii) each subcontractor agrees in writing to assign all Intellectual Property developed in the course of performing any such work to such Party.
- (b) Without limiting any other obligations of Partner hereunder, in the event that Partner is permitted to engage a Third Party in accordance with Section 2.2 to conduct any Partner-Conducted Clinical Trial (or portion thereof) or Manufacture or Commercialization of the Product pursuant to the terms hereof, Partner shall conduct due diligence and ongoing oversight with respect to such Third Party to ensure compliance with this Agreement, including that such Third Party can comply with all applicable terms and obligations of this Agreement (including the applicable Collaboration Protocol) and Applicable Laws.

# Section 5. Regulatory Activities.

# 5.1 <u>Regulatory Filings</u>.

- (a) <u>General</u>. The Global Development Plan shall set forth the regulatory strategy for seeking Regulatory Approval for the Product following completion of specified Development activities under the Global Development Plan in the Partner Territory and Company Territory. Under the oversight of the JDC and subject to <u>Section 4</u> and this <u>Section 5</u>, each Party shall be responsible for implementing such regulatory strategy in its respective territory.
- (b) <u>INDs</u>. As between the Parties, Partner shall use Commercially Reasonable Efforts to prepare and submit any INDs and amendments thereto for each Partner- Conducted Clinical Trial as required by Applicable Laws in the countries where Partner Sites have been selected at its sole cost and expense; *provided* that, if fulfilling such obligations with respect to the Partner-Conducted Clinical Trials would violate any Applicable Laws (including, by way of example, local Laws that require the submitting Person to have a presence in the applicable jurisdiction in order to submit an IND for a Clinical Trial with subjects in such jurisdiction or the Sponsor to submit the applicable IND), Partner shall notify Company and the Parties shall meet to discuss and determine whether any amendments hereto are required (*provided* that any such amendments shall be subject to <u>Section 15.4</u>). Following Partner's reasonable request and at Partner's expense, Company shall provide Partner with reasonable assistance with respect to preparation of the INDs for each Partner-Conducted Clinical Trial. At least thirty (30) days prior to the contemplated submission date of any such IND with respect to a Partner-Conducted Clinical Trial, Partner shall submit to Company a completed draft thereof, confer with Company thereon, and incorporate all comments provided by Company prior to submission to the applicable Regulatory Authorities. For clarity, except to the extent otherwise agreed upon by the Parties in writing, Partner shall not have the right to submit any INDs to any Regulatory Authorities with

respect to the Compound or the Product for any Clinical Trials that are not Partner-Conducted Clinical Trials. Partner shall reimburse Company for costs and expenses incurred by or on behalf of Company and Company Members in connection with fulfilling its obligations under this Section 5.1(b) for the Partner-Conducted Clinical Trials. For clarity, Company shall have the sole right and discretion to prepare and submit any INDs and amendments thereto for all Company- Conducted Clinical Trials and following Company's reasonable request and at Company's expense, Partner shall provide Company with assistance in connection therewith.

- (c) <u>Regulatory Approvals and Other Licenses</u>. Partner will be responsible for obtaining, under its name and at its cost, any import licenses or permits for the entry of the Product into the Partner Territory. Partner shall be responsible for preparing, filing and otherwise seeking Regulatory Approval for the Product in the Partner Territory, subject to the guidance of the JDC. For clarity, Company shall retain all rights to prepare, file and otherwise seek Regulatory Approval for the Product in the Company Territory. In no event shall Company file any applications for Regulatory Approval for use of the Product outside the Company Territory, and in no event shall Partner file any applications for Regulatory Approval for use of the Product outside the Partner Territory. Without limiting Section 5.1(d), upon the written request of either Party, the other Party shall, at the requesting Party's cost and expense, reasonably assist and cooperate with the other Party in the exercise of its rights and obligations set forth in this Section 5.1(c).
- (d) Review Rights. Prior to its submission of any applications for Regulatory Approval for which it has responsibility pursuant to Section 5.1(c), Partner shall provide Company with an opportunity to review and comment on such Regulatory Filings and Company shall provide its comments thereon (if any) within sixty (60) days, or such other period of time agreed upon by the Parties in writing. In the event that a Regulatory Authority establishes a response deadline for any Regulatory Filing or material action shorter than such period, the Parties shall cooperate to ensure Company has a reasonable opportunity for review and comment within such deadlines. Without limiting Partner's obligations under Section 11.1, the JDC shall discuss, and Partner shall incorporate, any such comments from Company (including with respect to the Product label), except to the extent in violation of any Applicable Laws. At Company's request, Partner shall provide the Company with an English translation of the Regulatory Approval along with the original document.

## 5.2 Meetings with Regulatory Authorities.

- (a) No later than thirty (30) days before commencement of each Calendar Quarter (or as soon as reasonably practicable if Partner becomes aware following such time), Partner shall provide Company with a schedule of any meetings or teleconferences with any Regulatory Authority (or related advisory committees) planned for the next Calendar Quarter in the Partner Territory that are related to the Product (each, a "Regulatory Meeting").
  - (i) In the case of any Regulatory Approval granted to Partner, and following the grant of such approval, Partner shall be responsible for any communications with the Regulatory Authorities occurring or required in connection with its regulatory responsibilities set forth in this <u>Section 5</u> with respect to the Product for use in the Partner Territory, and without limiting Partner's obligations hereunder, Company shall have the

right to provide input in preparation for such Regulatory Meetings and to the extent permitted by Applicable Laws, to have its representatives attend the Regulatory Meetings. Without limiting Partner's obligations hereunder, Partner shall implement any such input from Company, except to the extent in violation of any Applicable Laws.

- (ii) In the case of any IND or meetings with respect to any research or Development activities hereunder, as between the Parties, Company shall be responsible for such communications with the Regulatory Authorities occurring or required with respect to the Product, and without limiting Company's obligations hereunder, Partner shall provide Company with any input in preparation for, or that is otherwise required for, such Regulatory Meetings and in the case of any Partner-Conducted Clinical Trials, to the extent permitted by Applicable Laws, to have its representatives attend the Regulatory Meetings.
- (b) Partner further acknowledges that Company may be required to communicate with Regulatory Authorities in the Partner Territory as a result of any of its or the Company Members' Manufacturing in or for such territory. To the extent permitted by Applicable Laws and related to Partner's rights under this Agreement, Company shall keep Partner reasonably informed of such discussions and without limiting Company's obligations hereunder, Partner shall have the right to provide input in preparation for such discussions or communications and to the extent permitted by Applicable Laws, to have its representatives attend any such discussions with Regulatory Authorities in the Partner Territory.
- 5.3 <u>Regulatory Inspections</u>. Partner shall permit, and shall cause the other Partner Members to permit, Regulatory Authorities to conduct inspections of any Partner Member (including Partner Sites) relating to its Development, Manufacture or Commercialization of the Product upon request of any such Regulatory Authority. Partner shall promptly notify Company of any such inspection, shall supply Company with all information and correspondence related thereto and, without limiting Partner's obligations hereunder, Company shall have the right to provide input in preparation for, and in response to, such inspection and to the extent permitted by Applicable Laws, to have its representatives attend any such inspections in the Partner Territory. Following Partner's reasonable request, Company agrees to provide support to Partner in any such inspection and shall supply all necessary information pertinent thereto.
- 5.4 <u>Notification of Threatened Action</u>. Each Party shall notify the other Party in writing within twenty-four (24) hours of any information it receives regarding any threatened or pending action, inspection or communication by any Person or Regulatory Authority with respect to the Product, including any such threatened or pending actions, inspections or communications which may affect the safety or efficacy claims of the Product or its continued Development or Commercialization under this Agreement. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at an acceptable procedure for taking appropriate action; *provided* that, in the event that the Parties fail to agree, Company shall have final decision making authority.

## 5.5 <u>Right of Reference to Regulatory Filings.</u>

(a) Subject to the terms and conditions of this Agreement, Company hereby grants Partner a non-exclusive, sublicensable (solely in accordance with <u>Sections 2.2</u> and

- 4.17) Right of Reference, to any Regulatory Filings to the extent Controlled by Company in connection with Company's Development activities under the Global Development Plan, solely to the extent necessary for Partner to Develop, Manufacture or Commercialize the Product for use throughout the Partner Territory, in each case, to the extent permitted hereunder.
- (b) Subject to the terms and conditions of this Agreement, Partner hereby grants Company a non-exclusive, sublicensable (solely in accordance with Section 2.6 and 4.17), worldwide Right of Reference, to Regulatory Filings to the extent Controlled by Partner in connection with Partner's Development activities under the Global Development Plan, solely to the extent necessary for Company to Develop, Manufacture and Commercialize the Product, in each case, to the extent permitted hereunder.
- 5.6 <u>Complaints.</u> During the Term, each Party shall promptly forward to the other Party any complaints that it receives related to the Product. Company in the Company Territory, and Partner in the Partner Territory, shall respond to any complaints of which such Party becomes aware relating to the Product; *provided* that, following such Party's reasonable written request, the other Party shall provide reasonable cooperation in connection therewith. Notwithstanding the foregoing, as between the Parties, if a complaint pertains to the Manufacturing, appearance or general physical characteristics of the Product or other processes at the manufacturing facility, the Party responsible for Manufacturing the applicable batch(es) shall be solely responsible for responding to such complaint.
- 5.7 Recalls. Each Party shall notify the other Party in writing 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 the Product and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Partner shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Partner Territory; provided that prior to any implementation of such a recall, market suspension or market withdrawal, Partner shall consult with Company and shall reasonably consider Company's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the Partner Territory, as between the Parties, Partner shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Laws. For clarity, as between the Parties, Company shall have sole discretion with respect to all recalls in the Company Territory. To the extent a recall, market suspension or market withdrawal undertaken pursuant to this Section 5.7 arises due to Manufacture of a Product supplied by or on behalf of one Party to the other Party, the Party responsible for Manufacturing the applicable batch(es) shall be solely responsible for all costs and expenses related thereto. The Party with responsibility for conducting the applicable recall, market suspension or market withdrawal under this Section 5.7 shall otherwise be responsible for such costs and expenses.
- 5.8 <u>Pharmacovigilance Agreement</u>. As soon as reasonably practicable following the Effective Date, the Parties shall enter into a pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for the Parties with respect to the Product, including safety data sharing, adverse events reporting and safety signal and risk management (the "<u>Pharmacovigilance Agreement</u>"), which agreement shall be amended by the Parties from time to time to the extent necessary to comply with any changes in Applicable Laws or guidance received

from Regulatory Authorities. Each Party agrees not to enter into any clinical activity implicating pharmacovigilance obligations for the Product with respect to its respective Development activities under the Global Development Plan prior to execution of the Pharmacovigilance Agreement. Each Party agrees to comply, and shall cause its Party Members to comply, with its obligations under the Pharmacovigilance Agreement. In the event of any conflict or inconsistency between this Agreement and the Pharmacovigilance Agreement with respect to (a) safety-related matters, the Pharmacovigilance Agreement shall prevail and (b) any other matter, this Agreement shall prevail. Company shall maintain the global safety database for the Initial Product for so long as the Initial Product is under Development, Manufacture or Commercialization by the Parties.

## Section 6. <u>Commercialization</u>.

- 6.1 <u>General</u>. Subject to the oversight of the JDC and the terms and conditions of this Agreement (including this <u>Section 6</u>), Partner shall have the sole and exclusive responsibility, for Commercializing the Product for use throughout the Partner Territory, including
- (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities and other payors regarding the price and reimbursement status of the Product, (c) marketing and promotion, (d) booking sales and distribution and performance of related services, (e) handling all aspects of order processing, invoicing and collection, inventory and receivables, (f) providing customer support, including handling medical queries (with the Company's technical support as reasonably requested by the Partner, and in compliance with the regulator's requirements in the Partner Territory), and performing other related functions and (g) conforming its practices and procedures to Applicable Laws relating to the promotion, sales and marketing, access, and distribution of the Product.
- 6.2 <u>Commercialization Plan</u>. Reasonably in advance of (but in no event less than sixty (60) days prior to) the anticipated First Commercial Sale of the Product for use in a country or regulatory jurisdiction in the Partner Territory, Partner shall provide the JDC with a Commercialization plan that sets forth its anticipated Commercialization activities for the Product throughout the Partner Territory, for the JDC's review and approval (the "<u>Partner Commercialization Plan</u>"). On an annual basis (or more frequently if material changes are made to such plan), Partner shall update the Partner Commercialization Plan and will provide each such updated Partner Commercialization Plan to the JDC for its review and approval.
- 6.3 <u>Diligence</u>. During the Term, Partner shall use Commercially Reasonable Efforts to Commercialize the Product for all indications for which Regulatory Approval is granted in the Partner Territory.
- 6.4 <u>Commercial Updates</u>. Partner shall update the JDC at each regularly scheduled JDC meeting regarding its Commercialization activities with respect to the Product in the Partner Territory. Each such update shall be in a form to be agreed by the JDC and shall summarize Partner Members' significant Commercialization activities with respect to the Product in the Partner Territory, and shall contain at least such information at such level of detail reasonably required by Company to determine Partner's compliance with its diligence obligations set forth herein. Such updates shall include, on a country-by-county basis, Partner Members' sales and marketing activities.

6.5 <u>Standards of Conduct</u>. Partner shall, and shall cause applicable Partner Members to, perform all Commercialization activities with respect to the Product throughout the Partner Territory in a professional and ethical business manner and in compliance in all material respects with Applicable Laws.

## 6.6 Coordination of Commercialization Activities.

- (a) <u>Generally</u>. The Parties recognize that their collaboration may benefit from the coordination of certain activities in support of the Commercialization of the Product in both the Partner Territory and the Company Territory. As such, the Parties, through the JDC, may coordinate Commercialization strategies for the Product (*e.g.*, for branding and messaging, international congresses, advisory boards), and without limiting its obligations hereunder (including as set forth in this <u>Section 6</u> and <u>Section 11.1</u>), Partner shall conduct Commercialization activities for the Product in the Partner Territory in a manner consistent with such global strategy.
- (b) Promotional Materials. Company may provide promotional materials for use by the applicable Partner Members in performing Partner's obligations hereunder. Partner shall, and shall cause applicable Partner Members to, share their promotional materials for the Product with the JDC on a regular basis (for any materials not yet shared, no less frequently than each meeting of the JDC), and without limiting Partner's obligations under Section 6.5, the JDC shall have the right to review and comment on any of the Partner Members' promotional materials prior to their use in the Partner Territory, which comments shall be considered in good faith by Partner. If any such promotional materials are originally created in a language other than the English language, then at Company's request and at Company's expense, Partner shall provide an English translation along with the original materials to the JDC. Partner shall, and shall ensure that all applicable Partner Members, comply with Applicable Laws with respect to the use of promotional materials for the Product in the Partner Territory. Insofar as claims are allowed or authorized for the Product in Partner's Territory that are not so authorized where Company sells the Product, Partner agrees to work with Company in good faith and to take such reasonable action as is necessary to help ensure the claims made in Partner's Territory are not imputed to other jurisdictions.

#### (c) <u>Branding</u>.

(i) <u>Global Trademarks</u>. It is the Parties' intent to maintain consistent global branding for the Product to the extent permitted by Applicable Laws. To the extent such consistent global branding is permitted under Applicable Laws, Company shall own all Trademarks related to the Product and associated domain names in and outside the Partner Territory (collectively, the "<u>Global Trademarks</u>"). Subject to <u>Section 10.6(a)(i)</u>, as between the Parties, Company, shall be responsible for conducting Trademark searches ("<u>Trademark Searches</u>"), selecting, registering, prosecuting, defending and maintaining the Global Trademarks worldwide at its sole cost and expense; *provided*, that any costs or expenses incurred in connection with conducting Trademark Searches shall be borne equally between the Parties. As between the Parties, Company or its Subsidiary shall own all right, title, and interest in and to the Global Trademarks, all corresponding Trademark applications and registrations thereof, and all common law rights

thereto. All goodwill of the business associated with or symbolized by the Global Trademarks shall inure to the benefit of Company or its Subsidiary (as applicable). Partner acknowledges Company's (or its Subsidiary's, as applicable) exclusive ownership of the Global Trademarks in accordance with the foregoing and agrees not to take any action inconsistent with such ownership.

- (ii) <u>Local Trademarks</u>. If Company provides Partner with written notice that it is not obtaining a Global Trademark for the Product in any country or regulatory jurisdiction in the Partner Territory, or otherwise grants Partner prior written consent, Partner shall have the right to select an alternate Trademark (and associated domain names) for use with the Product in the Partner Territory (each, a "<u>Local Trademark</u>") in consultation with, and subject to the prior written approval (not to be unreasonably withheld, conditioned or delayed) of, Company. Partner shall be responsible, at its sole cost and expense, for developing, searching, filing, registering, maintaining, defending and enforcing the Local Trademarks. As between the Parties, Partner shall own all right, title and interest in and to the Local Trademarks, all corresponding Trademark applications and registrations thereof, and all common law rights thereto. All goodwill of the business associated with or symbolized by the Local Trademarks shall inure to the benefit of Partner. Company acknowledges Partner's exclusive ownership of the Local Trademarks in accordance with the foregoing and agrees not to take any action inconsistent with such ownership.
- (d) <u>Use of Trademarks</u>. Partner shall only promote, market, sell, offer for sale, import, distribute and otherwise Commercialize the Product in the Partner Territory under the applicable Global Trademark or Local Trademark, alone or in combination with Partner's G42 logo.
- (e) <u>Commercialization in Company Territory</u>. For clarity, as between the Parties, Company shall have the exclusive right to Commercialize the Product in the Company Territory at its own cost and expense, with or without Third Party(ies).
- (f) <u>Ex-Territory Sales</u>. Subject to Applicable Laws, neither Party shall engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located outside of its territory or accept orders for the Product from or sell the Product into such other Party's territory for its own account, and, if a Party receives any order for the Product in the other Party's territory, it shall refer such orders to the other Party, to the extent it is not prohibited from doing so under Applicable Laws.
- (g) Export Monitoring. Each Party shall use commercially reasonable efforts to monitor and prevent exports of the Product from its own territory for Commercialization in the other Party's territory using methods permitted under Applicable Laws that are commonly used in the industry for such purpose (if any), and shall promptly inform the other Party in writing of any such exports of the Product from its territory, and any actions taken to prevent such exports. Each Party agrees to use commercially reasonable efforts as permitted by Applicable Laws to take reasonable actions requested in writing by the other Party to prevent exports of the Product from its territory for Commercialization in the other Party's territory.

## Section 7. <u>Manufacture and Supply</u>.

7.1 <u>Supply, Generally</u>. The Parties acknowledge and agree that, as between the Parties, Company shall have the sole right to Manufacture the Product for Development.

# 7.2 <u>Clinical Supply</u>.

- Obligations. Solely for purposes of use in the Development activities hereunder, Company shall, itself or through any of its Subsidiaries or a Third Party (any such Third Party, a "CMO"), use Commercially Reasonable Efforts to supply Partner the Product for dosing subjects in the Partner-Conducted Clinical Trials as set forth in the Global Development Plan and placebo of such Product, in finished form ("Finished Product") in the quantities, and subject to the timeline, set forth in the Global Development Plan and in accordance with an applicable quality agreement to be entered into by the Parties prior to supply of the Finished Product (the "Quality Agreement"). To the extent Company is unable to meet the quantities or timeline set forth in the Global Development Plan, as between the Parties, Company shall endeavor to supply Finished Product on a pro rata basis such that each Party shall receive a percentage of Finished Product equal to the percentage of dosage units of Finished Product administered by such Party or its Party Members, as applicable, during the previous Calendar Quarter as compared to the aggregate dosage units of Finished Product administered by both Parties and their applicable Party Members during such Calendar Quarter; provided that in the event Company's inability to meet the quantities or timeline set forth in the Global Development Plan occurs during the first Calendar Quarter following the Effective Date, Finished Product shall be allocated between the Parties in a manner which would reasonably cause the least disruption to the Parties' Development activities hereunder, as determined by Company using its reasonable business judgment, on a good faith basis. Partner shall use, and shall cause all applicable Partner Members to use, all Finished Product supplied by Company under this Section 7.2 solely to conduct Development in the Partner Territory in accordance with the terms of this Agreement and the Global Development Plan.
- (b) <u>Price</u>. Finished Product supplied by Company for Development use in the Partner-Conducted Initial Clinical Trial will be supplied at a total cost of two thousand five hundred dollars (\$2,500) per subject (including any VAT, if applicable), regardless of whether such subject is dosed with the Initial Product or placebo. Along with each shipment of Finished Product, Company will invoice Partner, and Partner shall pay each such invoice within thirty (30) days after receipt thereof. Price of supply of the Finished Product for any other Partner-Conducted Clinical Trials or Development activities conducted hereunder shall be agreed upon by the Parties in writing prior to commencement of such Partner-Conducted Clinical Trial.
- (c) <u>Product Delivery.</u> Subject to <u>Section 5.1(c)</u>, risk of loss and damage for, and title to, Finished Product supplied under this <u>Section 7.2</u> shall pass to Partner on Delivery of the Finished Product. Company (itself or through any of its Subsidiaries or CMO) shall deliver the Finished Product DDP Abu Dhabi, or any other location that the Parties mutually agree upon in writing, (Delivery Duty Paid) INCOTERMS 2020 at the delivery location (as designated by the Partner) (the "<u>Delivery</u>").

## (d) <u>Acceptance and Non-Conforming Finished Product.</u>

- (i) In the event that any Finished Product supplied by Company to Partner under this Section 7.2, at the time of Delivery by Company pursuant to Section 7.2(c), is damaged, or shipment documentation including certificates of origin as required by applicable Governmental Authorities is missing or incomplete, or such Finished Product does not otherwise conform to the specifications therefor (as set forth in the Quality Agreement) ("Non-Conforming Product"), as soon as reasonably practicable following Partner's request, Company shall, at its cost, replace such Non-Conforming Product, and Partner shall, at Company's option and expense, return to Company or dispose of such Non-Conforming Product; provided, however, that Partner shall have notified Company in writing of the Non-Conforming Product before the earliest of (1) thirty (30) days after Delivery of such Finished Product, (2) five (5) days before the applicable Company Member is obligated to notify the CMO that manufactured such Finished Product of any non-conformity (provided that Partner has reasonable prior notice of such time periods), or (3) Partner's use of such Finished Product for any purpose (such period, the "Rejection Period"). If Partner does not notify Company in writing within the Rejection Period of such Non-Conforming Product, then Partner shall be deemed to have accepted the applicable Finished Product. Such replacement of Non-Conforming Product shall be Partner's sole remedy and Company's sole liability for Company's supply of Non-Conforming Product.
- (ii) If Partner notifies Company of any Non-Conforming Product in writing within the Rejection Period therefor, and Company disagrees that the applicable Finished Product is Non-Conforming Product and the Parties fail to resolve such disagreement within thirty (30) days after Company's receipt of Partner's written notice (or any applicable shorter period), then Company shall have the right to have a qualified independent third party laboratory test such Product to determine whether or not it so conforms. The determination of such tests shall be binding upon the Parties for all purposes hereunder; *provided* that if such tests are unable to determine whether or not such rejected Finished Product is Non-Conforming Product, such Finished Product shall be deemed to not be Non-Conforming Product. The expenses of the analysis or testing will be borne by the Party against which the laboratory rules.

#### (e) <u>Use of the Product.</u>

- (i) Partner shall (1) only use Finished Product supplied by or on behalf of Company for the sole purpose of conducting the Partner-Conducted Clinical Trials in accordance with the respective Collaboration Protocols and (2) ensure subject dosing compliance per the respective Collaboration Protocols for such Clinical Trials.
- (ii) For each dose administered to a subject in a Partner-Conducted Clinical Trial, Partner shall implement procedures and ensure that records are maintained specifying the date and time that such dose of the Finished Product is administered, the amount of the Finished Product administered to such subject, the lot number of the Finished Product from which such dosage came, and the number of the subject to which such dosage

was administered. Partner shall provide copies of such records to Company upon Company's reasonable request.

#### 7.3 <u>Commercial Supply and Manufacturing.</u>

- (a) <u>Commercial Supply By Company</u>. As soon as reasonably practicable after completion of the Initial Clinical Trials, Partner shall notify Company in writing if it would like Company to supply Partner Members with Initial Product for commercial sale in the Partner Territory and, in the event such notice has been provided, the Parties shall meet to negotiate in good faith the terms of a supply agreement (the "<u>Commercial Supply Agreement</u>") and related quality agreement, pursuant to which a Company Member (which may be its CMO) shall supply Partner with the Initial Product for Commercialization in accordance with the terms hereof. The Parties acknowledge and agree that such Commercial Supply Agreement shall specify that the Initial Product shall be supplied to Partner at a price equal to Company's cost of goods as set forth in such Commercial Supply Agreement.
- (b) <u>Commercial Supply By Partner</u>. Partner shall promptly notify Company in the event that a Partner Member plans to Manufacture the Product in accordance with the rights expressly granted to Partner hereunder and, at Company's option, the Parties shall meet to negotiate in good faith the terms of a Commercial Supply Agreement and related quality agreement, pursuant to which a Partner Member (which may be its CMO) shall supply Company with the Product for Commercialization outside of the Partner Territory in accordance with the terms hereof. The Parties acknowledge and agree that such Commercial Supply Agreement shall specify that the Product shall be supplied to Company or any Company Member, as applicable, on terms at least as favorable to Company as those under which Partner supplies the Product to a Third Party that is not an Affiliate.
- (c) <u>Manufacturing by Partner</u>. As soon as reasonably practicable following Partner notifying Company in writing of its intention to Manufacture the Products as per <u>Section 7.3(b)</u>, the Parties shall meet to negotiate in good faith the terms of a manufacturing agreement and related quality agreement (the "<u>Manufacturing Agreement</u>"), pursuant to which Company shall use Commercially Reasonable Efforts to provide Partner with the Compound and eCTD for the Product in accordance with the terms thereof.

# Section 8. Financial Provisions.

## 8.1 <u>Royalty Payments</u>.

- (a) <u>Royalty Rate</u>. Subject to this <u>Section 8.1</u>, during the Royalty Term, Partner shall make non-creditable royalty payments to Company on the Net Sales of the Product sold in the Partner Territory at a royalty rate of eight percent (8%) (the "<u>Royalty Rate</u>").
- (b) <u>Royalty Term</u>. Royalties shall be paid on a country-by-country basis in the Partner Territory from the First Commercial Sale of the Product in such country by or on behalf of a Partner Member until the latest of (i) expiration of the last-to-expire Valid Claim of the Company Patents Covering the Product in such country, (ii) the expiration of any Regulatory Exclusivity covering the Product in such country or (iii) ten (10) years after the First Commercial Sale of the Product in such country (the "<u>Royalty Term</u>").

- (c) <u>Royalty Reductions</u>. If the Applicable Laws in a particular country or regulatory jurisdiction require a royalty reduction after the expiration of the relevant Patents in such country or regulatory jurisdiction, and the Royalty Term for a particular Product in such country or jurisdiction remains in effect pursuant to <u>Section 8.1(b)</u>, then the Royalty Rate shall be reduced by twenty percent (20%) for the Product in such country (*e.g.*, a reduction from eight percent (8%) to six percent (6%)) during the remainder of the Royalty Term that extends beyond expiration of the relevant Patents.
- 8.2 <u>Company Payments to Third Party.</u> Company shall be solely responsible for all payments, including royalties and milestone payments, due with respect to the Novo Agreement; *provided* that, notwithstanding anything to the contrary herein, Partner shall cooperate with Company to provide Company (at Company's cost and expense) with any information and documentation that Company reasonably requests to fulfill its obligations under the Novo Agreement, subject to the obligations of confidentiality and non-use set forth in the Novo Agreement. For clarity, Partner shall be responsible for all other amounts owed by Partner to Third Parties with respect to its exercise of any rights granted hereunder.

#### Section 9. Payment; Records; Audits.

- 9.1 <u>Payment; Reports</u>. Royalty payments payable under <u>Section 8.1</u> shall be calculated and reported for each Calendar Quarter. All royalty payments due under <u>Section 8.1</u> shall be paid net sixty (60) days after the end of each Calendar Quarter and shall be accompanied by a report setting forth, on a country-by-country basis, Net Sales of the Product in the Partner Territory in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including the number of Products sold, the gross sales and Net Sales of Products (including the deductions from gross sales to arrive at Net Sales), the royalties payable, the exchange rates used and any adjustments to royalties in accordance with <u>Section 8.1</u>.
- 9.2 Exchange Rate; Methods of Payment. All payments hereunder shall be payable in U.S. Dollars. Wherever it is necessary to convert currencies for Net Sales invoiced in a currency other than the U.S. Dollar, such conversion shall be made into U.S. Dollars at the conversion rate existing in the United States (as reported in the *Wall Street Journal*) on the last Business Day of the applicable Calendar Quarter or, if such rate is unavailable, a substitute therefor reasonably selected by the Parties. All payments owed under this Agreement shall be made by wire transfer to a bank and account designated in writing by the Party entitled to receive such payment, unless otherwise specified in writing by such Party.

## 9.3 <u>Taxes</u>.

- (a) <u>Taxes on Income</u>. Each Party shall be solely responsible for the payment of (and all liabilities with respect to) all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.
- (b) <u>Tax Cooperation</u>. Each Party and its Affiliates shall be entitled to deduct and withhold from any amounts payable pursuant to this Agreement such amounts that are required to be deducted and withheld under any provision of Applicable Laws. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or

similar obligations in respect of any payments made by Partner to Company under this Agreement. To the extent Partner is required by Applicable Laws to deduct and withhold taxes on any payment to Company, Partner shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Company an official tax certificate or other evidence of payment of such taxes that is reasonably satisfactory to Company. Company shall provide Partner any tax forms that may be reasonably necessary in order for Partner to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty or Applicable Laws. Company shall use reasonable efforts to provide any such tax forms to Partner in advance of the due date.

- (c) <u>Taxes Resulting from Partner's Action</u>. Partner represents and warrants that, as of the Effective Date, Partner is not required by Applicable Laws to deduct or withhold taxes on any amounts payable to Company under this Agreement. If, pursuant to Applicable Laws, Partner is required to withhold taxes on any payment made to Company under this Agreement, then the sum payable by Partner (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Company receives a sum equal to the sum which it would have received if no taxes were required to be deducted and withheld under Applicable Laws. The Parties shall use commercially reasonable efforts to invoke the application of any applicable bilateral income tax treaty or similar agreement that would reduce or eliminate otherwise applicable taxes with respect to payments payable pursuant to this Agreement.
- Records; Audit. Each Party shall maintain complete and accurate records in sufficient detail in relation to this Agreement to permit the other Party to confirm the accuracy of the amount of royalty and other payments payable under this Agreement. Each Party shall keep such books and records for at least five (5) years following the Calendar Year to which they pertain or such longer period required by Applicable Laws. Upon reasonable prior notice, such records shall be inspected during regular business hours at such place or places where such records are customarily kept by an independent certified public accountant (the "Auditor") selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of confirming Net Sales and the corresponding payments made, or required to be made, by or to the audited Party pursuant to this Agreement. Before beginning its audit, the Auditor shall execute an undertaking acceptable to each Party by which the Auditor agrees to keep confidential all information reviewed during the audit. Such audits may occur no more often than once each Calendar Year and not more frequently than once with respect to records covering any specific period of time. Each Party shall only be entitled to audit the books and records from the three (3) Calendar Years prior to the Calendar Year in which the audit request is made. The Auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments to or by the audited Party under this Agreement. In the event that the final result of the inspection reveals an undisputed underpayment or overpayment, the underpaid or overpaid amount shall be settled within thirty (30) days after the Auditor's report. The auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party that resulted from a discrepancy in the financial report provided by the audited Party for the audited period, which underpayment or overpayment was more than seven and one half percent (7.5%) of the amount set forth in such report, in which case the audited Party shall reimburse the auditing Party for the costs for such audit.

9.5 <u>Late Payments</u>. In the event that any payment due under this Agreement is not paid within fifteen (15) days of when due in accordance with the applicable provisions of this Agreement, without limiting any rights or remedies hereunder, the payment shall accrue interest from the date due at the lesser of six percent (6%) per annum or the maximum rate under Applicable Laws.

# Section 10. Intellectual Property.

## 10.1 Ownership.

(a) <u>Background IP</u>. Subject to the rights and licenses expressly granted under this Agreement, as between the Parties, Company shall retain all rights, title and interest in, to and under any and all Company Background IP and Partner shall retain all rights, title and interest in, to and under any and all Partner Background IP.

# (b) <u>Developed IP</u>.

- (i) As between the Parties, Company shall own any and all:
- (1) Patents and Know-How discovered, invented or otherwise created solely by or on behalf of a Company Member in the course of exercising Company's rights or performing its obligations hereunder;
- (2) Patents and Know-How discovered, invented or otherwise created by or on behalf of either Party, its Affiliates, its licensees or its Sublicensees (to the extent applicable) solely or jointly together with the other Party, its Affiliates, its licensees or its Sublicensees (to the extent applicable), to the extent related to the Compound or Product; and
- (3) Patents and Know-How discovered, invented or otherwise created jointly by or on behalf of Partner or any of its Affiliates, its licensees or its Sublicensees, on the one hand, and Company or any of its Affiliates, licensees or Sublicensees, on the other hand, in the course of exercising its rights or performing its obligations hereunder (such Intellectual Property described in the foregoing (1) through (3), explicitly excluding the Partner Background IP, being referred to as the "Company Developed IP").
- (ii) As between the Parties, Partner shall own any and all Patents and Know-How discovered, invented or otherwise created solely by or on behalf of a Partner Member (to the extent applicable) in the course of exercising the rights that it is granted hereunder or that it retains as specified herein or otherwise; *provided* that such Intellectual Property is not Company Developed IP ("<u>Partner Developed IP</u>").
- (iii) For clarity, for purposes of this Agreement, inventorship will be determined in accordance with United States patent Laws (regardless of where the applicable activities occurred).

(c) <u>Assignment</u>. To the extent that a Party Member is assigned or otherwise obtains ownership of any right, title, or interest in or to any Intellectual Property in contravention of the foregoing (i) or (ii), such Party hereby assigns, and shall cause its Party Member to assign, to the other Party all such right, title and interest.

### 10.2 Patent Prosecution and Maintenance.

(a) Subject to Section 10.2(b), as between the Parties, Company, in the case of the Company IP, and Partner, in the case of the Partner IP (each, a "Prosecuting Party"), shall have the exclusive right to (i) prosecute and maintain, at its expense, all pending and new Patent applications included within such Intellectual Property and (ii) respond to oppositions, nullity actions, re-examinations, revocation actions and similar proceedings filed by Third Parties against the issuance of such Patents ("Prosecution Activities").

## (b) <u>Patents Exclusively Licensed to Partner.</u>

- (i) <u>Existing Patent Applications</u>. With respect to any Patents that have been filed, but have not issued, as of the Effective Date and are exclusively licensed to Partner hereunder in any country or regulatory jurisdiction in the Partner Territory, the Company shall remain responsible for all costs of prosecuting such Patent application following the Effective Date, subject to <u>Section 10.2(b)(iii)</u>.
- (ii) New Patent Applications. If, at any time during the Term, Company decides to file any Patent applications that have not been filed as of the Effective Date and, upon filing, would be exclusively licensed by Company to Partner hereunder in any country or regulatory jurisdiction in the Partner Territory, Company shall notify the JDC at the next scheduled JDC meeting and the JDC members shall discuss in good faith the countries and regulatory jurisdictions in the Partner Territory in which such application will be filed.
- (1) In the event that, for any such Patent application, the JDC members (or the Executive Officers) agree on any countries or regulatory jurisdictions (without either Party exercising its final decision making authority under Section 3.4(b)(i) or Section 3.4(b)(ii) if and to the extent applicable), then Company shall have the sole right to file such Patent applications in such countries and jurisdictions and the Parties shall share equally (on a 50-50 basis) the costs of filing and prosecuting such Patent applications, subject to Section 10.2(b)(iii).
- (2) In the event that, for any such Patent application, the JDC members and Executive Officers do not agree on any such countries or regulatory jurisdictions (without either Party exercising its final decision making authority under Section 3.4(b)(i) or Section 3.4(b)(ii) if and to the extent applicable), then Partner shall have the right to notify the Company in writing that, notwithstanding such failure to agree, Partner would like Company to file such Patent application in one or more of such countries or regulatory jurisdictions. If Partner provides such written notice within ten (10) Business Days of the JDC meeting when such matter is first discussed, then Company shall file such Patent

application, in Company's name, in such countries and regulatory jurisdictions identified in Partner's notice at Partner's sole cost and expense, subject to <u>Section 10.2(b)(iii)</u>.

- (iii) <u>Issued Patents</u>. In the event that Company elects, in any country or regulatory jurisdiction in the Partner Territory, not to continue to maintain an issued Patent exclusively licensed to Partner hereunder with respect to a country or regulatory jurisdiction in the Partner Territory (such Patent, a "<u>Company Abandoned Patent</u>") without the intent to pursue substantially similar subject matter in a continuation or divisional filing or an equivalent thereof, it shall notify Partner of such election in writing at least forty-five (45) days prior to any filing or payment due date, or any other due date that requires action ("<u>Election Notice</u>"). Following receipt of an Election Notice, and if requested by Partner, (1) Company shall and hereby does assign to Partner its right, title and interest in and to such Company Abandoned Patent in such country or regulatory jurisdiction (as applicable), and (2) upon the effective date of such assignment (A) Partner may continue maintenance of such Company Abandoned Patent in such country or regulatory jurisdiction at its sole cost and expense, in which case (B) Partner hereby grants Company a nonexclusive license to such Company Abandoned Patent for all uses other than those within the scope of the exclusive licenses granted to Partner with respect to such Patent under <u>Sections 2.1(a)</u>, (c) and (d). For clarity, any such Company Abandoned Patent shall not constitute a Company Patent hereunder, except with respect to <u>Section 8.1(b)</u>.
- (c) <u>Cooperation</u>. With respect to any Patents exclusively licensed to a Party that is not the Prosecuting Party, such Party will provide reasonable assistance to the Prosecuting Party, at the Prosecuting Party's expense, in connection with the Prosecution Activities, where such assistance shall include providing reasonable access to relevant Persons and executing all documentation reasonably requested by the Prosecuting Party.

## 10.3 Third Party Infringement.

- (a) <u>Notice</u>. Partner will promptly notify Company in writing of (i) any actual or threatened infringement, misappropriation, other violation, or challenge to the validity, scope or enforceability by a Third Party of any Company IP in the Partner Territory of which it becomes aware ("<u>Partner Territory Infringement</u>") and (ii) any allegation by a Third Party that any of such Third Party's Intellectual Property is infringed, misappropriated, or otherwise violated by the Development, Commercialization, or other Exploitation of the Product in the Partner Territory of which it becomes aware.
- (b) <u>Company Control</u>. Company shall have the first right (but not the obligation), at its own expense and by counsel of its own choice, to control enforcement of the Company IP against any actual or threatened infringement, misappropriation or other violation, or challenge to the validity, scope or enforceability by a Third Party, including any Partner Territory Infringement ("<u>Third Party Infringement</u>"). Prior to commencing any suit, action or proceeding with respect to a Partner Territory Infringement to the extent reasonably practicable, Company shall reasonably consult with Partner and shall consider Partner's timely recommendations regarding the proposed suit, action or proceeding, except to the extent delay may reasonably result in the loss of rights by or otherwise adversely impact Company.

- (c) <u>Partner Control</u>. Partner shall have the right (but not the obligation) to control, at its own expense and by counsel of its own choice, enforcement of the Company IP against any Partner Territory Infringement (i) if Company provides Partner with written notice that it is not exercising its right to control such enforcement, or (ii) if Company fails to initiate, or file the relevant response to, (as applicable) a suit, action or proceeding with respect to such Partner Territory Infringement prior to or upon the earlier of (1) expiration of the ninety (90)-day period following first receipt by Company of written notice from Partner of such Partner Territory Infringement or (2) thirty (30) days prior to the deadline for filing, or filing the applicable response to (as applicable), such suit, action or proceeding (including suits, actions or proceedings based on a Third Party's filing of a Paragraph IV Certification under 21 CFR §314.94(a)(12)(i)(A)(4)).
- (d) Rights of Non-Controlling Party. Notwithstanding anything to the contrary herein, the Party that is not controlling the suit, action or proceeding pertaining to enforcement of the Company IP against Third Party Infringement as described in this Section 10.3 shall cooperate fully, including if required to bring such action, the provision of a power of attorney, and agrees to be joined as a party plaintiff to such suit, action or proceeding, upon the reasonable request and expense of the Party controlling such action if necessary for standing purposes. The Party that is not controlling such a suit, action or proceeding shall have the right to be represented by counsel (which shall act in an advisory capacity only, except for matters solely directed to such Party) of its own choice and at its own expense (subject to the immediately preceding sentence in this Section 10.3(d)) in any such suit, action or proceeding. To the extent reasonably practicable, the Party that is controlling such suit, action or proceeding shall give the other Party timely written notice of any proposed settlement and shall not settle, stipulate to any facts or make any admission with respect to any such Partner Territory Infringement without such other Party's prior written consent (not to be unreasonably withheld, conditioned or delayed) if such settlement, stipulation or admission would (i) give rise to liability of such other Party or any its Affiliates, (ii) grant to a Third Party a license or covenant not to sue under any Intellectual Property that such Party or any of its Affiliates owns or has rights or (iii) otherwise impair such Party's or any of its Affiliates' rights under this Agreement.
- (e) <u>Recoveries</u>. Any and all recoveries resulting from a suit, action or proceeding relating to a claim of Third Party Infringement shall first be applied to reimburse each Party's costs and expenses in connection with such suit, action or proceeding, with any remaining recoveries allocated to the Party that controls such action, suit or proceeding in accordance with the terms hereof.
- 10.4 <u>Defense Actions</u>. Prior to Commercialization of the Product by or on behalf of Partner (including by any Partner Member to the extent permitted hereunder) in each country or regulatory jurisdiction in the Partner Territory, the Parties shall cooperate in good faith to have a patent attorney that is reasonably acceptable to both Parties conduct a freedom to operate analysis ("<u>FTO Analysis</u>") to determine whether Commercialization of the Product in such country or regulatory jurisdiction would be reasonably likely to become the subject of an IPR Claim (the cost and expense of any such FTO Analysis to be shared equally by the Parties) and, if based on such FTO Analysis, an IPR Claim is reasonably likely, the Parties shall promptly meet to consider the appropriate course of action. If the Product becomes the subject of an IPR Claim in a country or regulatory jurisdiction within the Partner Territory, Partner shall promptly (a) notify Company in writing and the Parties shall promptly meet to consider the IPR Claim and the appropriate course

of action and (b) take reasonable steps to mitigate any resulting Losses. If, in Company's reasonable discretion, it is not commercially reasonable to procure sufficient rights to one or more Patents that are the subject of the IPR Claim, or modify the Product, to ensure that such IPR Claim is not pursued by the applicable Third Party, Partner shall, and shall cause the Partner Members, to promptly cease Exploiting the Product in such country or regulatory jurisdiction (as applicable). Notwithstanding the foregoing, following receipt of the FTO Analysis, Partner shall have the right to commence or continue Commercialization of the Product in the applicable countries or regulatory jurisdictions in the Partner Territory its sole discretion; *provided* that Company's indemnification obligations under Section 12.1(b) shall not apply if the FTO Analysis identifies one or more Patents in the Partner Territory (nor shall they apply if Partner fails to comply with its obligations under the second sentence in this Section 10.4) and in each such case, Partner shall be obligated to indemnify Company in accordance with Section 12.2.

- 10.5 <u>Patent Term Extensions</u>. Subject to <u>Section 10.2(b)(iii)</u>, Company shall have the sole authority to select the appropriate Company Patents for patent term extensions, including supplementary protection certificates and any other extensions that are now available or become available in the future, for the Product in the Company Territory and Partner Territory, and shall consult with Partner with respect to such decisions for the Partner Territory and shall consider the comments and concerns of Partner in good faith. Partner shall cooperate with Company in obtaining such patent term extensions, including by signing all necessary papers.
- 10.6 <u>Trademarks</u>. Partner shall comply with reasonable policies provided by Company from time to time to maintain the goodwill and value of the Global Trademarks. Partner shall not, and shall cause its Affiliates not to, (i) use, seek to register, or otherwise claim rights in the Partner Territory to any Trademark that is confusingly similar to, misleading or deceptive with respect to, or that materially dilutes, any of the Global Trademarks or Local Trademarks or (ii) knowingly do, cause to be done, or knowingly omit to do any act, the doing, causing or omitting of which endangers, undermines, impairs, destroys or similarly affects, in any material respect, the validity or strength of any of the Global Trademarks or Local Trademarks (including any registration or pending registration application relating thereto) or the value of the goodwill pertaining to any of the Global Trademarks or Local Trademarks.

#### (a) <u>Enforcement of Trademarks</u>.

(i) Company shall have the first right, but not the obligation, at Company's expense and by counsel of its own choice, to (1) subject to Sections 12.1(b) and 12.3, defend the Global Trademarks, including defending against any alleged, threatened or actual claim by a Third Party that the use of any Global Trademark infringes, dilutes or misappropriates any Trademark of that Third Party or constitutes unfair trade practices, or any other claims that may be brought by a Third Party against a Party in connection with the use of or relating to any Global Trademark (a "Trademark Infringement Claim") and (2) to enforce the Global Trademarks, including taking such action as Company deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution or misappropriation of, or unfair trade practices or any other like offense relating to, any Global Trademark, it being agreed that the provisions of Sections 10.3(b), (d) and (e) shall apply; provided that, for the purpose of this

Section 10.6(a)(i), use of "Company IP" in Sections 10.3(b) and (d) shall be deemed to mean "Global Trademarks".

- (ii) Partner shall have the first right, but not the obligation, at Partner's expense and by counsel of its own choice, to enforce and defend the Local Trademarks in the Partner Territory, including (1) defending against any alleged, threatened or actual claim by a Third Party that the use of any Local Trademark in the Partner Territory infringes, dilutes or misappropriates any Trademark of that Third Party or constitutes unfair trade practices, or any other claims that may be brought by a Third Party against a Party in connection with the use of or relating to any Local Trademark in the Territory with respect to the Product and (2) taking such action as Partner deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution or misappropriation of, or unfair trade practices or any other like offense relating to, any Local Trademark in the Partner Territory by a Third Party.
- (iii) Each Party shall provide to the other Party all reasonable assistance requested by such Party in connection with any such action, claim or suit under this <u>Section 10.6(a)</u>, including allowing such Party access to such other Party's documents and to such other Party's personnel who may have possession of relevant information.
- 10.7 <u>Trademark License</u>. Subject to the terms and conditions of this Agreement, Company hereby grants to Partner an exclusive, royalty-free, limited license under the Global Trademarks solely to promote, market, sell, offer for sale, import, distribute and otherwise Commercialize the Product in the Partner Territory in accordance with the terms of this Agreement. Unless terminated in accordance with <u>Section 14.2</u>, such license shall be in effect, on a country-by-country basis, as long as the sale of the Product under a Global Trademark is not discontinued by Partner.

## Section 11. Representations, Warranties and Covenants.

#### 11.1 Mutual Representations, Warranties and Covenants.

- (a) Each Party represents and warrants to the other as of the Effective Date, and covenants, that:
- (i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof,
- (ii) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual or individuals executing this Agreement on its behalf have been duly authorized to do so by all requisite corporate or partnership action,
- (iii) this Agreement 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 or other Governmental Authority having jurisdiction over it,

- (iv) it has the right to grant the licenses granted by it under this Agreement; and
- (v) it has not, and will not during the term of such license, grant

any right to any Third Party that would conflict with the rights granted to the other Party hereunder.

- (b) Each Party covenants to the other that in the performance of its obligations under this Agreement, such Party shall comply with, and shall cause its Party Members and its respective Indemnitees to comply, with all Applicable Laws. Neither Party shall, nor shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith after consultation with counsel, may violate, any Applicable Laws.
- (c) Each Party hereby represents, warrants and covenants to the other Party that it is not debarred or disqualified under the FD&C Act, or any other comparable Applicable Laws in any country or jurisdiction, and it 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 Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any Person providing services to such Party, including any Party Member, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such Person to perform any such services.
- (d) Each Party acknowledges that the other Party may be subject to federal, state, local and international Laws related to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities (collectively, "Sunshine Reporting Laws"), and agrees to provide the other Party with all information regarding such payments or transfers of value by such Party as necessary for such other Party to comply in a timely manner with its reporting obligations under the Sunshine Reporting Laws.
- (e) Neither Party shall, and each Party shall ensure its respective Indemnitees and Party Members do not, directly or indirectly, including through Third Parties, (i) 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 Government Official, Governmental Authority, or other Person for purpose of obtaining or retaining business for or with, or directing business to, any Person, or (ii) request or accept any such improper payment or (iii) cause a violation of any Anti-Corruption Laws. For example, this includes knowingly providing any inducement for such Government Official or Person (i) to approve, reimburse, prescribe, or purchase a product, to influence the outcome of a Clinical Trial, or otherwise to benefit the Company's business activities improperly or (ii) with the intent to influence or reward, or the effect of influencing or rewarding any Person for acting in breach of an expectation of good faith, impartiality or trust, or which it was otherwise improper for the recipient to accept. Each Party

represents and warrants that as of the Effective Date, none of its respective Indemnitees or Party Members have, directly or indirectly, (i) promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Government Official, Governmental Authority or any other Person in connection with the performance of Partner's obligations under this Agreement, (ii) requested or accepted any such improper payment or (iii) caused a violation of any Anti-Corruption Laws, and each Party covenants that its respective Indemnitees and Party Members and others acting on its or their behalf or for its or their benefit shall not, directly or indirectly, engage in any of the foregoing.

- (f) Each Party shall take reasonable steps to ensure, so far as they lawfully can, that its execution and performance of this Agreement is conducted in compliance with all Applicable Laws, including Anti-Corruption Laws, Export Control Laws and Sanctions. In connection with this Agreement, neither Party shall, and each Party shall cause its respective Indemnitees and other Party Members not to, (i) violate Anti-Corruption Laws, Export Control Laws, Sanctions, or any other Applicable Laws or otherwise cause any reputational harm to the other Party or (ii) engage, directly or indirectly, in any activities or business, including any activities or business with or involving any Sanctioned Person or any Sanctioned Jurisdiction, to the extent such activities or business would be prohibited by Sanctions, Anti-Corruption or Export Control Laws if conducted by an entity formed in the United States, in a country that is a European Union member state, or in the United Kingdom.
- (g) Each Party shall promptly notify the other Party in writing if it has any information or reason to believe that there may be a material actual or potential violation, or any activities or business that may cause any of its respective Indemnitees or other Party Members to be in violation, of (i) Anti-Corruption Laws, Sanctions, Export Control Laws, or any other Applicable Laws, rules or regulations in the performance of this Agreement or the Development, Manufacture or Commercialization of the Product or (ii) any of its policies and procedures relating to the foregoing.
- (h) In connection with the performance of its obligations under this Agreement, each Party shall comply, and shall cause its respective Indemnitees and other Party Members to comply, with its own anti-corruption and anti-bribery policy, economic sanctions policy, export controls policy, and code of ethics ("Compliance Policies"). The Parties shall cooperate in good faith to ensure that each Party implements (to the extent necessary) and complies with a compliance program (which program shall include compliance with Compliance Policies and periodic training and shall be updated from time to time as necessary or otherwise appropriate), that is designed to ensure that such Party, its Indemnitees and Party Members comply with Section 11.1(f). Prior to commencing Commercialization of the Product in the Partner Territory or any other activities in connection with this Agreement that, if conducted improperly, could result in a breach of Section 11.1(f), Partner shall certify in writing that it has fully implemented such a compliance program (including Compliance Policies) and such program (including such Compliance Policies) is operating effectively. Each Party shall comply, and shall cause its respective Indemnitees and other Party Members to comply, with its own Compliance Policies. In connection with the performance of its obligations under this Agreement, each Party shall immediately notify the other Party Members to comply with any of its

Compliance Policies. Partner shall maintain adequate policies, controls and systems to ensure compliance with its Compliance Policies and the requirements of this <u>Section 11.1</u>.

- Each Party agrees to maintain and enforce, at all times during the Term, (i) a system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts with respect to any products, payments, or services provided under this Agreement (and each Party agrees, during the Term, to regularly monitor and audit its and its Party Members' business activities to ensure compliance with its policies, the Compliance Policies, the terms of this Agreement, and the adequacy of internal controls, and implements remediation in response to identified issues) and (ii) a compliance and ethics program containing adequate systems, policies, and procedures for the detection, investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Laws, including Anti-Corruption Law, with respect to the products, payments and services under this Agreement (such policies and procedures should set out rules governing interactions with HCPs and Government Officials, the engagement of Third Parties, and where appropriate, conducting due diligence, and the investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Laws). Each Party will have the right, upon reasonable prior written notice and during regular business hours, to conduct at its own cost and expense, inspections and audits of the other Party's books and records in the event of a suspected violation of, or to ensure compliance with the representations, warranties or covenants of this <u>Section 11.1</u>; provided, however, that in the absence of good cause for such inspections and audits, each Party shall exercise this right no more than once annually. Each Party acknowledges and agrees that the access rights provided in the foregoing sentence do not create or imply any obligation on the part of a Party to inspect or audit the other Party's books, records or accounts or otherwise limit the other Party's rights or remedies hereunder. Each Party agrees to permit, during the term of this Agreement and for five (5) years after final payment has been made under this Agreement, the other Party's external auditors access to any of its relevant books, documents, papers, and records involving transactions related to the products, payments or services provided under this Agreement, and the audited Party agrees to cooperate fully in any audit or in connection with any investigation regarding any potential violations of Applicable Laws, including all Anti-Corruption Laws, applicable in connection with the products, payments, or services provided under this Agreement.
- (j) Each Party agrees, at all times during the Term, to: (i) maintain truthful and complete documentation supporting, in reasonable detail, the work and services performed and any expenses incurred in connection with this Agreement and (ii) maintain financial books and records that timely, fairly, accurately, and completely reflect all financial transactions, in accordance with all Applicable Laws, including Anti-Corruption Laws (for example, invoices, reports, statements, books, and other records), and shall maintain such books and records during the Term and for five (5) years after final payment has been made under this Agreement.
- (k) In the event either Party, its Indemnitees or other Party Members engages in, is reported to have engaged in, or there is a reasonable basis to believe may have engaged in conduct that may constitute a violation of any Anti-Corruption Laws, Sanctions, Export Control Laws and its Compliance Policies, such Party shall perform a diligent investigation of the facts of the alleged or possible violation, appropriate disciplinary and remedial action by such Party up to and including termination of employment or relationship with any Person involved in

the violation or any relationship obtained through improper means, and confirmation to the other Party that it has taken appropriate remedial action.

- (l) Each Party shall cause its respective Indemnitees and Party Members working under its direction or control in connection with the performance of its obligations under this Agreement to submit to periodic training on compliance with Anti- Corruption, Laws, Sanctions, Export Control Laws and its Compliance Policies.
- (m) Each Party shall annually certify to the other Party in writing its compliance, in connection with the performance of its obligations under this Agreement, with the representations, warranties, or covenants in this <u>Section 11.1</u> in the form set forth in <u>Exhibit A</u>, which certification shall be issued by Party's Executive Officer.
- (n) Each Party shall have the right to immediately suspend or terminate this Agreement in its entirety, and without any further liability or obligation, in the event it has reason to believe that the other Party or any Indemnitee or Party Member of the other Party or others acting on its or their behalf or for its or their benefit has violated, is violating, or is reasonably likely to violate Anti-Corruption Laws, Sanctions, Export Control Laws, or any portion of this Section 11.1 in connection with performance of such Party's obligations under this Agreement. In the event a Party terminates this Agreement as set forth in the foregoing sentence, the terminating Party shall not pay for, and the breaching Party shall not be entitled to receive payment on account of, any services that have been completed and not previously paid for that involved any conduct of the breaching Party that the terminating Party reasonably suspects breaches this Section 11.1, or that causes, or is reasonably likely to cause, any of the representations, warranties or covenants in this Section 11.1 not to be true and correct or to otherwise be breached, as applicable. Further, breaching Party shall be liable for damages or remedies as provided by law, and the provisions of Section 12 shall apply as applicable.
- 11.2 <u>Additional Representations and Warranties by Company</u>. Company hereby represents and warrants to Partner as of the Effective Date:
- (a) Company is the sole owner of the Company Patents set forth on <u>Schedule 1</u> and all such Patents are subsisting, and to its Knowledge, valid and enforceable. <u>Schedule 1</u> sets forth a true a complete list of the Company Patents Controlled by the Company which are related to the Compound and to the development of the Product;
- (b) to its Knowledge, no Third Party is infringing, misappropriating or otherwise violating the Company IP within the Partner Territory;
- (c) no claim or litigation is or has been, in the past three (3) years, pending, or to its Knowledge, threatened in writing, by any Person against Company or its Subsidiaries alleging that the Company Patents are invalid or unenforceable or that the Development of the Product in the Partner Territory infringes, misappropriates or otherwise violates any Intellectual Property of any Person;
- (d) Company has used reasonable measures to protect the confidentiality of material Confidential Information included in the Company Know-How; and

- (e) Company and its Subsidiaries have conducted any and all preclinical studies and Clinical Trials for the Initial Product in material compliance with all Applicable Laws.
- 11.3 <u>Additional Representations, Warranties and Covenants by the Partner</u>. Partner hereby represents, warrants and covenants, as applicable, to Company:
- (a) Partner, on behalf of itself and all Partner Members, covenants that it has obtained or will obtain written agreements from each of its and their employees, consultants and contractors who perform Development activities pursuant to this Agreement, which agreements shall obligate such Persons to obligations of confidentiality and non-use that are no less restrictive than, and to assign Intellectual Property in a manner consistent with, the provisions of this Agreement; and
- (b) at all times during the Term, Partner will maintain its licenses, consents, authorizations and registrations to do business and continue to make any notifications as may be necessary or required by all Applicable Laws (including local laws, regulations, policies or administrative requirements) in order to provide the products or services encompassed within this Agreement.
- 11.4 <u>Disclaimer</u>. EXCEPT AS EXPRESSLY STATED IN THIS <u>SECTION 11</u>, IN THE COMMERCIAL SUPPLY AGREEMENT, THE MANUFACTURING AGREEMENT OR THE PURCHASE AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, VALIDITY, ENFORCEABILITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. EXCEPT TO THE EXTENT EXPRESSLY SET FORTH HEREIN, AND IN RESPECT OF THE DEVELOPMENT OF THE PRODUCT, ANY ITEMS PROVIDED BY COMPANY OR ITS SUBSIDIARIES HEREUNDER ARE MADE AVAILABLE ON AN "AS IS" BASIS, WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED, AND EACH PARTY HEREBY ACKNOWLEDGES AND AGREES THAT SUCH ITEMS ARE EXPERIMENTAL IN NATURE AND MAY HAVE UNKNOWN CHARACTERISTICS.

#### Section 12. Indemnification.

## 12.1 <u>Indemnification by Company</u>.

(a) Company hereby agrees to defend, indemnify and hold harmless Partner, its Affiliates and its and their respective directors, officers, employees, consultants and agents (each, a "<u>Partner Indemnitee</u>") from and against any and all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to: (a) the gross negligence, fraud or willful misconduct of any Company Indemnitee or other Company Member in connection with this Agreement (including in connection with the exercise any of Company's rights or performance of any of its obligations hereunder), (b) the Material Breach by Company of this Agreement, (c) the Development, Manufacturing, use, handling, storage, Commercialization or other disposition of the Product by any Company Indemnitee or other Company Member or (d)

death of or personal injury to any subject of the Initial Clinical Trial (or any other Collaboration Clinical Trial for which the related Collaboration Protocol is being developed by Company, and provided to Partner) arising out of such subject's use of the Product under any such Clinical Trial unless such death or personal injury is caused by a failure of any Partner Indemnitee or other Partner Member to comply with (i) the Collaboration Protocol, (ii) the applicable requirements in the Federal Food, Drug, and Cosmetic Act and its implementing regulations (including 21 CFR Parts 50, 54, 56, 58 and 312) and publicly-available FDA guidelines, (iii) cGCP, or (iv) any other Laws in the jurisdictions where such Collaboration Clinical Trial is being conducted, in each case, and to the extent such death or personal injury does not arise from Partner failing to comply with the terms of this Agreement; except to the extent that any of the foregoing (a) through (d) was caused by (x) the gross negligence or willful misconduct of any Partner Indemnitee or other Partner Member or (ii) material breach of this Agreement by Partner. Solely as used in this Section 12.1, "Material Breach by Company." means a material breach by Company of (1) Section 2.4(a) as a result of Company Commercializing the Product Developed under this Agreement and in accordance with the Global Development Plan outside of the Company Territory or (2) Sections 4.2 through 4.12, 4.15, 4.17, 5, 7.2, 7.3, 10.1(c), 11.1, 11.2, or 13, which in each case has not been cured within sixty (60) days of Partner providing written notice to Company of such material breach (provided that, in the case of any such breach that is cured in accordance with the foregoing, Losses that are indemnifiable hereunder shall include those Losses that arise as a result of such breach (whether such Losses arise prior to or after the date on which such breach is cured)).

- (b) Subject to Partner's obligations under Section 12.2(d), Company hereby agrees to defend, indemnify and hold harmless the Partner Indemnitees from and against fifty percent (50%) of all Losses incurred in connection with any IPR Claim or Trademark Infringement Claim; provided that (i) such Patents that are the subject of the IPR Claim were not identified by the FTO Analysis or such Trademarks that are the subject of the Trademark Infringement Claim were not identified or flagged by the intellectual property counsel or other intellectual property specialist in connection with the Trademark Search in the Partner Territory, as applicable and in the case of any IPR Claim, Partner complies with the second sentence of Section 10.4 and (ii) such infringement, misappropriation or other violation is not caused by, nor did it arise out of, Partner's or any Partner Member's failure to comply with the terms hereof or in the case of misappropriation of trade secrets, any action or omission by any Partner Member (subject to the remainder of this Section 12.1(b), each, a "Company Indemnifiable IPR Claim"). Notwithstanding the foregoing, Company shall not be obligated to indemnify the Partner Indemnitees as described in this Section 12.1(b) (i) to the extent the foregoing was caused by (x) the gross negligence or willful misconduct of any Partner Indemnitee or other Partner Member or
- (y) material breach of this Agreement by Partner or (ii) if Partner fails to comply with its obligations in Section 10.4. For clarity, (i) Partner shall be responsible for the remaining fifty percent (50%) of Losses incurred in connection with any Company Indemnifiable IPR Claim, for which Partner shall reimburse Company on a quarterly basis within sixty (60) days of Company providing Partner with an invoice for Losses incurred during the applicable Calendar Quarter and
- (ii) for purposes of <u>Section 12.3</u>, Company shall be the Indemnifying Party for any IPR Claim in respect of which Company has indemnification obligations under this <u>Section 12.1(b)</u>.

12.2 <u>Indemnification by Partner</u>. In addition to, and not in lieu of, Partner's indemnification obligations under <u>Section 10.4</u>, Partner hereby agrees to defend, indemnify and hold harmless Company, its Affiliates and its and their respective directors, officers, employees,

consultants and agents (each, a "Company Indemnitee") from and against any and all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to: (a) the gross negligence, fraud or willful misconduct of any Partner Indemnitee or other Partner Member in connection with this Agreement (including in connection with the exercise any of Partner's rights or performance of any of its obligations hereunder), (b) the Material Breach by Partner of this Agreement, (c) subject to Company's obligations under Section 12.1(a)(d), death of or personal injury to any subject of any Partner-Conducted Clinical Trials caused by a failure of any Partner Indemnitee or other Partner Member to comply with (i) the Collaboration Protocol,

(ii) the applicable requirements in the Federal Food, Drug, and Cosmetic Act and its implementing regulations (including 21 CFR Parts 50, 54, 56, 58 and 312) and publicly-available FDA guidelines, (iii) cGCP, (iv) use, handle, store, distribute or dispose of the Finished Product provided for use in any Clinical Trials hereunder according to the specifications for the Product, cGMP and current good distribution practices or (iv) any other Applicable Laws in the jurisdictions where such Partner-Conducted Clinical Trials are being conducted, (d) any IPR Claim or Trademark Infringement Claim to the extent not a Company Indemnifiable IPR Claim or (e) any Partner Indemnitee's or other Partner Member's use of any (1) Intellectual Property in material breach of this Agreement or (2) Local Trademark; except to the extent that any of the foregoing (a) through (e) was caused by (x) the gross negligence or willful misconduct of any Company Indemnitee or other Company Member or (y) material breach of this Agreement by Company. Solely as used in this Section 12.2. "Material Breach by Partner" means (1) a material breach by any Partner Indemnitee or other Partner Member of (i) Sections 2.1(a) or 2.1(d) as a result of Commercializing or Manufacturing the Product outside of the Partner Territory, (ii) Sections 2.1(b) or 2.1(c) as a result of Developing the Product outside the scope of the Global Development Plan or (iii) Sections 2.2, 2.8, 4.2, 4.3, 4.5 through 4.12, 4.15, 4.16, 4.17, 5, 6.2, 6.4, 6.5, 6.6, 7.2(e), 10.1(c), 11.1, 11.3, or 13, which in each case has not been cured within sixty (60) days of Company providing written notice to Partner of such material breach (provided that, in the case of any such breach that is cured in accordance with the foregoing, Losses that are indemnifiable hereunder shall include those Losses that arise as a result of such breach (whether such Losses arise prior to or after the date on which such breach is cured)) or (2) a failure of Partner to pay all amounts due and payable under Section

#### 12.3 <u>Indemnification Procedures</u>.

- (a) If a Company Indemnitee or Partner Indemnitee ("<u>Indemnitee</u>"); *provided* that, solely for purposes of <u>Section 11</u>, "<u>Indemnitee</u>" shall mean (i) Company, its Subsidiaries and its and their respective directors, officers, employees, consultants and agents and
- (ii) Partner Indemnitees) learns of any Third Party Claim that a Party ("<u>Indemnifying Party</u>") may be obligated to indemnify hereunder, such Indemnitee shall notify ("<u>Indemnity Notice</u>") such Indemnifying Party in writing, describing such claim in reasonable detail as promptly as practicable (and in any event within fifteen (15) calendar days) after becoming aware of such claim. Failure to give an Indemnity Notice shall not relieve the Indemnifying Party of its indemnification obligations hereunder, except to the extent that such Indemnifying Party is materially prejudiced by such failure.
- (b) An Indemnifying Party has the right to elect to assume direction and control of the defense (including the right to settle claims for monetary compensation), at its own

cost and by its own counsel (which shall be reasonably satisfactory to the Indemnitee), any Third Party Claim; provided that the Indemnifying Party shall not be entitled to defend such claim, and shall pay the reasonable fees and expenses of one separate counsel for all Indemnitees, if such claim for indemnification relates to or arises in connection with any criminal action, indictment or allegation. Within thirty (30) calendar days after the Indemnity Notice (or sooner, if the claim requires), the Indemnifying Party shall notify the Indemnitee in writing if it is elects to assume direction and control of the defense and, in such event, the Indemnitee shall entrust its defense to the Indemnifying Party in the context of the Third Party Claim and may employ separate counsel to take advice from (but not control) such claim at its sole cost and following the Indemnifying Party's reasonable request and at the Indemnifying Party's cost, shall reasonably cooperate with the Indemnifying Party in the prosecution or defense thereof. If the Indemnifying Party fails to provide an election notice in accordance with the foregoing, or the Indemnifying Party is not permitted to defend the claim in accordance with the first sentence of this Section 12.3(b), the Indemnitee may defend such claim at the Indemnifying Party's cost and for clarity, it shall not be a defense to such obligation to pay such costs that the Indemnifying Party was not consulted in the defense thereof, that such Indemnifying Party's views or opinions as to the conduct of such defense were not accepted or adopted, that such Indemnifying Party does not approve of the quality or manner of the defense thereof or that such Third Party Claim was resolved by reason of a settlement rather than by a judgment or other determination of liability.

- (c) Unless the Indemnifying Party fails to assume defense of a Third Party Claim, or the Indemnifying Party is not permitted to defend the claim in accordance with the first sentence of Section 12.3(b), the Indemnitees may not settle or compromise any Third Party Claim without the Indemnifying Party's prior written consent. No Indemnifying Party shall settle any Third Party Claim without the Indemnitee's prior written consent if such settlement will (i) permit any injunction, declaratory judgment, other order or other non-monetary relief to be entered, directly or indirectly, against any Indemnitee or (ii) ascribe any fault on any Indemnitee. Without limiting the foregoing, the Indemnifying Party shall not, without prior written consent of the Indemnitee, settle any Third Party Claim or consent to the entry of any judgment which does not include as an unconditional term thereof the delivery by the claimant or plaintiff to the Indemnitee of a written release from all Losses in respect of such Third Party Claim.
- 12.4 <u>Limitation of Liability</u>. EXCEPT FOR LIABILITY FOR BREACH OF <u>SECTION 13</u>, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *PROVIDED*, *HOWEVER*, THAT THIS <u>SECTION 12.4</u> SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS <u>SECTION 12</u>.

## Section 13. Confidentiality.

13.1 <u>Confidential Information</u>. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that each Party (the "<u>Recipient</u>") receiving any Confidential Information of the other Party (the "<u>Disclosing Party</u>") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of Disclosing

Party, and both Parties shall keep confidential and, subject to <u>Sections 13.2</u> through <u>13.5</u>, shall not publish or otherwise disclose the terms of this Agreement. Recipient may use Disclosing Party's Confidential Information only to the extent required to exercise its rights or fulfill its obligations under this Agreement, and subject to <u>Section 13.3</u>, or, where Company is Recipient, the Novo Agreement, subject to compliance with the terms of <u>Section 13.3(d)</u>. Recipient shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors and other representatives do not disclose, or use in violation of the terms hereof, the Confidential Information of the Disclosing Party. Recipient shall promptly notify Disclosing Party in writing upon discovery of any unauthorized use or disclosure of the Confidential Information of Disclosing Party. Each Party shall be responsible for any breach of this <u>Section 13</u> by its Party Members and their respective Affiliates and its and their respective employees, directors and officers, and such other Persons to which a Recipient provides Confidential Information of the Disclosing Party as if such Persons were a party to this Agreement.

- 13.2 Exceptions. The obligations of confidentiality and restriction on use under Section 13.1 shall not apply to any information that Recipient can prove by competent written evidence (a) is now, or hereafter becomes, through no act or failure to act on the part of Recipient, generally known or available to the public, (b) is known by Recipient at the time of receiving such information, as evidenced by its records, other than by previous disclosure of Disclosing Party, or its Party Members, Affiliates or its or their employees, agents, consultants, or contractors, (c) is hereafter furnished to Recipient without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right or (d) is independently discovered or developed by Recipient without the use of, or access to, Confidential Information of Disclosing Party.
- 13.3 <u>Authorized Disclosure</u>. Recipient may disclose Confidential Information of Disclosing Party to the extent expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:
- (a) submission of Regulatory Filings to Develop, Manufacture and Commercialize the Product and obtain Regulatory Approval for the Product to the extent expressly permitted hereunder;
  - (b) prosecuting or defending litigation to the extent permitted by this Agreement;
  - (c) complying with applicable orders of courts or other Governmental Authorities;
- (d) in the case of Company as the Disclosing Party, disclosures under and in accordance with the Novo Agreement; *provided* that Novo is under written obligations of confidentiality and non-use as set forth in the Novo Agreement;
- (e) disclosure to its Party Members, Affiliates and its and their employees, consultants, contractors and agents, in each case on a need-to-know basis in connection with the Development, Manufacture or Commercialization of the Product in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and
- (f) disclosure to potential and actual investors, acquirors, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; *provided* that such Party redacts the financial terms and other provisions of this Agreement that are not reasonably required to be disclosed in connection with such potential investment, acquisition or collaboration.

Notwithstanding the foregoing, in the event Recipient is required to make a disclosure of Disclosing Party's Confidential Information pursuant to Section 13.3(b) or Section 13.3(c), it shall, except where impracticable, give reasonable advance written notice to Disclosing Party of such disclosure and use efforts to secure confidential treatment of such Confidential Information at least as diligent as Recipient would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 13.3(b) or Section 13.3(c) shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Section 13.

- 13.4 <u>Publicity; Public Disclosures</u>. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any press releases or announcements relating to this Agreement, which shall be agreed in advance by the Parties prior to the issuance thereof; *provided* that a Party may not unreasonably withhold, condition or delay consent to such releases by more than five (5) Business Days and that either Party may issue press releases or disclosures to the SEC or other applicable Governmental Authorities as it determines, based on advice of counsel, is reasonably necessary to comply with Applicable Laws or the rules and regulations of any applicable stock exchange. Each Party shall provide the other Party with advance written notice of legally required disclosures to the extent practicable and the Parties shall consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; *provided* that each Party shall have the right to make such filings as it reasonably determines necessary under Applicable Laws.
- 13.5 <u>Publications</u>. Partner may not publish or otherwise disclose any results or other Data related to this Agreement unless it obtains prior written consent from Company as per the provisions of this <u>Section 13.5</u>, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, written consent of Company shall not be required to publish any information that does not constitute Confidential Information. If Partner wishes to publish research papers or research reports related to the Collaboration Clinical Trials, Partner shall give Company at least forty-five (45) calendar days to review the draft contents of any publication, abstract, poster or slide deck related to such Clinical Trial before it is presented at the conferences and the draft contents of any journal article before it is submitted for publication, shall consult with the Company with respect thereto, so that the Company can review each proposed submission to identify patentable subject matter and/or any inadvertent disclosure of Confidential Information (including Confidential Information contained in any unpublished Patent application in relation to the Product) and Partner shall comply with Company's request to delete references to its Confidential Information in any such paper or other materials. Absent any response from

Company within such forty-five (45) calendar day period, Partner shall be free to assume that Company has no objection to the proposed publication and shall have the right to proceed.

- 13.6 <u>Prior Confidentiality Agreement</u>. As of the Effective Date, the terms of this <u>Section 13</u> shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement; *provided, however*, that this <u>Section 13</u> shall be in addition to, and not in limitation of, the confidentiality provisions of the Purchase Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.
- 13.7 <u>Equitable Relief.</u> Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this <u>Section 13</u>. In addition to all other remedies, a Party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this <u>Section 13</u>.
- 13.8 <u>Survival</u>. The obligations and prohibitions contained in this <u>Section 13</u> shall survive the expiration or termination of this Agreement for a period of seven (7) years; *provided* that, with respect to any Confidential Information that qualifies as a trade secret under Applicable Laws, such obligations and prohibitions shall survive for so long as such Confidential Information qualifies as a trade secret under Applicable Laws.

#### Section 14. Term and Termination.

#### 14.1 Term.

- (a) This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this <u>Section 14</u>, shall expire upon expiration of the last Royalty Term in the Partner Territory (the "<u>Term</u>").
- (b) Notwithstanding anything to the contrary herein, on a country-by- country basis, upon the expiration of the Agreement in accordance with <u>Section 14.1(a)</u>,
  - (i) the licenses granted to Company under <u>Sections 2.4(a)</u> and <u>2.4(c)</u> shall be deemed to be perpetual, fully paid-up and royalty-free (except to the extent expressly set forth herein) solely with respect to the Product Commercialized by the Company in such country as of the expiration date, but shall be on a non-exclusive basis. The Parties understand and agree that such licenses exclude any license in the Local Trademarks; and
  - (ii) the licenses granted to Partner under <u>Sections 2.1(a)</u> and <u>2.1(d)</u> shall be deemed to be perpetual, non-exclusive, fully paid up and royalty-free solely with respect to Products Commercialized by Partner in the Partner Territory as of the date of expiration.

#### 14.2 Termination for Cause.

- (a) <u>Material Breach</u>. Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement or the Closing Note and has not cured such breach within sixty (60) days (thirty (30) days with respect to any payment breach) after written notice of such breach from the non-breaching Party.
- (b) <u>Bankruptcy</u>. Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the Laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within sixty (60) days after the commencement thereof.
- (c) <u>Material Safety Issue</u>. Company shall have the right to terminate this Agreement immediately upon written notice if it reasonably deems it necessary to protect the safety, health or welfare of subjects enrolled in any Collaboration Clinical Trial on the basis of a Material Safety Issue.
- (d) <u>Clinical Hold</u>. In the event a Clinical Hold is imposed on any Collaboration Clinical Trial, the Parties shall meet to discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last, and how they might address the issue that caused the Clinical Hold. If such Clinical Hold has not been lifted ninety (90) days after such Clinical Hold has been imposed, Company shall have the right (in its sole discretion) to immediately terminate this Agreement.
- (e) <u>Sanctioned Person Termination</u>. In the event that either Party becomes a Sanctioned Person (whether due to a Change of Control or otherwise), such Party shall immediately notify the other Party in writing and the notified Party shall have the right to terminate this Agreement upon written notice. In the event that a Sublicensee becomes a Sanctioned Person (whether due to Change of Control or otherwise), such Sublicensee shall be immediately terminated by Partner and Partner shall immediately notify Company. Either Party shall have the right to immediately suspend or terminate this Agreement in its entirety in the event a Sublicensee of the other Party becomes a Sanctioned Person and such Sublicensee is not terminated by such Party immediately after written notice received from the other Party.
  - 14.3 <u>Effects of Termination</u>. In the event of termination of this Agreement:
    - (a) <u>Licenses</u>.
      - (i) <u>Licenses Granted to Partner</u>.
  - (1) <u>Termination by Company</u>. Subject to <u>Sections 14.3(c)</u> and <u>14.3(d)</u>, in the event this Agreement is terminated by

Company as set forth herein, all licenses granted by Company to Partner hereunder, and sublicenses granted by Partner to any Company IP, shall automatically terminate.

- (2) <u>Termination by Partner</u>. Subject to <u>Sections 14.3(c)</u> and <u>14.3(d)</u>, in the event this Agreement is terminated by Partner as set forth herein, (1) the licenses granted by Company to Partner pursuant to <u>Sections 2.1(b)</u> and <u>(c)</u>, and sublicenses granted by Partner under and in accordance with <u>Sections 2.1(b)</u> and <u>(c)</u>, shall automatically terminate and (2) the licenses granted by Company to Partner pursuant to <u>Sections 2.1(a)</u> and <u>2.1(d)</u>, and sublicenses granted by Partner under and in accordance with <u>Sections 2.1(a)</u> and <u>2.1(d)</u>, shall be deemed perpetual solely with respect to Products Commercialized by Partner in the Partner Territory as of the effective date of termination; *provided* that on a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term, such licenses shall be deemed to be nonexclusive, fully paid-up and royalty-free.
- (ii) <u>Licenses Granted to Company.</u> All licenses granted by Partner to Company under <u>Section 2.4(b)</u>, and sublicenses granted by Company, to any Partner IP shall automatically terminate upon termination of the Agreement. All licenses granted by Partner to Company under <u>Sections 2.4(a)</u> and <u>(c)</u>, and sublicenses granted by Company, to any Partner IP shall automatically terminate upon termination of the Agreement (i) by Partner in accordance with <u>Section 14.2</u> or (ii) by Company on the basis of <u>Sections 14.2(c)</u> (Material Safety Issue) or <u>14.2(d)</u> (Clinical Hold); *provided* that such Clinical Hold is not imposed as a result of the acts or omissions of Partner. Except as expressly set forth in the preceding sentence, upon termination of this Agreement, all licenses to Partner IP (excluding Partner Background IP) granted by Partner to Company under <u>Sections 2.4(a)</u> and <u>2.4(c)</u> shall continue solely with respect to the Products Commercialized by the Company as of the termination date and shall be deemed to be nonexclusive, fully paid-up and royalty-free. The Parties understand and agree that such licenses set forth in the preceding sentence exclude any license to the Local Trademarks. In the event of termination of this Agreement by the Company pursuant to <u>Sections 14.2(a)</u>, <u>14.2(b)</u> or <u>14.2(e)</u>, Partner shall grant to Company an exclusive and royalty free license to use the Local Trademarks in the Partner Territory, solely to the extent necessary to use, promote, market, sell, offer for sale, import into, distribute and otherwise Commercialize (but not to Develop or Manufacture) the Product for a transitional period of twelve (12) months following the effective date of termination, except to the extent a longer period of time is required for approval from Regulatory Authorities for Commercialization.
- (b) <u>Transfers</u>. In the event this Agreement is terminated by Company as set forth herein or by the Parties by mutual written agreement, Partner shall, at Company's written request, to the extent permitted under Applicable Laws, promptly following the effective date of termination: (i) assign and transfer to Company (or its designee) all of Partner's right, title, and interest in and to any and all Regulatory Filings (including Regulatory Approvals), and materials, in each case, to the extent related to Development or Commercialization of the Product and (ii) disclose to Company all documents embodying the foregoing that are in any Partner Member's possession or control or that any Partner Member is able to obtain using reasonable

efforts. In the event of termination of this Agreement by the Company pursuant to Section 14.2(a), 14.2(b) or 14.2(e) Partner shall, at Company's request and to the extent permissible under Applicable Laws, transfer to the Company clinical and commercial agreements (to the extent assignable and not cancelled). If any such contracts described in the foregoing sentence are not assignable to Company or its designee, but are reasonably necessary for Company to continue Development or Commercialization of the Product in the Partner Territory, then Partner shall reasonably cooperate with Company to negotiate for the continuation of such services for Company from such entity, for a reasonable period (not to exceed twelve (12) months) after termination at Company's cost until Company establishes an alternate, validated source of such services.

- Partner shall cease performing all work not necessary for the orderly close-out of its activities or obligations hereunder or required by Applicable Laws. Partner shall either, as directed by Company: (i) wind-down any ongoing Development activities (including Clinical Trials) of the Product conducted by any Partner Member in an orderly fashion or (ii) promptly transfer such Development activities to Company or its designee, in compliance with all Applicable Laws; *provided* that, (1) in the event of termination by Company in accordance with Section 14.2(c) or 14.2(d), Partner shall proceed as specified in clause (i) above and (2) in the event of termination by Company in accordance with Section 11.1(n) or 14.2(e), Partner shall proceed as specified in clause (ii) above. Company shall remain responsible for the costs of the activities for which it was responsible under the Global Development Plan from the effective date of termination until completion of such Clinical Trial (or early termination of such Clinical Trial by Company).
- (d) Commercial Wind-Down. Except to the extent this Agreement is terminated by Company in accordance with Section 11.1(n), 14.2(c), 14.2(d) or 14.2(e) or terminated by the Partner in accordance with Section 11.1(n), 14.2(e), 14.2(d) or 14.2(e) or terminated by the Partner in accordance with Section 11.1(n), 14.2(a), 14.2(b) or 14.2(e), Partner shall, as directed by Company, (i) continue certain ongoing Manufacturing (if any) and Commercialization activities of Partner Members with respect to the Product in the Partner Territory for a period of up to six (6) months as determined by Company and (ii) handoff such Manufacturing (if any) and Commercialization activities to Company or its designee, on a timetable to be set by Company, not to exceed six (6) months, and in compliance with all Applicable Laws. During such commercial wind-down period, Partner shall continue to book sales and pay royalties to Company. Except as necessary to conduct the foregoing activities as directed by Company, Partner shall immediately discontinue its (and shall ensure that Partner Members immediately discontinue their) promotion, marketing, offering for sale, and servicing of the Product and use of all Global Trademarks and Local Trademarks. In addition, Partner shall immediately deliver to Company (at Company's expense) all samples, demonstration equipment, sales and marketing materials, catalogs, and literature related to the Product in Partner's possession or control.
- (e) <u>Transition Assistance</u>. Partner shall use commercially reasonable efforts to seek an orderly transition of the Development, and in the event of termination of this Agreement by Company, the Manufacture (if any) and Commercialization, of the Product to Company or its designee. Except to the extent this Agreement is terminated by Partner for Company's material breach of this Agreement in accordance with <u>Section 14.2(a)</u> or pursuant to

Section 14.2(e), without limiting any other rights of Company hereunder, (i) Company may, in its sole discretion, postpone the effective date of such termination for up to six (6) months and (ii) Partner shall, at no cost to Company, provide reasonable consultation and assistance for a period of no more than ninety (90) days after the effective date of such termination (and in any case not to exceed a total of two hundred (200) hours of working time) to transfer or transition Development, and in the event of termination of this Agreement by Company pursuant to Sections 14.2(a), (b) or (e), Manufacture (if any) and Commercialization, of the Product to Company hereunder (including the transfer of all Company Developed IP not already in Company's possession). Such assistance does not include sharing Partner's Background IP.

- (f) <u>Remaining Inventories</u>. Company shall have the right, at its discretion, to purchase from Partner any or all of the inventory of the Product held by Partner as of the date of termination at a price equal to the transfer price paid by Partner to acquire such inventory from Company. Company shall notify Partner in writing within sixty (60) days after the date of termination whether Company elects to exercise such right.
- (g) <u>Confidential Information</u>. Upon Disclosing Party's request, Recipient shall promptly return to Disclosing Party or, at Disclosing Party's option, destroy, all copies of the Confidential Information in Recipient's or its Party Members' possession and shall certify in writing as to such destruction. Notwithstanding the foregoing, Recipient (a) may retain a single copy of the Confidential Information in its legal files for the sole purpose of ascertaining its ongoing rights and responsibilities respecting such information and (b) shall not be required to destroy any computer files created during automatic system back up that are subsequently stored securely by Recipient. Recipient shall continue to be bound by the terms and conditions of this Agreement with respect to such retained Confidential Information in accordance with <u>Section 13</u>.
- 14.4 <u>Survival</u>. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: <u>Sections 2.1(a)</u> and (d) (solely in accordance with <u>Section 14.3(a)(i)</u>), <u>2.3</u>, <u>2.4</u> (solely in accordance with <u>Sections 14.1(b)</u> and <u>14.3(a)(ii)</u>), <u>Sections 4.5(b)(ii)</u>, <u>4.13</u>, <u>4.16</u>, <u>5.4</u> through <u>5.7</u>, <u>8</u>, <u>9</u>, <u>10.1</u>, <u>12</u>, <u>13</u> (as set forth in <u>Section 13.8</u>), <u>14.1(b)</u>, <u>14.3</u> and <u>15</u>.

#### Section 15. General Provisions.

- 15.1 <u>Fees and Expenses</u>. Except as set forth in the Transaction Documents, each Party will pay its own direct and indirect expenses incurred by it in connection with the preparation and negotiation of this Agreement and the consummation of the transactions contemplated by this Agreement, including all fees and expenses of its advisors and representatives.
- 15.2 <u>Notices</u>. All notices, requests, consents and other communications under this Agreement to either Party must be in writing and are deemed duly delivered when (a) delivered if delivered personally or by nationally recognized overnight courier service (costs prepaid), (b) transmitted via e-mail (including via attached .pdf document) to the e-mail address set out below or (c) received or rejected by the addressee, if sent by United States of America certified or registered mail, return receipt requested; in each case to the following addresses or email of the

individual (by name or title) designated below (or to such other address, email or individual as a Party may designate by notice to the other Party):

# If to Company:

vTv Therapeutics, LLC Richard Nelson

3980 Premier Dr., Suite 310 High Point, NC 27265

Email: rnelson@vtvtherapeutics.com Attention: Chief Executive

Officer

With a copy (which will not constitute notice) to:

Skadden, Arps, Slate, Meagher & Flom LLP One Manhattan West

New York, New York 10001

Email: peter.serating@skadden.com

michael.zeidel@skadden.com Attention: Peter D.

Serating

Michael J. Zeidel

#### If to Partner:

G42 Healthcare Dr. Fahed Al Marzoogi, COO

MBA UAI Campus, Madasar City, Building 1B Masdar, Abu Dhabi, United

**Arab Emirates** 

Email: fahed.almarzooqi@g42.ai G42.Legal@g42.ai

Attention: Dr. Fahed Al Mazoogi, COO

- 15.3 Entire Agreement. The Transaction Documents and the Confidentiality Agreement (together with the exhibits and schedules thereto) and the other written agreements entered into between the Parties as of the date hereof, contain the entire understanding of the Parties with respect to the subject matter hereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the Parties acknowledge have been merged into such documents, exhibits and schedules.
- 15.4 <u>Amendments and Waivers</u>. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Parties or, in the case of a waiver, by the Party against whom enforcement of any such waived provision is sought. No waiver of any default with respect to any provision, condition or requirement of this Agreement will be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor will any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

## 15.5 <u>Successors and Permitted Assigns</u>.

- (a) Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to (i) a wholly owned Subsidiary; *provided* that such Party shall remain primarily liable for any acts or omissions of such Subsidiary or (ii) to any Third Party who acquires all or substantially all of the business or assets of the assigning Party by merger, sale of assets or otherwise; *provided* that in no event may either Party assign or transfer this Agreement or any rights or obligations hereunder to a Sanctioned Person. Any permitted assignee shall, in writing to the non-assigning Party, expressly assume performance of such assigning Party's rights and obligations. Any permitted assignment is binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 is null, void and of no legal effect.
- (b) Notwithstanding anything in this Agreement to the contrary, in no event shall the Intellectual Property licensed to Partner by Company or any of its Affiliates include any Intellectual Property to the extent Controlled by any Third Party (the "Acquiror") or any of its Affiliates that acquires all or any part of, or otherwise undergoes a Change of Control with, Company or any Affiliate of Company (any such transaction, an "Acquisition Transaction"), which Intellectual Property (i) is Controlled, immediately prior to the effective date of the applicable Acquisition Transaction, by the Acquiror or any of its Affiliates (other than, for clarity, Company or any of its Affiliates (other than, for clarity, Company or any of its Affiliates immediately prior to the effective date of the acquisition) on or after the effective date of such Acquisition Transaction, but was not created using any Intellectual Property licensed from Partner pursuant to the terms hereof.
- 15.6 <u>No Third-Party Beneficiaries</u>. This Agreement is intended for the benefit of the Parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.
- 15.7 <u>Severability</u>. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction will not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. In the event that any provision hereof would, under Applicable Laws, be invalid or unenforceable in any respect, each of the Parties intend that such provision will be construed by modifying or limiting it so as to be valid and enforceable to the maximum extent compatible with, and possible under, Applicable Laws.
- 15.8 Remedies. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement are not performed by either Party in accordance with their specific terms or were otherwise breached by such Party. Without prejudice to the dispute resolution provisions of Section 15.11, the Parties accordingly agree that, in addition to any other remedy to which the Parties are entitled at law or in equity, each Party is entitled to injunctive relief to prevent breaches of this Agreement by the other Party and otherwise to enforce specifically the provisions of this Agreement against the other Party. Each Party expressly waives

any requirement that the other Party obtain any bond or provide any indemnity in connection with any action seeking injunctive relief or specific enforcement of the provisions of this Agreement.

- 15.9 <u>Business Days</u>. If the last or appointed day for the taking of any action or the expiration of any right required or granted in this Agreement or any other Transaction Document is not a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.
- 15.10 <u>Construction</u>. The Parties agree that each of them and their respective counsel has reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting Party will not be employed in the interpretation of this Agreement or any amendments hereto.

## 15.11 Governing Law; Venue and Dispute Resolution.

- (a) All questions concerning the construction, validity, enforcement and interpretation of this Agreement will be governed by and construed and enforced in accordance with the internal procedural and substantive laws of the laws of England and Wales, without regard to the principles of conflicts of law thereof.
- (b) Except for any matters to be determined in accordance with Section 3.4, any dispute, controversy, or claim arising out of or relating to this Agreement (and any subsequent amendments thereof), or the breach, termination, or validity thereof, and any question of the arbitral tribunal's jurisdiction or the existence, scope or validity of this arbitration agreement or the arbitrability of any claim (each a "Dispute"), shall be resolved by final and binding arbitration administered by the London Court of International Arbitration (the "LCIA"), in accordance with the Arbitration Rules of United Nations Commission on International Trade Law then in effect (the "UNCITRAL Rules"), except as modified herein, with the LCIA being the appointing authority for purposes of the UNCITRAL Rules.
- (c) The seat of arbitration shall be New York, New York, and the arbitration shall be conducted in the English language. The arbitration, and any decisions and awards arising thereunder, will be subject to the Federal Arbitration Act (9 U.S.C. § 1 et seq.).
- (d) The arbitral tribunal shall consist of one arbitrator (the "<u>Arbitral Tribunal</u>") mutually agreed by the Parties. If the Parties cannot mutually agree upon the selection of the Arbitral Tribunal within thirty (30) days of the notice of arbitration, the arbitrator shall be appointed by the LCIA.
- (e) Any arbitration hereunder shall be confidential, and the Parties and their representatives agree not to disclose to any Third Party the existence or status of the arbitration or any information related thereto, except and to the extent that disclosure is required by Applicable Laws or is required to protect or pursue a legal right.
- (f) In addition to monetary damages, the Arbitral Tribunal shall be empowered to award equitable relief, including an injunction and specific performance of any obligation under this Agreement.

- (g) The award of the Arbitral Tribunal shall be final and binding upon the Parties thereto, and shall be the sole and exclusive remedy between the Parties regarding any Dispute presented to the Arbitral Tribunal. Judgment upon any award may be entered in any court having jurisdiction over any party or any of its assets.
- (h) The Arbitral Tribunal shall have the power to award attorneys' fees, costs and related expenses, as well as the costs of the arbitration, to such extent and to such Parties as it sees fit, in accordance with the UNCITRAL Rules.
- (i) Nothing in this <u>Section 15.11</u>, shall preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction including a temporary restraining order, preliminary injunction or other interim relief concerning a Dispute either prior to or during any arbitration if necessary to protect the interest of such Party or to preserve the status quo pending the arbitration proceeding.
- Gi) The Parties submit to the non-exclusive jurisdiction of the federal and state courts located in the Borough of Manhattan, New York County in the State of New York (the "New York Courts"), for the enforcement of any arbitral award rendered hereunder and to compel arbitration or for interim or provisional remedies in aid of arbitration. The Parties hereby unconditionally and irrevocably waive any right to stay or dismiss any such proceeding brought before the New York Courts on the basis of inappropriate or improper venue. Each Party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service will constitute good and sufficient service of process and notice thereof. Nothing contained herein will be deemed to limit in any way any right to serve process in any other manner permitted by law. Furthermore, nothing herein shall affect the Parties' right to bring legal action or proceedings to enforce an arbitral award in any other court of competent jurisdiction.
- 15.12 <u>Force Majeure</u>. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any Force Majeure Event. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Written notice of a Party's failure or delay in performance due to Force Majeure Event must be given to the other Party within ten
- (10) days after its occurrence. All delivery dates under this Agreement that have been affected by Force Majeure Event shall be tolled for the duration of such force majeure.
- 15.13 <u>Interpretation</u>. Except as expressly set forth herein, in the event of a conflict between this Agreement and the Schedules, this Agreement shall control.
- 15.14 <u>Counterparts and Execution</u>. This Agreement may be executed in two or more counterparts, all of which when taken together will be considered one and the same agreement and will become effective when counterparts have been signed by each Party and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by email

delivery of a ".pdf" format data file, such signature will create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

(Signature Page Follows)

IN WITNESS WHEREOF, the Parties hereto have caused this Collaboration and License Agreement to be executed and entered into by their duly authorized representatives as of the Effective Date.

# vTv THERAPEUTICS LLC

By: vTv Therapeutics Inc., its managing member

By: <u>/s/ Richard S. Nelson</u> Name: Richard S. Nelson

Title: Interim Chief Executive Officer

[Signature Page to Collaboration and License Agreement]

IN WI1NESS WHEREOF, the Parties hereto have caused this Collaboration and License Agreement to be executed and entered into by their duly authorized representatives as of the Effective Date.

vTv Therapeutics, LLC

By:<u>/s/</u> Name: Richard Nelson

Title: Interim Chief Executive Officer Cogna Technology Solutions

LLC

By: /s/ Peng Xiao Name: Peng Xiao Title: Authorised Signatory

[Signature Page to Collaboration and License Agreement]

# Schedule 1

# Company Patents

For the avoidance of doubt, the licenses granted to Partner with respect to Company Patents under <u>Section 2.1</u> are limited to the Partner Territory and expressly exclude any Patents with respect to other countries or regulatory jurisdictions unless expressly set forth in the Global Development Plan.

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
US	11/453,330	6/14/2006	7,598,391	10/6/2009	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Issued	vTv Therapeutics LLC
US	12/757,217	4/9/2010	7,851,636	12/14/2010	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Issued	vTv Therapeutics LLC
US	12/942,297	11/9/2010	8,263,634	9/11/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Issued	vTv Therapeutics LLC
DE	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
FR	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
GB	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
AT	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC

[Schedule 1]

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
BE	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
СН	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
CZ	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
DK	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
ES	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
FI	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
GR	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
HU	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
IE	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
IT	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC

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CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
NL	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
PT	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
SE	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
TR	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
AU	2005203930	1/6/2005	2005203930	2/16/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
BR	PI0506662-0	1/6/2005	PI0506662-0	5/25/2021	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
CA	2551324	1/6/2005	2551324	11/27/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
CN	200580002021.6	1/6/2005	ZL200580002021.6	1/4/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
IL	176257	1/6/2005	176257	7/31/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
IN	3624/DELNP/2006	1/6/2005	252466	5/16/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
JP	2006-548114	1/6/2005	4834840	10/7/2011	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
KR	10-2006-7013454	1/6/2005	10-1196313	10/25/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
MX	PA/a/2006/007667	1/6/2005	297252	3/21/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
RU	2006122209	1/6/2005	2386622	4/20/2010	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
ZA	2006/05467	1/6/2005	2006/05467	5/28/2008	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
нк	07107531.4	1/6/2005	1103074	8/17/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
NO	20063351	1/6/2005	337003	12/21/2015	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
PL	05700554.8	1/6/2005	1723128	11/7/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
JP	2011-103784	1/6/2005	5415477	11/22/2013	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC
KR	10-2012-7000490	1/6/2005	10-1126225	3/6/2012	HETEROARYL-UREAS AND THEIR USE AS GLUCOKINASE ACTIVATORS	Granted	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
US	14/071,976	1/5/2013	10,004,782	6/26/2018	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Issued	vTv Therapeutics LLC
US	15/983,249	5/18/2018	10,588,943	3/17/2020	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Issued	vTv Therapeutics LLC
US	16/744,956	1/16/2020	10,980,861	4/20/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Issued	vTv Therapeutics LLC
EP	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
DE	13726933.8	5/15/2013	602013077007.7	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
FR	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
GB	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
BE	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
СН	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
ES	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
IE	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
IT	13726933.8	5/15/2013	2849776	4/21/2021	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
CA	2,872,021	5/15/2013			GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Published	vTv Therapeutics LLC
CN	201380024802.X	5/15/2013			GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Published	vTv Therapeutics LLC
JP	2015-512779	5/15/2013	6234443	11/2/2017	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
MX	MX/a/2014/013105	5/15/2013	360304	10/29/2018	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
нк	15103235.2	5/15/2013			GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Published	vTv Therapeutics LLC
AU	2017203835	5/15/2013	2017203835	3/7/2019	GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Granted	vTv Therapeutics LLC
KR	10-2021-7006420	5/15/2013			GLUCOKINASE ACTIVATOR COMPOSITIONS FOR THE TREATMENT OF DIABETES	Pending	vTv Therapeutics LLC
US	17/480,856	9/21/2021			SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Pending	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
EP	14710738.7	2/28/2014	2964197	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
DE	14710738.7	2/28/2014	602014062792.7	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
FR	14710738.7	2/28/2014	2964197	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
GB	14710738.7	2/28/2014	2964197	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
СН	14710738.7	2/28/2014	2964197	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND	Granted	vTv Therapeutics LLC
					METHODS OF MAKING AND USING THE SAME		
ES	14710738.7	2/28/2014	2964197	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
IE	14710738.7	2/28/2014	2964197	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
IT	14710738.7	2/28/2014	502020000058210	3/25/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
AU	2014226292	2/28/2014	2014226292	1/17/2019	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
CA	2,903,440	2/28/2014	2,903,440	4/13/2021	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
JP	2015-561469	2/28/2014	6441829	11/30/2018	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
MX	MX/a/2015/011110	2/28/2014	372548	3/23/2020	SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Granted	vTv Therapeutics LLC
нк	42021034616.9	2/28/2014			SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Published	vTv Therapeutics LLC
CN	202011088593.3	2/28/2014			SOLID COMPOSITIONS COMPRISING A GLUCOKINASE ACTIVATOR AND METHODS OF MAKING AND USING THE SAME	Published	vTv Therapeutics LLC
US	16/741,224	1/13/2020	10,952,993	3/23/2021	THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Issued	vTv Therapeutics LLC
US	17/178,402	2/18/2021			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
US	17/178,404	2/18/2021			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
EP	19740096.3	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
AU	2019287437	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
CA	3,093,025	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
CN	201980028636.8	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
JP	2020-563743	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
KR	10-2020-7029851	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
MX	MX/a/2020/008905	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
нк	62021031811.4	6/10/2019			THERAPEUTIC USES OF GLUCOKINASE ACTIVATORS IN COMBINATION WITH INSULIN OR INSULIN ANALOGS	Published	vTv Therapeutics LLC
wo	PCT/US2021/017743	2/12/2021			SULFOXIDE AND SULFONE GLUCOKINASE ACTIVATORS AND METHODS OF USE THEREOF	Published	vTv Therapeutics LLC
wo	PCT/US2021/036082	6/7/2021			CRYSTALLINE FORMS OF {2-[3- CYCLOHEXYL-3- (TRANS-4- PROPOXY- CYCLOHEXYL)- UREIDO]- THIAZOL-5- YLSULFANYL}-ACETIC ACID AND AND USES THEREOF	Published	vTv Therapeutics LLC
wo	PCT/US2021/036084	6/7/2021			SALTS OR CO-CRYSTALS OF {2- [3-CYCLOHEXYL-3- (TRANS-4- PROPOXY- CYCLOHEXYL)- UREIDO]- THIAZOL-5- YLSULFANYL}-ACETIC ACID AND USES THEREOF	Published	vTv Therapeutics LLC
US	13/114,964	5/24/2011	9,359,313	6/7/2016	Use of Metformin In Combination With A Glucokinase Activator And Compositions Comprising Metformin And A Glucokinase Activator	Issued	vTv Therapeutics LLC
US	14/988,143	2/11/2016	9,855,251	1/2/2018	Use of Metformin In Combination With A Glucokinase Activator And Compositions Comprising Metformin And A Glucokinase Activator	Issued	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
US	15/687,824	8/28/2017	10,064,846	9/4/2018	Use of Metformin In Combination With A Glucokinase Activator And Compositions Comprising Metformin And A Glucokinase Activator	Issued	vTv Therapeutics LLC
US	16/058,512	8/8/2018	10,363,244	7/30/2019	Compositions Comprising Metformin and A Glucokinase Activator	Issued	vTv Therapeutics LLC
DE	11787250.7	5/24/2011	2576524	10/25/2017	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
FR	11787250.7	5/24/2011	2576524	10/25/2017	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
GB	11787250.7	5/24/2011	2576524	10/25/2017	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
ES	11787250.7	5/24/2011	2576524	10/25/2017	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising	Granted	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
					Metformin and a Glucokinase Activator		
IE	11787250.7	5/24/2011	2576524	10/25/2017	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
IT	11787250.7	5/24/2011	2576524	10/25/2017	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
AU	2011258460	5/24/2011	2011258460	6/4/2015	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
CA	2,799,591	5/24/2011	2,799,591	6/11/2019	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
CN	201180025744.3	5/24/2011	ZL201180025744.3	3/4/2015	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
JP	2013-512164	5/24/2011	5902676	3/18/2016	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
KR	10-2012-7033687	5/24/2011	10-1860120	5/15/2018	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
MX	MX/a/2012/013617	5/24/2011	347372	4/25/2017	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
TW	100118368	5/25/2011	1508723	11/21/2015	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC
нк	13108290.5	5/24/2011	1181044	3/4/2015	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC

CNTRY	APPLICATION NO.	DATE FILED	PATENT NO.	GRANT DATE	TITLE	STATUS	OWNER
KR	10-2018- 7006115	5/24/2011	10-1878252	7/9/2018	Use of Metformin in Combination with a Glucokinase Activator and Compositions Comprising Metformin and a Glucokinase Activator	Granted	vTv Therapeutics LLC

## Schedule 2

## **Knowledge Individuals**

For Company: Richard Nelson Carmen Valcarce Jennifer Freeman

<u>For Partner:</u> Dr. Fahed Al Marzooqi Divyesh Mahajan Joanne Norman

### Schedule 3

### **Partner Territory**

Cyprus, Lebanon, Syria, Israel, Jordan, Saudi Arabia, Kuwait, Qatar, Bahrain, United Arab Emirates, Iran, Iraq, Oman, Yemen, Nigeria, Ethiopia, Egypt, Democratic Republic of the Congo, Tanzania, South Africa, Kenya, Uganda, Algeria, Sudan, Morocco, Angola, Mozambique, Ghana, Madagascar, Cameroon, Cote d'Ivoire, Niger, Burkina Faso, Mali, Malawi, Zambia, Senegal, Chad, Somalia, Zimbabwe, Guinea, Rwanda, Benin, Burundi, Tunisia, South Sudan, Togo, Sierra Leone, Libya, Congo, Liberia, Central African Republic, Mauritania, Eritrea, Namibia, Gambia, Botswana, Gabon, Lesotho, Guinea-Bissau, Equatorial Guinea, Mauritius, Eswatini, Djibouti, Comoros, Cabo Verde, Sao Tome & Principe, Seychelles, Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russia, Tajikistan, Turkmenistan, Afghanistan, Ukraine, Uzbekistan, India, Pakistan, Turkey, Malaysia and Indonesia

# Schedule 4

# **Transfer of Responsibilities**

# Responsibilities for Partner-Conducted Clinical Trial

	TASK	Company	Partner
I.	PROTOCOL	Company	1 at thei
1.	Preparing drafts and final versions of the Collaboration Protocol (subject to JDC approval)	X	
2	Distributing copies of the Collaboration Protocol to the Partner Sites		X
3.	Preparing drafts and final versions of country-specific appendices (subject to JDC approval)		X
4.	Preparing translations of the Collaboration Protocol and distributing copies of such translations to the Partner Sites		X
5.	Preparing drafts and final versions of amendments to the Collaboration Protocols (subject to JDC approval)	X	
6.	Distributing copies of the amendments/country-specific appendices of the Collaboration Protocol		X
7.	Tracking Partner Site acceptance and approval of the Collaboration Protocol, any amendments thereto and country-specific appendices thereof		X
8.	Obtaining ethics committees', including IRBs, approval of Collaboration Protocol / amendments		X
II.	DATA CAPTURES		
1.	Initial CRF Draft Preparation		X
2.	Provisions of the CRF to the Partner Sites		X
3.	Technical support for eCRFs		X
4.	Clinical Trial Master File creation and maintenance		X
5.	Clinical Trial Database creation and maintenance, including obtaining and inputting data from Clinical Investigators		X
6.	Provide SAS datasets to Company to the defined specifications (1) when fifty percent (50%) of subjects have been dosed for six (6) months (where the Collaboration Protocol provides for interim analysis); (2) when the data in the Clinical Trials Database is equivalent to one hundred percent (100%) of total data expected to be recorded in the Clinical Trials Database; (3) if a safety signal is		X

identified; or (4) if a request is received from any applicable Regulatory Authorities  SUBLECTS  1. Preparing (subject to JDC approval), implementing and complying with the Subject Recruitment Plan  2. Preparing the form of Informed Consent documents (and any amendments thereto) for use in the Collaboration Clinical Trial  3. Preparing translation of the form of Informed Consent, including authorization to share private information with Company consistent with all Applicable Laws  4. Ensuring that subjects are given proper informed consent and make informed and knowing signatures  5. Distribution of the Informed Consent to the Partner Sites/approved CROs  6. Obtaining ethics committees*, including IRBs, approval of the Informed Consent and authorization  7. VINCAL SUPPLY  1. Supply and labelling of Finished Product for the Partner Sites  2. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  4. Compliance with the Pharmacovigilance Agreement  7. VINTICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  7. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  8. A Responding to queries from ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  4. Responding to queries from ethics committees, including IRBs,		TASK	Company	Partner
1. Preparing (subject to JDC approval), implementing and complying with the Subject Recruitment Plan  2. Preparing the form of Informed Consent documents (and any amendments thereto) for use in the Collaboration Clinical Trial  3. Preparing translation of the form of Informed Consent, including authorization to share private information with Company consistent with all Applicable Laws  4. Ensuring that subjects are given proper informed consent and make informed and knowing signatures  5. Distribution of the Informed Consent to the Partner Sites/approved CROs  K. A. CINICAL SUPPLY  1. Supply and labelling of Finished Product for the Partner Sites  Y. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  Y. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X. X. X. X. X. Y. ETHICS ACTIVITIES  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws and remain in good standing throughout the Clinical Trial  X. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X. X. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial		identified; or (4) if a request is received from any applicable Regulatory Authorities		
2. Preparing the form of Informed Consent documents (and any amendments thereto) for use in the Collaboration Clinical Trial  3. Preparing translation of the form of Informed Consent, including authorization to share private information with Company consistent with all Applicable Laws  4. Ensuring that subjects are given proper informed consent and make informed and knowing signatures  5. Distribution of the Informed Consent to the Partner Sites/approved CROs  6. Obtaining ethics committees', including IRBs, approval of the Informed Consent and authorization  7. X  1. Supply and labelling of Finished Product for the Partner Sites  8. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  7. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  7. X  7. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Irial  8. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  8. X	III.	SUBJECTS		
3. Preparing the Collaboration Clinical Trial  3. Preparing translation of the form of Informed Consent, including authorization to share private information with Company consistent with all Applicable Laws  4. Ensuring that subjects are given proper informed consent and make informed and knowing signatures  5. Distribution of the Informed Consent to the Partner Sites/approved CROs  6. Obtaining ethics committees', including IRBs, approval of the Informed Consent and authorization  X  IV. CLINICAL SUPPLY  1. Supply and labelling of Finished Product for the Partner Sites  2. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  V. ETHICS ACTIVITES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites of Such returns/destruction of Submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	1.			X
share private information with Company consistent with all Applicable Laws  4. Ensuring that subjects are given proper informed consent and make informed and knowing signatures  5. Distribution of the Informed Consent to the Partner Sites/approved CROs  6. Obtaining ethics committees', including IRBs, approval of the Informed Consent and authorization  X  CLINICAL SUPPLY  1. Supply and labelling of Finished Product for the Partner Sites  2. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	2.		X	
4. Ensuring that subjects are given proper informed consent and make informed and knowing signatures  5. Distribution of the Informed Consent to the Partner Sites/approved CROs  6. Obtaining ethics committees*, including IRBs, approval of the Informed Consent and authorization  X  IV. CLINICAL SUPPLY  1. Supply and labelling of Finished Product for the Partner Sites  2. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	3.			Y
6. Obtaining ethics committees', including IRBs, approval of the Informed Consent and authorization  X  V. CLINICAL SUPPLY  1. Supply and labelling of Finished Product for the Partner Sites  2. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  X  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	4.			
IV. CLINICAL SUPPLY  1. Supply and labelling of Finished Product for the Partner Sites	5.	Distribution of the Informed Consent to the Partner Sites/approved CROs		X
1. Supply and labelling of Finished Product for the Partner Sites  2. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  X X  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	6.			X
2. Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  4. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  4. X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	IV.	CLINICAL SUPPLY		
Product, in accordance with Applicable Laws  3. Maintain records that document shipment, receipt, disposition, return and destruction of the Finished Product supplied for the Clinical Trial  4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  X  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	1.	Supply and labelling of Finished Product for the Partner Sites	X	
4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  V. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	2.	Providing relevant instructions to Company with respect to labelling of Finished Product, in accordance with Applicable Laws		X
4. Assure the return/destruction of all unused Finished Product from Partner Sites and maintain records of such returns/destruction  V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X X X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  X X  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	3.			X
V. PHARMACOVIGILANCE  1. Compliance with the Pharmacovigilance Agreement  X X X  VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	4.			
VI. ETHICS ACTIVITIES  1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	V.	PHARMACOVIGILANCE		
1. Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites  2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	1.	Compliance with the Pharmacovigilance Agreement	X	X
2. Tracking proof of submission of safety reports to the Regulatory Authorities, ethics committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial	VI.	ETHICS ACTIVITIES		
committees, including IRBs, and Clinical Investigators, in accordance with Applicable Laws  3. Ensuring that ethics committees, including IRBs, have all necessary qualifications and remain in good standing throughout the Clinical Trial  X	1.	Ensure that a copy of, and updates to, the Investigator's Brochure are promptly provided to the Partner Sites		X
and remain in good standing throughout the Clinical Trial  X	2.	committees, including IRBs, and Clinical Investigators, in accordance with		X
	3.			Y
	4	Degranding to granica from othics committees in all dies IDDs		

	TASK	Company	Partner
5.	Complying with Applicable Laws relating to disclosure and approval from ethics committees, including IRBs		X
6.	Paying any fees associated with ethics committees, including IRBs,		X
7.	Establishing and maintaining material and specimen handling guidelines		X
VII.	SELECTION OF INVESTIGATORS		
1.	Selection of Clinical Investigators/Partner Sites (subject to JDC approval) and ensuring that such Clinical Investigators and/or Partner Sites are appropriately qualified and eligible to conduct the Clinical Trial under the Collaboration Protocol		
2			X
2. 3.	Communication of termination to the Partner Sites		X
3.	Ensuring that the Partner Sites comply with all Applicable Laws (including GCP)		X
4.	Entering into the Clinical Study Agreement with the Partner Sites		X
5.	Paying all expenses associated with the Partner-Conducted Clinical Trial and ensuring that such payments are in compliance with Applicable Laws, and Regulatory Authority and ethics committee, including IRBs, requirements		
			X
6.	Obtaining executed Financial Disclosure Forms from the relevant Persons		X
7.	Conduct of initiation/opening visit for the Clinical Trial at each Partner Site		X
8.	Confirming all documentation and approvals are in place for activation of the Partner Sites		X
9.	Formally activating a Partner Site		X
VIII.	AUDITING AND MONITORING		
1.	Complying with the Monitoring Plan with respect to the Clinical Trial		V
2.	Complying with the audit requirement		X
IX.	INVESTIGATOR MEETINGS		Λ
1.	Planning and conducting the Investigator Meetings		X
2.	Cost of Investigator Meetings		X
X.	DATA MANAGEMENT		Λ
1.	Preparing (subject to JDC approval) and complying with the Data Management Plan		
			X

Source verification of data records, as set forth in the Monitoring Plan  Subject randomization, per the Collaboration Protocol  Ensuring timely data completion and review  Updating Clinical Trials Database  TRIAL CLOSEOUT  Decision on appropriate time for closure of each Site subject to and in accordance with the Collaboration Protocol  Partner Site closure on a timely basis as data is completed and subjects off study  SAFETY MONITORING  Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  COMMUNICATION  Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request  Providing the JDC with pertinent information regarding the Partner- Conducted	Partner
4. Ensuring timely data completion and review 5. Updating Clinical Trials Database  XI. TRIAL CLOSEOUT 1. Decision on appropriate time for closure of each Site subject to and in accordance with the Collaboration Protocol 2. Partner Site closure on a timely basis as data is completed and subjects off study  XII. SAFETY MONITORING 1. Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  XIII. COMMUNICATION 1. Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	X
5. Updating Clinical Trials Database  XI. TRIAL CLOSEOUT  1. Decision on appropriate time for closure of each Site subject to and in accordance with the Collaboration Protocol  2. Partner Site closure on a timely basis as data is completed and subjects off study  XII. SAFETY MONITORING  1. Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  XIII. COMMUNICATION  1. Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	X
TRIAL CLOSEOUT  1. Decision on appropriate time for closure of each Site subject to and in accordance with the Collaboration Protocol  2. Partner Site closure on a timely basis as data is completed and subjects off study  XII. SAFETY MONITORING  1. Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  XIII. COMMUNICATION  1. Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	X
Decision on appropriate time for closure of each Site subject to and in accordance with the Collaboration Protocol  Partner Site closure on a timely basis as data is completed and subjects off study  SAFETY MONITORING  Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  COMMUNICATION  Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	X
with the Collaboration Protocol  Partner Site closure on a timely basis as data is completed and subjects off study  SAFETY MONITORING  Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  COMMUNICATION  Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	
XII. SAFETY MONITORING  1. Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  XIII. COMMUNICATION  1. Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	X
1. Conducting safety monitoring and ensuring all appropriate informed consent documents (and any required updates) are obtained  XIII. COMMUNICATION  1. Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	X
documents (and any required updates) are obtained  XIII. COMMUNICATION  1. Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	
Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	
Obtaining and managing copies of all correspondence with the Partner Sites and providing such to JDC at the JDC's request	X
providing such to JDC at the JDC's request	
2. Providing the JDC with pertinent information regarding the Partner- Conducted	X
Clinical Trial as agreed upon by the JDC, including all correspondence with Regulatory Authorities and ethics committees, including IRBs	
	X
XIV. STATISTICAL ANALYSIS AND TRIAL REPORT	
1. Statistical analysis of any data pursuant to the Statistical Analysis Plan and providing such analysis to Company X	
2. Preparation of final report and providing such report to Company	X
XV. CROs	
1. Selection of CRO (subject to Company's approval).	X
2. Enter into the written CRO agreement with the approved CRO	X
XVI. REGULATORY AFFAIRS	
1. Initial development of Investigator's Brochure X	
2. Updates to Investigator's Brochure X	
3. Compilation of IND and any amendments	X
4. Submission of IND to applicable Regulatory Authorities (to the extent permitted by Applicable Laws) and any amendments	X

TASK			
		Company	Partner
5.	Submission of Partner Site Information to the Regulatory Authorities		
			X
6.	End of Clinical Trial notice.		X
7.	CofA, CofC, TSE/BSE Certification, GMP Compliance Statement	X	
8.	Translations of any documents for submission to the Regulatory Authorities		
			X
9.	Authorization of first CTS shipment to Partner Sites	X	
10.	Collection of Regulatory Documents from Partner Sites		X
11.	End of Study Declaration to ethics committees, including IRBs		X

#### Exhibit A

## **Anti-Corruption Compliance Certification**

Pursuant to Section 11.1(m) of the Collaboration and License Agreement between vTv Therapeutics LLC ("<u>Company</u>") and Cogna Technology Solutions LLC ("<u>Partner</u>") dated May \_\_\_\_, 2022 (the "<u>Agreement</u>"), I, [Name], on behalf of [Party], hereby certify that to my knowledge:

- 1. [Party] has provided a copy of the Compliance Policies and communicated regarding such documents to all persons acting on its behalf in connection with work und this Agreement, including any employees, agents, contractors or subcontractors.
- 2. With respect to any products, payments or services provided under this Agreement, [Party] has not taken any action directly or indirectly to knowingly (i) offer, promise, provide, or authorize the offer or provision of money or anything of value, in order to improperly or corruptly seek to influence any Government Official or any other Person in order to obtain or retain business or any other improper business advantage; (ii) request or accept any such improper payment; or (iii) cause a violation of any Anti-Corruption Law. For example, this includes knowingly providing any inducement for such Government Official or person to approve, reimburse, prescribe, or purchase a product, to influence the outcome of a clinical trial, or otherwise to benefit Company's business activities improperly;
- 3. [Party] has ensured that it and every agent, contractor, or subcontractor performing services in connection with the Agreement has agreed to comply with and be bound by the provisions of the Agreement that address compliance with Anti-Corruption Laws;
- 4. [Party] has met all relevant disclosure obligations required under the Agreement;
- 5. [Party] has informed [Other Party] in good faith of any significant changes in information provided during precontractual due diligence; and
- 6. To the extent required by the Agreement, [Party] has provided training on its policies and Anti-Corruption Laws to its officers, directors, employees, and appropriate third parties.
- 7. Capitalized terms used but not defined herein shall have the meaning assigned to such term in the Agreement.

COMPAN	Y NAME: _	NAME:
TITLE: _	_DATE:	

[Exhibit A]

#### SECTION 302 CERTIFICATION

#### I, Paul J. Sekhri, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of vTv Therapeutics Inc. (the "registrant");
- 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 this 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 15d-15(e)) and internal control over financial reporting (as defined in Securities 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.

Date: August 15, 2022

By: /s/ Paul J. Sekhri

Paul J. Sekhri

President and Chief Executive Officer

#### SECTION 302 CERTIFICATION

#### I, Barry Brown, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of vTv Therapeutics Inc. (the "registrant");
- 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 this 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 15d-15(e)) and internal control over financial reporting (as defined in Securities 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 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.

Date: August 15, 2022

By: /s/ Barry Brown

Barry Brown

Chief Accounting Officer

# 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 of vTv Therapeutics Inc. (the "Company") on Form 10-Q for the period ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul J. Sekhri, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of the Company that, to my knowledge:

- 1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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.

Date: August 15, 2022

By: /s/ Paul J. Sekhri

Paul J. Sekhri

President and Chief Executive Officer

# 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 of vTv Therapeutics Inc. (the "Company") on Form 10-Q for the period ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Barry Brown, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of the Company that, to my knowledge:

- 1. The Report fully complies with the requirements of Section 13(a) or 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.

Date: August 15, 2022

By: /s/ Barry Brown

Barry Brown

Chief Financial Officer