UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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, 2021

OR

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

For the transition period from

Commission File Number: 001-39696

to

COMPASS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of incorporation or organization)

80 Guest St., Suite 601 Boston, Massachusetts (Address of principal executive offices) 82-4876496 (I.R.S. Employer

Identification No.)

02135

(Zip Code)

Registrant's telephone number, including area code: (617) 500-8099

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

	Trading	
Title of each class	Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CMPX	OTCQB Stock 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 \boxtimes No \square

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 \boxtimes No \square

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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
 Accelerated filer

 Non-accelerated filer
 Smaller reporting company

 Emerging growth company
 Image: Smaller reporting company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes \Box No \boxtimes As of August 10, 2021, the registrant had 61,694,565 shares of common stock, \$0.0001 par value per share, outstanding.

Summary Risk Factors

A summary of certain risk factors affecting our business and prospects is included below. You should carefully consider the risks described below together with all of the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the information included the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as the "Risk Factors" included in item 1A in this Quarterly Report on From 10-Q and our <u>Annual Report on Form 10-K for the fiscal year ended December 31, 2020</u>. If any of the events described below actually occurs, our business, results of operations, cash flows or prospects could be harmed. If that were to happen, you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

- We have a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We have never generated revenue from product sales and may never be profitable.
- We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.
- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and
 experience delays in developing and commercializing or be unable to develop or commercialize our current and future product
 candidates.
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.
- Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.
- Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- The successful commercialization of our product candidates will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain

i

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

- If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected.
- Others may claim an ownership interest in our intellectual property and our product candidates, which could expose us to litigation and have a significant adverse effect on our prospects.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We will incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance efforts.
- Our business, results of operations and future growth prospects could be materially and adversely affected by the COVID-19 pandemic.
- We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.
- Because our shares of common stock are quoted on the OTCQB instead of a national exchange or quotation system, our investors may experience significant volatility in the market price of our stock and have difficulty selling their shares.
- Because we became a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, by means
 other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major
 brokerage firms.
- Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	1
Item 1.	Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets (Unaudited)	1
	Condensed Consolidated Statements of Operations (Unaudited)	2
	Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)	
	(Unaudited)	3
	Condensed Consolidated Statements of Cash Flows (Unaudited)	4
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	23
Item 4.	Controls and Procedures	23
PART II.	OTHER INFORMATION	24
Item 1.	Legal Proceedings	24
Item 1A.	Risk Factors	24
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	43
Item 3.	Defaults Upon Senior Securities	43
Item 4.	Mine Safety Disclosures	43
Item 5.	Other Information	43
Item 6.	Exhibits	43
<u>Signatures</u>		44

iii

Compass Therapeutics, Inc. and Subsidiaries Condensed Consolidated Balance Sheets

Assets		June 30, 2021 (Unaudited)		cember 31, 2020 (Note 1)
Current assets:		(Onauditeu)		
Cash and cash equivalents	\$	31,208	\$	47,076
Prepaid expenses and other current assets	Ψ	3,326	Ψ	3,126
Total current assets		34,534		50,202
Property and equipment, net		1,178		1,126
Restricted cash		210		263
Operating lease, right-of-use ("ROU") asset		4,630		203
Other assets		4,030		320
Total assets	\$		<u>۴</u>	
	Ф	40,872	\$	51,911
Liabilities and Stockholders' Equity Current liabilities:				
Accounts payable	\$	559	\$	1,061
Accounts payable	φ	1,174	φ	1,001
Operating lease obligations, current portion		1,049		1,571
Current portion of long-term debt		5,611		7,467
			. <u> </u>	
Total current liabilities		8,393		10,099
Long-term debt, net of current portion		2 604		1,867
Operating lease obligations, long-term portion		3,604		
Total liabilities		11,997		11,966
Stockholders' equity:				
Preferred stock, \$0.0001 par value; 10,000 shares authorized and no shares issued and				
outstanding as of June 30, 2021 and December 31, 2020		—		—
Common stock, \$0.0001 par value: 300,000 shares authorized; 62,323 and 52,117 shares issued at June 30, 2021 and December 31, 2020, respectively; 61,666 and 51,221 shares outstanding at June 30,				
2021 and December 31, 2020, respectively		6		5
Additional paid-in-capital		243,503		191,348
Accumulated deficit		(214,634)		(151,408)
Total stockholders' equity		28,875		39,945
Total liabilities and stockholders' equity	\$	40,872	\$	51,911
	Ψ	+0,072	Ψ	51,511

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Compass Therapeutics, Inc. and Subsidiaries Condensed Consolidated Statements of Operations (Unaudited) (In thousands, except per share data)

Three Months Ended Six Months Ended June 30, June 30, 2021 2020 2021 2020 Operating expenses: 2,985 Research and development \$ 2,905 \$ \$ 7,609 \$ 6,556 General and administrative 2,166 2,085 4,798 4,345 50,618 In-process R&D 50,618 ____ Total operating expenses 55,689 5,070 63,025 10,901 Loss from operations (55,689) (5,070) (63,025) (10,901) Other expense, net (102) (471) (185) (1,026) Loss before income tax expense (5,541) (63,210) (11,927) (55,791)Income tax expense (13) (16) (13) (32) \$ Net loss (55,804)\$ (5,557)\$ (63, 223)\$ (11,959) Net loss per share - basic and diluted \$ (1.07) \$ (0.41) \$ (1.23) \$ (1.16)51,913 10,335 Basic and diluted weighted average shares outstanding 13,603 51,582

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Compass Therapeutics, Inc. and Subsidiaries Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit) (Unaudited) (In thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-in		Accumulate d		Sto	Total ockholder s'		
	Shares	Amo	ount	Shares Amount		Capital		Deficit		Equity		
Balance at December 31, 2020		\$		51,221	\$	5	\$	191,348	\$	(151,408)	\$	39,945
Vesting of share-based awards	_		_	92		_		_		_		—
Stock-based compensation						_		948				948
Net loss	_			_		_		_		(7,422)		(7,422)
Balance at March 31, 2021			_	51,313		5		192,296		(158,830)		33,471
Common shares issued for Trigr acquisition	_			10,265		1		50,299		_		50,300
Vesting of share-based awards	_		_	88		_		_		_		—
Stock-based compensation	_		_	_		_		908		_		908
Net loss	_			_		_		_		(55,804)		(55,804)
Balance at June 30, 2021		\$	_	61,666	\$	6	\$	243,503	\$	(214,634)	\$	28,875

	Convertible Preferred Stock		Commo	n Stock	Additional Paid-in	Accumulate d	Total Stockholder s'	
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Defic it)	
Balance at December 31, 2019	207,164	\$ 129,870	7,034	\$ 1	\$ 3,304	\$ (121,908)	\$ (118,603)	
Vesting of share-based awards		_	88	_	_	_	_	
Stock-based compensation		_	_	_	247	_	247	
Net loss		_	_	_	_	(6,402)	(6,402)	
Balance at March 31, 2020	207,164	129,870	7,122	1	3,551	(128,310)	(124,758)	
Common shares issued to former shareholders of Olivia Ventures Inc.	_	_	1,000	_	_	_		
Conversion of Compass Therapeutics LLC prefer red shares into common shares	(207,16	(100.070)			400.007		100.070	
upon consummation of the reverse merger	4)	(129,870)	30,630	3	129,867		129,870	
Common shares issued in private placement, net of issuance costs of \$6,902	—	_	12,097	1	53,580	_	53,581	
Payment to non- participating Compass Therapeutics								
LLC members upon consummation of Merger	_	_	(14)	—	(69)	_	(69)	
Vesting of share-based awards	—	—	62	—		—	—	
Stock-based compensation	—	—	—	—	183	—	183	
Net loss	_	—	—	_	—	(5,557)	(5,557)	
Balance at June 30, 2020		\$ —	50,897	\$5	\$ 187,112	\$ (133,867)	\$ 53,250	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Compass Therapeutics, Inc. and Subsidiaries Condensed Consolidated Statements of Cash Flows (Unaudited)

(In thousands)

	For the Six Mont Ended June 30			
		2021		2020
Cash flows from operating activities:				
Net loss	\$	(63,223)	\$	(11,959)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		304		900
Loss (gain) on disposal of equipment		(44)		8
Noncash interest expense		22		50
Share-based compensation		1,856		430
Write off of in-process R&D		50,618		_
Change in fair value of derivative liability		_		556
ROU asset amortization		518		_
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		(200)		(982)
Other long-term assets				32
Accounts payable		(502)		952
Accrued expenses		(398)		(1,998)
Operating lease liability		(495)		—
Settlement of derivative liability				(1,050)
Net cash used in operating activities		(11,544)		(13,061)
Cash flows from investing activities:				
Purchases of property and equipment		(424)		(16)
Asset acquistion costs		(318)		—
Proceeds from sale of equipment		115		55
Net cash (used in) provided by investing activities		(627)		39
Cash flows from financing activities:				
Proceeds from issuance of common stock		—		60,482
Issuance costs from issuance of common stock		—		(5,517)
Repayment of borrowings under loan		(3,750)		(1,875)
Net cash (used in) provided by financing activities		(3,750)		53,090
Net change in cash, cash equivalents and restricted cash		(15,921)		40,068
Cash, cash equivalents and restricted cash at beginning of period		47,339		25,566
Cash, cash equivalents and restricted cash at end of period	\$	31,418	\$	65,634
Supplemental disclosure of cash flow information				
Cash paid for interest	\$	226		486
Supplemental disclosure of financing activities				
Acquisition of equipment included in accrued expenses	\$	_	\$	_
Deferred offering costs included in accrued expenses	\$	_	\$	(1,384)
Payment to non-participating Compass LLC investors, within accrued expenses	\$		\$	(69)
ROU asset acquired through operating leases	\$	5,148	\$	
Acquisition of Trigr Therapeutics, Inc.	\$	50,300	\$	
The accompanying notes are an integral part of these unaudited condensed con	colidated financia	Latatamant	. —	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Compass Therapeutics, Inc. and Subsidiaries Notes to Unaudited Condensed Consolidated Financial Statements

1. Nature of Business and Basis of Presentation

Compass Therapeutics, Inc. ("Compass" or the "Company") is a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases. Our scientific focus is on the relationship between angiogenesis and the immune system. Our pipeline includes novel product candidates that leverage our understanding of the tumor microenvironment, including both angiogenesis-targeted agents and immune-oncology focused agents. These product candidates are designed to optimize critical components required for an effective anti-tumor response to cancer. These include modulation of the microvasculature via angiogenesis-targeted agents; induction of a potent immune response via activators on effector cells in the tumor microenvironment; and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance. We plan to advance our product candidates through clinical development as both standalone therapies and in combination with our proprietary drug candidates as long as their continued development is supported by clinical and nonclinical data. References to Compass or the Company herein include Compass Therapeutics, Inc. and its wholly-owned subsidiaries. The Company was incorporated as Olivia Ventures, Inc. ("Olivia") in the State of Delaware on March 20, 2018. Prior to the Company's reverse merger with Compass Therapeutics LLC (the "Merger"), Olivia was a "shell company" (as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended).

The Company is subject to risks and uncertainties common to companies in the biotechnology and pharmaceutical industries. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2021 and its results of operations and changes in convertible preferred stock and stockholders' equity (deficit) for the three and six months ended June 30, 2021 and 2020 and cash flows for the six months ended June 30, 2021 and 2020. Operating results for the six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

The unaudited condensed consolidated financial statements include the accounts of Compass Therapeutics, Inc. and its subsidiaries, and have been prepared by the Company in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated balance sheet at December 31, 2020 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements. Accordingly, these condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements in the Company's <u>Annual Report on Form 10-K</u> for the year ended December 31, 2020 (the "Annual Report").

Going Concern

These financial statements have been prepared on the basis that the Company is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. The Company has not generated any revenues from operations since inception and does not expect to do so in the foreseeable future. We have funded our operations primarily with proceeds from the sale of our equity securities and borrowings from debt arrangements. Through June 30, 2021, we have received \$132.0 million in gross proceeds from the sale of equity securities and \$15.0 million in term loan borrowings under the Credit Facility. Following the completion of the Merger, we completed a private placement of our common stock of \$60.5 million.



As of June 30, 2021, we had cash and cash equivalents of \$31.2 million. This cash balance is not sufficient to fund the Company's current operating plan for at least the next twelve months following the filing of this Quarterly Report. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is exploring opportunities to secure additional funding through equity or debt financings or through collaborations, licensing transactions or other sources.

COVID-19 Update

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business and have taken important steps to help ensure the safety of our employees and to reduce the spread of COVID-19 community-wide. We are ensuring that essential staffing levels at our operations remain in place, including maintaining key personnel in our laboratory facilities. We have implemented stringent safety measures designed to create a safe and clean environment for our employees as we continue to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic.

We have been able to continue to pursue patient dosing and monitoring of our Phase 1 clinical trial of CTX-471 without significant delays. However, over the last six months we have experienced increased delays in patient enrollment in several of our trial sites. In order to address the reduction in patient enrollment, we have recently added three new sites. In addition, there have been delays in sourcing of selected supplies required for the manufacturing of material to be used in our future clinical trials, and these delays may impact the timing of initiation of our future clinical trials We expect that COVID-19 may continue to directly or indirectly impact (i) our employees and business operations or personnel at third-party suppliers and other vendors in the U.S. and other countries; (ii) the availability, cost or supply of materials; and (iii) the timeline for our ongoing clinical trial and potential future trials. We are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials, as well as on our industry and the healthcare system.

2. Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report, except as noted below.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases*, which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the condensed consolidated financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The Company adopted this standard on January 1, 2021. See Note 7 for additional details on the Company's accounting for leases.

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2022. The Company does not expect the adoption of ASU 2019-12 to have a material impact on its financial position and results of operations upon adoption.



3. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

		Fair Value	Measu	rements as o	f June 3	0, 2021 Usir	ng:	
	ii Ma Ident	ited Prices n Active arkets for cical Assets Level 1)	OI	gnificant Other oservable Inputs Level 2)	Unot I	nificant oservable nputs evel 3)	Fa	ir Value
Assets								
Cash equivalents - money market	\$	28,859	\$	—	\$	—	\$	28,859
Total assets	\$	28,859	\$	_	\$		\$	28,859
				ments as of I	Decemb	er 31, 2020 l	Jsing:	
	i M	oted Prices n Active arkets for tical Assets		ignificant Other bservable Inputs	Unol	nificant oservable nputs		
		(Level 1)	(Level 2)	(L	evel 3)	Fa	ir Value
Assets		(Level 1)	(Level 2)	(L	evel 3)	Fa	ir Value
Assets Cash equivalents - money market	\$	(Level 1) 43,631	(\$	(Level 2)	(L \$	evel 3) 	Fa \$	ir Value 43,631

4. Property and Equipment

Property and equipment consist of the following (in thousands):

	Ju	December 31, 2020		
Equipment	\$	5,389	\$	5,356
Furniture and fixtures		22		629
Leasehold improvements		200		896
Software		364	_	180
Total property and equipment-at cost		5,975		7,061
Less: Accumulated depreciation		(4,797)		(5,935)
Property and equipment, net	\$	1,178	\$	1,126

Total depreciation expense for three months ended June 30, 2021 and 2020, was \$0.1 million and \$0.4 million, respectively. Total depreciation expense for six months ended June 30, 2021 and 2020, was \$0.3 million and \$0.9 million, respectively.

5. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	ıne 30, 2021	December 31, 2020		
Compensation and benefits	\$ 572	\$	976	
Research and development expenses	356		212	
Legal and professional fees	-		326	
Other	246		57	
Total accrued expenses	\$ 1,174	\$	1,571	

6. Debt

The aggregate principal amount of debt outstanding consisted of the following (in thousands):

	June 30, 2021			December 31, 2020		
Current portion of debt	\$	5,625	\$	7,500		
Less: unamortized debt discount		(14)		(33)		
Current portion of debt, net of debt discount	\$	5,611	\$	7,467		
Long-term debt, net of current portion	\$	_	\$	1,875		
Less: unamortized debt discount		—		(8)		
Long-term debt, net of current portion	\$		\$	1,867		

The Company entered into, and subsequently amended, a term loan facility with Pacific Western Bank, Inc. (the "Credit Facility"), and received \$15.0 million debt proceeds. The loans bear interest at the greater of (i) 6.25% and (ii) the prime rate plus an applicable margin of 2.0%. The interest rate was 6.25% at June 30, 2021. In an event of default, as defined in the Credit Facility, the interest rate applicable to borrowings would be increased by 5.0%. The Company made interest-only payments through March 31, 2020. In April 2020, the Company became obligated to make equal monthly principal payments of \$625,000 through March 31, 2022 when the notes mature. The Credit Facility allows for prepayment of the outstanding principal at any time, subject to a prepayment charge that is dependent on the prepayment date.

The Credit Facility agreement contains a provision whereby the Company was obligated to pay a success fee of \$1.1 million upon the achievement of certain liquidity events. Upon consummation of the Merger, the Company success fee payment became due and was paid in its entirety in June 2020.

The Credit Facility contains a negative pledge on the Company's intellectual property and also contains customary indemnification obligations and customary events of default, including, among other things, (i) non-payment, (ii) breach of warranty, (iii) non-performance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (iv) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) key person event, (xi) regulatory matters, and (xii) key contracts. In addition, the Company must maintain a minimum cash balance of \$6.0 million beginning in April 2020. In the event of default under the Credit Facility, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 5%.

The borrowings are collateralized by substantially all of the Company's assets, excluding intellectual property, and contains affirmative and negative covenants including restrictions on the Company's ability to incur additional indebtedness, pay dividends, encumber its property, or engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses. The Company was in compliance with its covenants as of June 30, 2021.

The Company recognized interest expense of \$0.1 million and \$0.2 million during the three months ended June 30, 2021 and 2020, respectively. The Company recognized interest expense of \$0.3 million and \$0.5 million during the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, the aggregate minimum future principal payments due in connection with the Credit Facility, as amended, are as follows (in thousands):

Year Ending December 31,	
2021	\$ 3,750
2022	1,875
	\$ 5.625

7. Leases

The Company adopted ASU 2016-02, *Leases (Topic 842)*, or ASU 2016-02, effective January 1, 2021, using the modified retrospective transition method, in which the new standard is applied as of the date of initial adoption. The Company recognized and measured agreements executed prior to the date of initial adoption that were considered leases on January 1, 2021. No cumulative effect adjustment of initially applying the standard to the opening balance of retained earnings was made upon adoption. The Company elected the package of practical expedients permitted under the transition guidance that will retain the lease classification and initial direct costs for any leases that exist prior to adoption of the standard. In addition, the Company elected the accounting policy of not recording short-term leases with a lease term at the commencement date of 12 months or less on the condensed consolidated balance sheet as permitted by the new standard.

The Company has evaluated its leases and determined that it has one lease that is classified as an operating lease. The classification of this lease is consistent with the Company's determination under the previous accounting standard.

When available, the Company will use the rate implicit in the lease to discount lease payments to present value; however, the Company's current lease does not provide an implicit rate. Therefore, the Company used its incremental borrowing rate to discount the lease payments based on the date of the lease commencement.

The Company has one operating lease for its corporate office and laboratory facility ("Facility") that was signed in December 2020. The Company moved into the Facility in January 2021. The Facility lease has an initial term of four years and five months, beginning on January 1, 2021. The Facility lease contains scheduled rent increases over the lease term. The discount rate used for the Facility lease is 6.25%, and the remaining lease term of the Facility lease is three years and eleven months as of June 30, 2021.

The table below presents the undiscounted cash flows for the lease term. The undiscounted cash flows are reconciled to the operating lease liabilities recorded on the condensed consolidated balance sheet:

	(000's)
Remainder of 2021	\$	749
Years ending December 31,		
2022		1,315
2023		1,348
2024		1,382
2025		426
Total minimum lease payments		5,220
Less: amount of lease payments representing interest		(567)
Present value of future minimum lease payments		4,653
Less: operating lease obligations, current portion		(1,049)
Operating lease obligations, long-term portion	\$	3,604

8. Stock-Based Compensation

In June 2020, the Company's board of directors adopted the 2020 Stock Option and Incentive Plan (the "2020 Plan") and reserved 2.93 million shares of common stock for issuance under this plan. The 2020 Plan includes automatic annual increases. The increase on January 1, 2021 was 2.08 million shares. As of June 30, 2021, 1.64 million shares remain available for future grant.

The 2020 Plan authorizes the board of directors or a committee of the board to grant incentive stock options, nonqualified stock options and restricted stock awards to eligible officers, employees, consultants and directors of the Company. Options generally vest over a period of four years and have a contractual life of ten years from the date of grant.

Stock-based compensation expense for the six months ended June 30, 2021 and 2020 was classified in the condensed consolidated statement of operations as follows:

	Six Months Ended June 30,					
		2021		2020		
	(000's)					
Research and development	\$	298	\$	112		
General and administrative		1,558		318		
Total	\$	1,856	\$	430		

As of June 30, 2021, remaining unrecognized compensation cost related to options and restricted stock awards to be recognized in future periods totaled \$9.0 million

Restricted Stock

Prior to the adoption of the 2020 Plan, the Company issued restricted stock. A summary of the Company's restricted stock activity during the six months ended June 30, 2021 is as follows:

	Shares	Fai	r Value
Weighted Average Fair Value	(000's)	Pe	r Share
Unvested, December 31, 2020	896	\$	1.78
Granted	—	\$	—
Vested	(180)	\$	1.87
Forfeited or canceled	(59)	\$	1.60
Unvested, June 30, 2021	657	\$	1.78

As of June 30, 2021, stock compensation expense for restricted stock is expected to be recognized over a weighted average period of 2.1 years.

Stock Options

The following table summarizes the stock option activity for the 2020 Plan:

	Number of Unvested Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual
	(000's)	Price Per Share	Life (in years)
Outstanding at December 31, 2020	2,159	\$ 5.00	9.1
Granted	1,424	\$ 5.36	9.7
Exercise	—	\$ 5.00	—
Forfeited/cancelled	(211)	\$ 5.00	—
Outstanding at June 30, 2021	3,372	\$ 5.15	9.2
Vested at June 30, 2021	1,123	\$ 5.00	8.7

For the six months ended June 30, 2021, the weighted average grant date fair value for options granted was \$3.95. The aggregate intrinsic value for options outstanding as of June 30, 2021 was \$3 thousand. There was no aggregate intrinsic value for vested options as of June 30, 2021. As of June 30, 2021, stock option expense for options is expected to be recognized over a weighted average period of 3.0 years.

There were no stock options granted for the six months ended June 30, 2020. The weighted average assumptions used in the Black-Scholes pricing model to determine the fair value of stock options granted during the six months ended June 30, 2021 were as follows:

Expected term (in years)	6.1
Risk-free rate	0.76%
Expected volatility	89.3%

9. Merger Transaction

On May 11, 2021 the Company and Trigr Therapeutics, Inc. ("TRIGR"), a private biotechnology company, entered into a definitive merger agreement (the "Merger Agreement"). Pursuant to the Merger Agreement, the Company, through its wholly owned subsidiaries and a two-step merger structure, acquired all of the outstanding shares of TRIGR (the "Merger"). On June 25, 2021, the Merger was consummated. Consideration payable to TRIGR shareholders at closing totaled an aggregate of 10,265,133 shares of the Company's common stock with a fair value of \$50.3 million (after giving effect to elimination of fractional shares that would otherwise be issued). In addition, TRIGR shareholders are eligible to receive up to \$9 million, representing earnout payments based on three independent events. The first potential earnout payment is \$2 million related to a milestone payment under the Elpiscience agreement, due the Company upon IND approval of CTX-009 in China, and remitted to the TRIGR shareholders. The Company will act as a conduit to this transaction and will remit to the former TRIGR shareholders up to \$2 million related to this milestone payment received from Elpiscience. The second potential earnout payment of \$2 million, is contingent upon the Company entering into a regional license agreement with a specific third party. Since the Company has not entered into a regional license agreement with that third party and assesses the probability of reaching such agreement with that party to be low, no provision is being made. The third and last potential earnout is \$5 million which is dependent on the Company successfully filing a biologics license application and being granted marketing approval for the product candidate acquired in the transaction, CTX-009. As CTX-009 is in early clinical development and the clinical development of CTX-009 and regulatory strategy are subject to substantial risk, it is not probable that this payment will be made and as such, no provision is being made.

To determine whether the transaction meets the definition of a business acquisition or an asset acquisition in accordance with ASC 805-10-55, we had to assess the nature of the transaction and the fair value of the assets acquired in the transaction. Our assessment suggest that the fair value of the transaction is substantially concentrated in a license to a single identifiable asset, CTX-009, and a potential financial interest (in the form of royalties) in an additional set of early-stage similar assets. The guidance further requires a business acquisition to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. Because all asset acquisitions include inputs, the existence of a substantive process is what distinguishes a business acquisition from an asset acquisition. Our assessment is that there is no process or outputs that are being acquired with the TRIGR acquisition. Accordingly, the Company allocated the \$50.3 million transaction amount and \$0.3 million of transaction costs to the acquired license. As the license is considered in process R&D, the Company expensed the acquired asset on the transaction date.

10. Related Parties and Related-Party Transactions

On October 16, 2014, the Company entered into a collaboration agreement with Adimab, LLC. The Company's co-founder has a direct ownership interest in Adimab, LLC. The Company recorded no research and development expenses in connection with this agreement during the six months ended June 30, 2021 and 2020.

In connection with the acquisition of TRIGR and upon consummation of the merger agreement on June 25, 2021, Miranda Toledano, who previously served as the Chief Financial Officer and Chief Operating Officer of TRIGR, was appointed to Compass Board of Directors as an independent director. Additionally, to facilitate the transition of CTX-009 from TRIGR, the Company entered into a consulting agreement with Ms. Toledano on June 25, 2021 for a period of six months.

11. Other Expense

Other income and expense consisted of the following:

	Three Months Ended June 30,			Six Months End June 30,				
		2021		2020		2021		2020
		(00))'s)			(00))'s)	
Interest income	\$	9	\$	7	\$	24	\$	48
Interest expense		(111)		(242)		(253)		(518)
Change in fair value of derivative liability				(236)		_		(556)
Realized gain on disposal of equipment				_		44		
Total other income (expenses)	\$	(102)	\$	(471)	\$	(185)	\$	(1,026)

12. License, Research and Collaboration Agreements

Collaboration Agreements

ABL Bio Agreements

In November 2018, the Company's wholly owned subsidiary TRIGR and ABL Bio ("ABL Bio") Corporation, a South Korean biotechnology company ("ABL Bio"), entered into exclusive global (excluding South Korea) license agreement (the "TRIGR License Agreement") which granted TRIGR a license to ABL001, ABL Bio's bispecific antibody targeting DLL4 and VEGF-A (renamed CTX-009). Under the terms of the agreement, ABL Bio and TRIGR would jointly develop CTX-009, with ABL Bio responsible for development of CTX-009 throughout the end of Phase 1 clinical trial and TRIGR responsible for the development of CTX-009 from Phase 2 and onward. ABL Bio received a \$5 million upfront payment and is eligible to receive up to \$405 million in development, regulatory and commercial milestone payments and tiered single-digit royalties on net sales of CTX-009 in Oncology, and ABL Bio is also eligible to receive up to \$185 million in development, regulatory and commercial milestone payments and tiered single-digit royalties on net sales of CTX-009 in Oncology, and ABL Bio is also eligible to receive up to \$185 million in development, regulatory and commercial milestone payments and tiered, single-digit royalties on net sales of CTX-009 in Ophthalmology. The financial terms of the agreement were amended in May 2021 but remain substantially similar to the terms in the TIRGR License Agreement. As a result of the TRIGR acquisition, the TRIGR License Agreement was assigned to the Company and the Company has assumed all the rights and liabilities of the agreement. See Note 9 for further information on the TRIGR transaction.

In May 2021, TRIGR and ABL Bio terminated license agreements to several preclinical assets. As a result of the return of these assets to ABL Bio and termination of the license agreements, the Company is eligible to receive royalties on potential royalty payments that ABL Bio is eligible to get from its future licensees to two bispecific antibodies ABL101 and ABL103 that were previously licensed to TRIGR.

Adimab Agreement

The Company entered into a collaboration agreement with Adimab, LLC on October 16, 2014. The agreement includes provisions for payment of royalties at rates ranging in the single digits as a percentage of future net sales within a specified term from the first commercial sale. There were no milestone payments made during the first six months of 2021. As of June 30, 2021, future potential milestone payments in connection with this agreement amounted to \$1.8 million.

Other License and Research Agreements

FUJIFILM Diosynth Biotechnologies Agreement

The Company entered into a scope of work ("SOW") under a master services agreement with FUJIFILM Diosynth Biotechnologies on July 20, 2020. The Company made cash payments of \$0.9 million and recorded \$0.2 million in research and development expense during the three months ended June 30, 2021. The Company made cash payments of \$1.2 million and recorded \$1.2 million in research and development expense during the six months ended June 30, 2021. As of June 30, 2021, future payments in connection with this SOW amounted to \$1.8 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of the financial condition and results of operations of Compass Therapeutics, Inc. should be read in conjunction with the financial statements and the notes to those statements included in this Quarterly Report on Form 10-Q for the period ended June 30, 2021. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risk, uncertainties and assumptions. You should read the "Risk Factors" section of this Quarterly Report on Form 10-Q and the "Risk Factors" section included in our <u>Annual Report on Form 10-K for the fiscal year ended December 31, 2020</u>, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases. Our scientific focus is on the relationship between angiogenesis and the immune system. Our pipeline includes novel product candidates that leverage our understanding of the tumor microenvironment, including both angiogenesis-targeted agents and immune-oncology focused agents. These product candidates are designed to optimize critical components required for an effective anti-tumor response to cancer. These include modulation of the microvasculature via angiogenesis-targeted agents; induction of a potent immune response via activators on effector cells in the tumor microenvironment; and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance. We plan to advance our product candidates through clinical development as both standalone therapies and in combination with our proprietary drug candidates as long as their continued development is supported by clinical and nonclinical data.

On June 25, 2021, the Company and Trigr Therapeutics, Inc. ("TRIGR"), a private biotechnology company, consummated a definitive merger agreement (the "Merger Agreement"). Pursuant to the Merger Agreement, the Company, through its wholly owned subsidiaries and a two-step merger structure, acquired all of the outstanding shares of TRIGR (the "Merger"). Consideration payable to TRIGR shareholders at closing totaled an aggregate of 10,265,133 shares of Compass' common stock (after giving effect to elimination of fractional shares that would otherwise be issued). In addition, TRIGR shareholders are eligible to receive up to \$9 million, representing earnout payments which are dependent on certain events, including \$5 million which is dependent on biologics license application approval of a product candidate acquired in the transaction, renamed CTX-009.

The Company currently has two product candidates in clinical development:

CTX-009 (formerly designated TR009/ABL001/NOV1501) is an anti-DLL4 x VEGF-A bispecific antibody, which has been added to the Company's pipeline via the acquisition of TRIGR. It is undergoing clinical development in patients with advanced solid tumors in South Korea. A Phase 1 dose escalation study and a Phase 1b dose expansion monotherapy study have been completed and a Phase 1b combination study is ongoing in South Korea. Data from CTX-009's Phase 1 dose escalation and dose expansion monotherapy study demonstrate an approximately 20% Overall Response Rate (ORR) at the targeted therapeutic doses, with confirmed partial responses per RECIST criteria in heavily pre-treated colorectal and gastric cancer patients in whom multiple therapies have failed, including VEGF-targeted therapeutics, anti-PD-1/PD-L1 regimens and chemotherapies. Interim results from the ongoing Phase 1b combination study testing the tolerability and activity of CTX-009 in combination with irinotecan or paclitaxel suggest that CTX-009 is well tolerated in combination with chemotherapy. As of May 31, 2021, there have been four partial responses in the Phase 1b study with an ORR of 23.5% and Clinical Benefit Rate (CBR) of 76%. The Phase 1b study enrollment is complete, and as of July 31, 2021, four patients remain in the study. In addition, a Phase 2a study in patients with cholangiocarcinoma has begun in South Korea, and patients are being screened and enrolled in the study. In contrast to historical anti-DLL4 antibodies, the administration of CTX-009 has not been associated with severe pulmonary hypertension. Full data from the ongoing Phase 1b studies are expected to be provided later in 2021.

CTX-471 is a monoclonal antibody agonist of CD137, a key co-stimulatory receptor on immune cells. In July 2019, we initiated a Phase 1 trial evaluating the safety and tolerability of CTX-471 as a monotherapy in oncology patients who were previously treated with PD-1 or PD-L1 immune checkpoint inhibitors and subsequently relapsed or progressed after a period of stable disease. The design of this trial includes a dose escalation stage (Phase 1a) followed by a dose expansion stage (Phase 1b). The dose escalation stage of the Phase 1 trial has been completed and CTX-471 was observed to be generally well-tolerated. The dose expansion stage of the trial is currently ongoing and, as of June 21, 2021, 18 patients have received at least one dose of CTX-471. Of the 18 patients treated so far, 15 patients have reached their first tumor evaluation at week 9, of which 9 had stable disease. Subsequently, one of those patients who has

advanced small cell lung cancer had a partial response at Week 17 and this response has been confirmed at week 25. As of June 21, 2021, there have been no treatment-related serious adverse events (SAEs) in the Phase 1b dose expansion stage of the trial. We expect to complete the Phase 1b stage of the trial during the first half of 2022. The next step for development of CTX-471 is the initiation of a Phase 1b combination study with a PD-1 or PD-L1 blocker in the first half of 2022.

In addition to our product candidates in clinical development, we have a bispecific antibody, **CTX-8371**, that simultaneously targets both PD-1 and PD-L1, the targets of well-known and widely used checkpoint inhibitor antibodies. IND-enabling studies with CTX-8371 were initiated in August 2020. We are targeting an IND submission for CTX-8371 in the second quarter of 2022.

We have funded our operations primarily with proceeds from the sale of our equity securities and borrowings from debt arrangements. Through June 30, 2021, we have received \$132.0 million in gross proceeds from the sale of equity securities, \$15.0 million in term loan borrowings under a credit facility with Pacific Western Bank, or the Credit Facility, and \$60.5 million in gross proceeds from the sale of our common stock in a private placement in June 2020.

We have incurred significant operating losses since inception and have not generated any revenue from the sale of products and we do not expect to generate any revenue from the sale of products in the near future, if at all. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our treatments and any future product candidates. Our net losses were \$55.8 million and \$5.6 million for the three months ended June 30, 2021 and 2020, respectively, and \$63.3 million and \$12.0 million for the six months ended June 30, 2021 and 2020, respectively. The losses for the three and six months ended June 30, 2021 include \$50.6 million of in-process R&D expense related to the TRIGR merger, which was a stock only transaction. We had an accumulated deficit of \$214.7 million at June 30, 2021. We expect to continue to incur significant expenses for at least the next several years as we advance through clinical development, develop additional product candidates and seek regulatory approval of any product candidates that complete clinical development. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity and debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. As of June 30, 2021, we had \$31.2 million in cash and cash equivalents. Based on our research and development plans, we expect that such cash resources will not enable us to fund our operating expenses and capital expenditure requirements for the next 12 months. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

COVID-19 Update

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business and have taken important steps to help ensure the safety of our employees and to reduce the spread of COVID-19 community-wide. We are ensuring that essential staffing levels at our operations remain in place, including maintaining key personnel in our laboratory facilities. We have implemented stringent safety measures designed to create a safe and clean environment for our employees as we continue to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic.

We have been able to continue to pursue patient dosing and monitoring of our Phase 1 clinical trial of CTX-471 without significant delays. However, over the last six months we have experienced increased delays in patient enrollment in several of our trial sites. In order to address the reduction in patient enrollment, we have recently added three new sites. In addition, there have been delays in sourcing of selected supplies required for the manufacturing of material to be used in our future clinical trials, and these delays may impact the timing of initiation of our future clinical trials We expect that COVID-19 may continue to directly or indirectly impact (i) our employees and business operations or personnel at third-party suppliers and other vendors in the U.S. and other countries; (ii) the availability, cost or supply of materials; and (iii) the timeline for our ongoing clinical trials and potential future trials. We are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials, as well as on our industry and the healthcare system.

Components of Results of Operations

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates, CTX-471 and CTX-8371, as well as unrelated discovery program expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and equity-based compensation expense, for employees engaged in research and development functions
- expenses incurred under agreements with organizations that support our platform program development
- Contract Manufacturing Organizations ("CMO") that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services
- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches
- costs related to compliance with quality and regulatory requirements
- facilities and equipment expenses

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of any future product candidates.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization.



In-Process R&D

In-process R&D expenses consists of the acquisition of Trigr Therapeutics, Inc., whose primary asset is CTX-009, an anti-DLL4 x VEGF-A bispecific antibody. As we expense research and development costs as incurred, the cost of this acquisition was expensed. See Note 9, to the financial statements contained in this Form 10-Q for further description of the accounting of this transaction.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and business development, and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our business operations.

Other expense, net

Other expense consists of interest expense, interest income and realized losses on sales of furniture and equipment.

Interest expense consists primarily of cash interest under our Credit Facility that we entered into in March 2018 and the related noncash interest attributable to the amortization of deferred financing costs incurred in connection with this facility.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020:

	т	hree M	onths Ended June 30	,	
	2021		2020		Change
	 		(000's)		
Operating expenses:					
Research and development	\$ 2,905	\$	2,985	\$	(80)
General and administrative	2,166		2,085		81
In-process R&D	50,618		_		50,618
Total operating expenses	 55,689		5,070		50,619
Loss from operations	 (55,689)		(5,070)		(50,619)
Other expense, net	(102)		(471)		369
Loss before income tax expense	 (55,791)		(5,541)		(50,250)
Income tax expense	(13)		(16)		3
Net loss	\$ (55,804)	\$	(5,557)	\$	(50,247)

Research and development expenses

Research and development expenses were flat for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The Company spent \$0.2 million less on early development programs for the three months ended June 30, 2021 than for the same period in 2020. The Company spent an additional \$0.3 million in clinical expense related to CTX-471 and \$0.3 million less in manufacturing expense related to CTX-8371 for the three months ended June 30, 2021 than for the same period in 2020.

We track outsourced development, outsourced personnel costs and other research and development costs of specific programs. In 2021, we began tracking our internal personnel costs on a program-by-program basis. Research and development expenses are summarized by program in the table below:

	Three Months Ended June 30,				
	2	021		2020	
		0's)			
CTX-471	\$	698	\$	954	
CTX-8371		284		33	
NKP30 cell engagement platform		10		_	
CTX-009		105		_	
Unallocated research and development expenses		1,808		1,998	
Total research and development expenses	\$	2,905	\$	2,985	

In-Process R&D

In-process R&D was \$50.6 million for the three months ended June 30, 2021 and consisted of costs related to the TRIGR acquisition. There were no in process R&D expenses in 2020. See Note 9 for further description.

General and Administrative Expenses

General and administrative expenses increased by \$0.1 million to \$2.2 million for the three months ended June 30, 2021 from \$2.1 million for the same period in 2020. Stock compensation increased by \$0.6 million, partially offset by lower personnel and facilities expenses.

Other Expense, Net

We recognized interest expense of \$0.1 million and \$0.2 million during the three months ended June 30, 2021 and 2020, respectively. The reduction in interest is from a lower outstanding loan balance.

Income Tax Expense

During the three months ended June 30, 2021 and 2020, we recognized income tax expenses of \$13 and \$16 thousand, respectively, which were primarily attributable to the services that Compass Advisors, Inc., our wholly-owned subsidiary, provided at cost plus a profit margin.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020:

2021		ths Ended June 30,		Change
 2021				Change
		(000's)		
\$ 7,609	\$	6,556	\$	1,053
4,798		4,345		453
50,618		—		50,618
 63,025		10,901		52,124
 (63,025)		(10,901)		(52,124)
(185)		(1,026)		841
 (63,210)		(11,927)		(51,283)
(13)		(32)		19
\$ (63,223)	\$	(11,959)	\$	(51,264)
\$	4,798 50,618 63,025 (63,025) (185) (63,210) (13)	\$ 7,609 \$ 4,798 50,618 63,025 (63,025) (185) (63,210) (13)	(000's) \$ 7,609 \$ 6,556 4,798 4,345 50,618 63,025 10,901 (63,025) (10,901) (185) (1,026) (63,210) (11,927) (13) (32)	$\begin{array}{ c c c c c c c }\hline & & & & & & & & & & & & & & & & & & &$

Research and development expenses

Research and development expenses increased by \$1.1 million from \$6.6 million for the six months ended June 30, 2020 to \$7.6 million for the six months ended June 30, 2021. The was primarily attributable to an increase in manufacturing costs related to CTX-8371 of \$0.9 million.

We track outsourced development, outsourced personnel costs and other research and development costs of specific programs. In 2021, we began tracking our internal personnel costs on a program-by-program basis. Research and development expenses are summarized by program in the table below:

	Six Months Ended June 30,				
	:	2021		2020	
		(00			
CTX-471	\$	1,696	\$	1,812	
CTX-8371		1,778		86	
NKP30 cell engagement platform		127		—	
CTX-009		105		_	
Unallocated research and development expenses		3,903		4,658	
Total research and development expenses	\$	7,609	\$	6,556	

In-process R&D

In-process R&D was \$50.6 million for the six months ended June 30, 2021 and consisted of costs related to the TRIGR acquisition. There were no in-process R&D expenses in 2020. See Note 9 for further description.

General and administrative expenses

General and administrative expenses increased by \$0.5 million to \$4.8 million for the six months ended June 30, 2021 from \$4.3 million for the same period in 2020. The increase was primarily attributable to the issuance of stock options in the second half of 2020 and first quarter of 2021, which resulted in increased stock compensation expense of \$1.5 million. This increase was partially offset by reduced personnel and facilities costs.

Other expense, net

We recognized interest expense of \$0.3 million and \$0.5 million during the six months ended June 30, 2021 and 2020, respectively. The reduction in interest is from a lower outstanding loan balance.

A fair value of the derivative related to the Credit Facility was increased by \$0.3 million as of June 30, 2020. Following our reverse merger with Compass Therapeutics LLC in June 2020, the derivative was settled.

Income tax expense

During the six months ended June 30, 2021, we recognized income tax expenses of \$13 thousand. During the six months ended June 30, 2020, we recognized income tax expenses of \$32 thousand.



Liquidity and Capital Resources

Since our inception, we have devoted substantially all of our efforts to organizing and staffing our Company, business planning, raising capital, research and development activities, building our intellectual property portfolio and providing general and administrative support for these operations. To date, we have funded our operations primarily with proceeds from the sale of our equity securities and borrowings from debt arrangements. Through June 30, 2021, we have received \$132.0 million in gross proceeds from the sale of equity securities and \$15.0 million in term loan borrowings under the Credit Facility. Following the completion of the Merger, we completed a private placement of our common stock and received gross proceeds of \$60.5 million. As of June 30, 2021, we had cash and cash equivalents of \$31.2 million.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- our ability to establish additional collaborations on favorable terms, if at all;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current stockholders' interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or 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 have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Going Concern

As of June 30, 2021, we had cash and cash equivalents of \$31.2 million. The Company has not generated any revenues from operations since inception and does not expect to do so in the foreseeable future. We have funded our operations primarily with proceeds from the sale of our equity securities and borrowings from debt arrangements. Through June 30, 2021, we have received \$132.0 million in gross proceeds from the sale of equity securities and \$15.0 million in term loan borrowings under the Credit Facility. Following the completion of the Merger, we completed a private placement of our common stock of \$60.5 million. Our cash balance is not sufficient to fund the Company's current operating plan for at least the next twelve months following the filing of this Quarterly Report. These factors raise substantial doubt about the Company's ability to continue as a going concern. We are exploring opportunities to secure additional funding through equity or debt financings or through collaborations, licensing transactions or other sources.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Six months Ended June 30,				
	2021			2020	
		(000)'s)		
Cash used in operating activities	\$	(11,544)	\$	(13,061)	
Cash provided by (used in) investing activities		(627)		39	
Cash provided by (used in) financing activities		(3,750)		53,090	
Net increase (decrease) in cash, cash equivalents and restricted cash	\$	(15,921)	\$	40,068	

Operating Activities

During the six months ended June 30, 2021, we used \$11.5 million of cash in operating activities, resulting from our net loss of \$63.3 million, offset by non-cash charges of \$53.3 million and the change in operating assets and liabilities of \$1.6 million. Our non-cash charges are from the TRIGR acquisition expense of in-process R&D of \$50.6 million, depreciation and amortization of \$0.3 million, share-based compensation expense of \$1.9 million, offset by \$44 thousand of gain on disposal of equipment.

During the six months ended June 30, 2020, we used \$13.1 million of cash in operating activities, resulting from our net loss of \$12.0 million and the change in operating assets and liabilities of \$3.0 million, offset by non-cash charges of \$1.9 million. Our non-cash charges were comprised of depreciation and amortization of \$0.9 million, share-based compensation expense of \$0.4 million, non-cash interest expense of \$50,000, and a change in fair value of our derivative liability of \$0.5 million. The change in our operating assets was primarily related to the settlement of a derivative liability and a decrease in our accounts payable and accrued expenses and due to the timing in which we pay our vendors.

Investing Activities

During the six months ended June 30, 2021, cash used in investing activities was \$0.6 million attributed to \$0.4 million in leasehold improvements and purchases of equipment and \$0.3 million for acquisition costs related to TRIGR, partially offset by the sale of property and equipment. During the six months ended June 30, 2020, cash provided by investing activities was \$39 thousand attributable to the sale of property and equipment.

Financing Activities

During the six months ended June 30, 2021, we had \$3.8 million in principal payments under the Credit Facility. During the six months ended June 30, 2020, we received cash of \$53.1 million from financing activities primarily from the closing of the private placement in June 2020 which resulted in net proceeds of \$55.0 million. This was partially offset by \$1.9 million in principal payments related to the 2018 Credit Facility.

Indebtedness

In March 2018, we entered into the Credit Facility with Pacific Western Bank which matures on March 1, 2022 and consists of \$15.0 million in term loans. The term loans bear interest at the greater of (i) 6.25% and (ii) the prime rate plus an applicable margin of 2.0%. As of June 30, 2021, the interest rate was 6.25%. We made interest-only payments through June 30, 2020, and beginning in April 2020, we began to make equal monthly principal payments of \$625 thousand. Payments are scheduled through March 2022. As of June 30, 2021, \$5.6 million was outstanding.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of clinical trials for our product candidate or any future product candidates we may develop;
- the initiation, progress, timing, costs and results of nonclinical studies for our product candidates or any future product candidates we may develop;
- our ability to maintain our relationships with key collaborators;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce 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 licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- the costs of continuing to grow our business, including hiring key personnel and maintain or acquiring operating space;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;



- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We will require additional funding to execute the current plans of the Company. The plans are to initiate at least one Phase 2 clinical trial of CTX-009, complete Part 2 of our ongoing Phase 1 clinical trial of CTX-471 and commence the planned Phase 1 development of CTX-8371, subject to satisfactory completion of IND-enabling activities for that product candidate. We expect that we will require additional funding to complete the clinical development of CTX-009, CTX-471 and CTX-8371, commercialize our product candidates, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for CTX-009, CTX-471 or CTX-8371 or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize ourselves.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes from the quantitative and qualitative disclosures about market risk previously disclosed in Item 7A of our <u>Annual Report on Form 10-K</u> for the fiscal year ended December 31, 2020.

Critical Accounting Policies and Significant Judgments and Estimates

See Note 2 of the financial statements included in this Quarterly Report on Form 10-Q for the period ended June 30, 2021 and Part II, Item 7 "Critical Accounting Policies and Significant Judgements and Estimates" in our <u>Annual Report on Form 10-K for the fiscal year ended</u> <u>December 31, 2020</u> for our critical accounting policies and estimates.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of June 30, 2021. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that occurred during the quarter ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

As of the date of this Quarterly Report on Form 10-Q, we are not involved in any material legal proceedings. However, from time to time, we could be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, Item 1A "Risk Factors" in our <u>Annual Report on Form 10-K for the fiscal year ended December 31, 2020</u>, which could materially affect our business, financial condition, or results of operations.

Additional risk factors from the <u>Annual Report on Form 10-K</u> are as follows:

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

Based on our current operating plans, we do not have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. We have incurred significant losses since inception and expect to incur significant and increasing losses for at least the next several years. We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, could force us to delay or reduce our product development and clinical trials.

We may experience increased costs, disruptions or other difficulties with the integration of TRIGR.

On June 25, 2021, we consummated the acquisition of all outstanding shares of TRIGR Therapeutics, Inc., or TRIGR. As a result of this acquisition, we also acquired certain assets of TRIGR, including CTX-009 (formerly designated TR009/ABL001/NOV1501), an anti-DLL4 x VEGF-A bispecific antibody that is undergoing clinical development in patients with advanced solid tumors in South Korea. A Phase 1 dose escalation study and a Phase 1b dose expansion monotherapy study have been completed, and a Phase 1b combination study is ongoing. We plan to file an IND in the United States and continue the development of this product candidate across multiple indications. While we have invested, and continue to invest, significant resources in due diligence, planning and integration of TRIGR, it is possible that significant issues and potential unknown liabilities may arise during the course of the integration and ongoing development of CTX-009, which may result in increased costs, delays in the initiation of clinical trials and other difficulties that are not presently contemplated.

We have not historically developed the product candidate we acquired in our recent acquisition of TRIGR and are relying on TRIGR's prior research to advance this product candidate and intellectual property obtained by TRIGR.

The product candidate that was acquired in the TRIGR acquisition, CTX-009, was initially developed by TRIGR and its licensor ABL Bio. We have not yet demonstrated an ability to develop, advance, or run clinical trials with this product candidate. In addition, our intellectual property rights covering the product candidate that was acquired in the TRIGR acquisition, CTX-009, were developed by TRIGR and its licensor, ABL Bio. We were not responsible for obtaining, maintaining or enforcing such intellectual property rights and we are relying on the previous work of TRIGR and its licensor to have adequately protected such intellectual property. We are relying on TRIGR's previous work to continue our development of this product candidate. As a result, we cannot ensure that we will be able to successfully advance this product candidate going forward or that the intellectual property rights were protected at a level comparable to our previously disclosed intellectual property.

Certain of our clinical trials are conducted in overseas jurisdictions, which may subject us to delays and expenses.



We are conducting certain clinical trials in overseas jurisdictions. For example, clinical trials for CTX-009 are currently being conducted in South Korea. Regulators in the United States, such as the FDA, or in other foreign jurisdictions, may not support our trial design and protocol, which would delay our clinical development plans and increase our expenses.

In addition, there are risks inherent in conducting clinical trials in overseas jurisdictions, which may subject us to delays and expenses, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct clinical trials;
- differing and conflicting regulatory requirements;
- foreign exchange fluctuations;
- manufacturing, customs, shipment, and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

The following risk factors from the <u>Annual Report on Form 10-K</u> have been modified:

We have a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our founding in 2014, we have incurred significant net losses. Our net losses were \$29.5 million and \$34.7 million for the years ended December 31, 2020 and 2019, respectively, and as of December 31, 2020 and June 30, 2021, we had an accumulated deficit of \$151.4 million and \$214.7 million, respectively. In addition, as of December 31, 2020 and June 30, 2021, we had stockholders' equity of \$39.9 million and \$28.9 million, respectively. We have funded our operations to date primarily with proceeds from private placements of preferred and common equity and borrowings under the 2018 loan and security agreement with Pacific Western Bank, or the 2018 Credit Facility. Since commencing operations, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, identifying business development opportunities, raising capital, securing intellectual property rights related to our product candidates, conducting discovery, and research and development activities for our product candidates.

We expect that it will be several years, if ever, before we have a commercialized product. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance the preclinical and clinical development of our existing product candidates and our research programs;
- leverage our research and development capabilities, including our proprietary StitchMabs TM technology, to advance additional product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, regulatory, scientific and administrative personnel;
- expand our operational, financial and management systems and increase personnel, including to support our clinical development and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;

- establish a marketing, sales, distribution and medical affairs infrastructure to commercialize any products for which we may obtain marketing approval and commercialize, whether on our own or jointly with a partner;
- acquire or in-license other technologies or engage in strategic partnerships; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our existing or future collaborators', success in:

- completing preclinical studies and clinical trials of our product candidates, including our ongoing and planned clinical trials of CTX-009, CTX-471 and CTX-8371;
- seeking and obtaining marketing approvals for any product candidates that we or our collaborators develop;
- identifying and developing new product candidates;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a marketing, sales, distribution and medical affairs infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving coverage and adequate reimbursement by hospitals and third-party payors, including governmental authorities, such as Medicare and Medicaid, private insurers and managed care organizations, for product candidates, if approved, that we or our collaborators develop;
- obtaining market acceptance of product candidates, if approved, that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and knowhow;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.



We anticipate incurring significant costs associated with commercializing any product candidate that is approved for commercial sale. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials for the development of any of our product candidates, for example, as a result of any setbacks or delays due to the COVID-19 pandemic. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we receive marketing approval for any product candidates, we will require significant additional amounts of cash in order to launch and commercialize such product candidates. In addition, other unanticipated costs may arise. Because the designs and outcomes of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of and commercialize any product candidate we develop. Additionally, any COVID-19 related program setbacks or delays due to changes in federal, state, or local laws and regulations or clinical site policies could impact our programs and increase our expenditures. Our future capital requirements depend on many factors, including:

- the scope, progress, timing, results and costs of researching and developing CTX-009, CTX-471, CTX-8371 and our other product candidates, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approval for CTX-009, CTX-471, CTX-8371 and any future product candidates we develop, if clinical trials are successful;
- the costs of manufacturing CTX-009, CTX-471, CTX-8371 and any future product candidates for preclinical studies and clinical trials and in preparation for marketing approval and commercialization;
- the impact of COVID-19 on the initiation or completion of preclinical studies or clinical trials, the third-parties on whom we rely, and the supply of our product candidates;
- the costs of commercialization activities, including marketing, sales and distribution costs, for CTX 009, CTX-471, CTX-8371 and any future product candidates we develop, whether alone or with a collaborator, if any of these product candidates are approved for sale;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements on favorable terms, if at all;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of any such litigation;
- our current collaboration and license agreements remaining in effect and our achievement of milestones and the timing and amount of milestone payments we are required to make, or that we may be eligible to receive, under those agreements;
- the timing, receipt and amount of sales of, on our future products, if any; and
- the emergence of competing therapies and other adverse developments in the oncology and immunology market.

Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity and debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. As of June 30, 2021, we had cash and cash equivalents of \$31.2 million. Based on our research and development plans, we expect that these



cash resources will not enable us to fund our operating expenses and capital expenditure requirements over the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in, and progress of, our development activities, acquisitions of additional product candidates and changes in regulation.

If we raise additional capital through marketing, sales and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, future revenue streams or research programs, technologies or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through additional sales of common stock or securities convertible or exchangeable into common stock, investors' ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain additional financing on favorable terms when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, or other research and development activities or one or more of our development programs.

Risks related to the discovery and development of our product candidates

Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval and ultimately commercialize them.

We are early in our development efforts. We will be conducting our first clinical trials since acquiring CTX-009, currently our lead product candidate, and are currently conducting clinical trials for CTX-471. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of CTX-009, CTX-471, CTX-8371 and any other current or future product candidates we develop, which may never occur. Our current product candidates, including CTX-009, CTX-471, CTX-8371 and any future product candidates we develop will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstration of effectiveness to pricing and reimbursement authorities, sufficient cGMP manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The clinical and commercial success of our current and future product candidates will depend on several factors, including the following:

- timely and successful completion of preclinical studies and our clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- Our plans to successfully submit investigational new drug, or IND, applications with the FDA for CTX-009, CTX-8371 and/or other current and future product candidates;
- our ability to complete preclinical studies for current or future product candidates;
- successful enrollment in, including maintaining or reaching target enrollment levels during the COVID-19 pandemic, and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- our ability to establish agreements with third-party manufacturers on a timely and cost-efficient manner;



- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities;
- receipt and maintenance of timely marketing approvals from applicable regulatory authorities;
- successfully launching commercial sales of our product candidates, if approved;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval;
- our compliance with any post-approval requirements imposed on our products, such as post-marketing studies, a Risk Evaluation and Mitigation Strategy, or REMS, or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost prohibitive;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- our ability to identify bispecifics; and
- enforcing and defending intellectual property rights and claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that CTX-009, CTX-471, CTX-8371 or any other current or future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. Although certain trials (or portions thereof) of CTX-009 and CTX-471 have been completed, we may experience delays in completing any planned clinical trials and development efforts. Additionally, we

cannot be certain the ongoing and planned preclinical studies or clinical trials for CTX-009, CTX-471, CTX-8371 or any other future product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- results from preclinical studies or clinical trials may not be predictive of results from later clinical trials of any product candidate;
- the FDA or other regulatory authorities, Institutional Review Boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or may produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product candidate development programs;
- the number of patients required for clinical trials may be larger than we anticipate, or we may have difficulty in recruiting and enrolling patients to participate in clinical trials, including as a result of the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications and clinical trial subjects;
- enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or may fail to return for post-treatment follow-up at a higher rate than we anticipate. For example, we have experienced some challenges in the enrollment of patients into our ongoing Phase 1 clinical trial of CTX-471, and there can be no assurance that we will not encounter similar challenges in the future for this trial or other trials;
- our CROs and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- any of our product candidates could cause undesirable side effects that could result in significant negative consequences, including the inability to enter clinical development or receive regulatory approval;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates;



- the supply, quality or timeliness of delivery of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- we may need to change the manufacturing site and potentially the CMO for our product candidates from those that are able to produce clinical supply for our Phase 1 clinical trials to those with the capacity and ability to perform commercial manufacturing and/or the production of clinical material for our later stage clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, or by the IRBs of the institutions in which such trials are being conducted, ethics committees or the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. The FDA or other regulatory authorities may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials. For example, we are conducting and may in the future conduct additional "open-label" clinical trials. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Openlabel clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, including as a result of the COVID-19 pandemic, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates.

Any such events would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates stopping early.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.



With the exception of CTX-009, which is undergoing clinical trials in South Korea, and CTX-471, which is currently being tested in a Phase 1 clinical trial, all of our product candidates are still in the discovery or preclinical stage, and the risk of failure for such product candidates is high. In addition, any one or more of our product candidates that have not yet entered the clinic may never advance into clinical development. For instance, in early 2021, we conducted a review of our pipeline and made the strategic decision to deprioritize the development efforts for our NKp30 innate cell engager platform and to refrain from advancing CTX-8573 to IND-enabling studies. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity and potency, including efficacy, in humans. To meet these requirements we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to:

- an inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- any setbacks or delays on account of the COVID-19 pandemic; and
- the FDA or foreign regulatory authorities not permitting the reliance on preclinical or other data from published scientific literature.

Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication, and failures can occur at any stage of testing. As with most biological products, use of our current or future product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. There have been serious adverse side effects reported in response to antibody therapeutics and bispecifics in oncology.

Immuno-oncology drugs have been observed to cause side effects, generally related to over activation of the immune system. These include colitis, diabetes, pituitary inflammation, thyroiditis, myocarditis, liver inflammation, thrombocytopenia, among others. Our immuno-oncology product candidates, including CTX-471, may have similar or additional side effects. We completed the Phase 1a stage of the clinical trial evaluating the safety and tolerability of CTX-471 in mid-2020. In this study, all of the 19 patients enrolled received at least one dose of CTX-471. There were two treatment-related serious adverse events reported that included hypoxia, which resolved, and thrombocytopenia purpura, which also resolved. Two dose-limiting toxicities of immune-related thrombocytopenia were also reported. The second stage (Phase 1b) of our CTX-471 Phase 1 trial is currently ongoing.

As of June 21 2021, 18 patients in the Phase 1b stage had received at least one dose of CTX-471. As of June 21 2021, no severe treatmentrelated emergent side effects have been reported in the Phase 1b stage; however, severe treatment related side effects may emerge at a later time in the study. In addition to any potential side effects caused by the product or product candidate, the administration process or related procedures also can cause adverse side effects. If



unacceptable adverse events occur, our clinical trials or any future marketing authorization could be suspended or terminated.

We are developing CTX-8371 as a potential bispecific antibody that simultaneously targets both PD-1 and PD-L1, the targets of well-known and widely used checkpoint inhibitor antibodies. While we have observed so far in preclinical testing that simultaneous targeting of both PD-1 and PD-L1 has been associated with less toxicity than targeting either PD-1 alone or PD-L1 alone, there can be no assurance that CTX-8371 will not demonstrate unacceptable toxicities in later testing that may render it unsafe or intolerable.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Antibody therapeutics and bispecifics and their method of action of harnessing the body's immune system are powerful and could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that CTX-009, CTX-471, CTX-8371 or any other product candidate is safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed.

In addition, we intend to pursue CTX-009 and CTX-471 in part in combination with other therapies and may develop CTX-8371 and future product candidates in combination with other therapies, which exposes us to additional risks relating to undesirable side effects or other properties. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. The other therapies we are using in combination may be removed from the market, or we may not be able to secure adequate quantities of such materials for which we have no guaranteed supply contract, and thus be unavailable for testing or commercial use with any of our approved products. The other therapies we may use in combination with our product candidates may also be supplanted in the market by newer, safer or more efficacious products or combinations of products.

Even if we successfully advance one of our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trial may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

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

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;



- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues, which would materially harm our business. In addition, if one or more of our product candidates or our antibody therapeutic development approach generally prove to be unsafe, our entire technology platform and pipeline could be affected, which would also materially harm our business.

As an organization, we have limited experience designing and implementing clinical trials and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. We also expect to continue to rely on third parties to conduct our clinical trials.

See "—Risks Related to Reliance on Third Parties—We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for CTX-009, CTX-471, CTX-8371 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize CTX-009, CTX-471, CTX-8371 and any current or future product candidates we develop and our business could be materially harmed."

Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for BLA submission and FDA approval of CTX-009, CTX-471, CTX-8371 or current or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop.

Because the number of subjects in our Phase 1 clinical trial of CTX-471 is small, the results from this trial, once completed, may be less reliable than results achieved in larger clinical trials.

Nineteen patients were enrolled in our Phase 1a dose escalation stage of the trial and as of June 21 2021, 18 patients have received at least one dose of CTX-471 in the Phase 1b dose expansion stage of the trial. A study design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of studies with smaller sample sizes and heterogeneous patient populations, such as our ongoing Phase 1 clinical trial of CTX-471, can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects and with more homogeneous patient populations. As a result, there may be less certainty that CTX-471 would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of CTX-471, we may not achieve a statistically significant result or the same level of statistical significance seen, if any, in our Phase 1 clinical trial. Similarly, if we conduct a clinical trial of any other product candidate we develop, including CTX-471, with a



smaller sample size, the results of any such trial may be less reliable than results achieved in larger clinical trials and may provide less certainty of achieving statistically significant effects in any future clinical trials.

We have chosen to prioritize development of CTX-009, CTX-471 and CTX-8371. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on other candidates or indications for which there may be a greater likelihood of success or may be more profitable.

Because we have limited resources, we have strategically determined to prioritize development of CTX-009, CTX-471 and CTX-8371 rather than other product candidates. This decision is based, in part, on the significant resources required for developing and manufacturing antibody therapeutics and bispecifics. To date, no regulatory authority has granted approval for an antibody therapeutic targeting CD137, also known as 4-1BB, as well as the target of CTX-471. Of note, several drugs targeting CD137 have been tested in early-stage clinical trials, and at least one of these drugs had severe side effects. It is possible that CTX-471 may have similar adverse effects, including toxicity, in humans. As a result, we may be foregoing other potentially more profitable antibody therapies or drugs with a greater likelihood of success. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities.

Similarly, our potential decisions to delay, terminate or collaborate with third parties with respect to certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our current or future product candidates or misread trends in the oncology, autoimmunology or biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

Risks related to regulatory approval of our product candidates

Regulatory agencies may not agree with the design of our clinical development programs for one or more of our product candidates that we intend to utilize to support an expedited development process.

We intend to pursue an accelerated approval pathway for one or more of our product candidates, such as CTX-009, where we believe our proposed adaptive design of our clinical development program for this product candidate could support expedited development. However, we have not yet reached any agreement with the FDA or comparable foreign regulatory authorities on the availability of such a strategy, nor have we initiated discussions to seek such agencies' feedback on such pathway. There can be no assurance that we will be successful in reaching alignment with regulatory authorities with the effect and purpose of shortening the development path for any of our product candidates.

We intend to develop CTX-009 and CTX-471 in part in combination with other therapies and may develop CTX-8371 and future product candidates in combination with other therapies, which exposes us to additional regulatory risks.

We intend to develop CTX-009 in combination with other therapies, such as chemotherapy, and CTX-471 in part in combination with other therapies, such as trastuzumab, and may develop CTX-8371 and future product candidates in combination with one or more currently approved cancer therapies. These combinations have not been previously tested in the clinic and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

In addition, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any of these approved therapeutics. Therefore, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination



therapies are commonly used for the treatment of cancer diseases, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer.

We may also evaluate CTX-009, CTX-471, CTX-8371 or any future product candidate in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell CTX-009, CTX-471, CTX-8371 or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve these other biological products or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biological products we choose to evaluate in combination with CTX-009, CTX-471, CTX-8371 or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

Risks related to the commercialization of our product candidates

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. The number of patients who receive second- and third-line treatment is significantly smaller than the number of patients who receive first-line treatment, and the prognosis of patients who receive second- or third-line treatment is often poorer than that of patients who receive first-line treatment.

We may initially seek approval for CTX-009, CTX-471, CTX-8371 and any other product candidates we develop as second- or third-line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the types of cancer or autoimmune diseases we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

If we are unable to establish marketing, sales and distribution capabilities for CTX-009, CTX-471, CTX-8371 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for CTX-009, CTX-471, CTX-8371 and any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own marketing, sales and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:



- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own marketing, sales and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish marketing, sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks related to healthcare, insurance and legal matters

Enacted healthcare legislation, changes in healthcare law and implementation of regulations, as well as changes in healthcare policy, may increase the difficulty and cost for us to commercialize our product candidates, may impact our business in ways that we cannot currently predict, could affect the prices we may set, and could have a material adverse effect on our business and financial condition.

In the United States and in some foreign jurisdictions, there have been and likely will continue to be a number of legislative and regulatory changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, expands the types of entities eligible for the 340B drug discount program, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must now agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the previous Trump Administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. Also, in December 2018, the Centers for Medicare and Medicaid Services, or CMS, issued a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit



reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional congressional action is taken. However, the Medicare sequester reductions under the BCA will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the BBA, among other things, amended the ACA, effective January 1, 2019, to increase the point-of-sale discount (from 50% under the ACA to 70%) that is owed by pharmaceutical manufacturers who participate in Medicare Part D and, closed the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, at the federal level, the previous Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the previous Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the previous Trump Administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. HHS has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other proposed measures may require additional authorization to become effective, Congress has indicated that they will continue to seek new legislative and/or administrative measures to control drug costs.

On July 24, 2020 and September 13, 2020, then-President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. On December 28, 2020, a judge in the U.S. District Court for the Northern District of California granted a preliminary injunction prohibiting CMS from implementing the MFN rule. On August 6, 2021, CMS released a proposed rule that would rescind the MFN rule, although the timing of its adoption remains uncertain as of the date hereof.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that the federal and state governments will pay for healthcare products and services. This could result in reduced demand for any product candidate or complementary or companion diagnostics we develop or could result in additional pricing pressures.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Risks related to manufacturing of our product candidates

The loss of our third-party manufacturing partners or our, or our partners', failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We have contracted with qualified third-party contract manufacturing organizations, or CMOs, to manufacture our product candidates for preclinical and clinical trials. If approved, commercial supply of CTX-009, CTX-471, CTX-8371 and any future product candidates may also be manufactured at one or more CMOs.

The facilities used by our CMOs to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process at our CMOs, and are completely dependent on them for compliance with current regulatory requirements. If we or our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments or on account of global pandemics or similar events, including the COVID-19 pandemic. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Therefore, we will likely need to change our CMOs for manufacturing of any product candidates that advance to later-stage trials to those that can support commercial-scale manufacturing. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing antibody therapeutics and bispecifics, including our product candidates, is complex, time-consuming, highly regulated and subject to several risks, including:



- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- we will likely need to change our CMOs for manufacturing of any product candidates that advance to later-stage trials to those that can support large-scale manufacturing for later stage clinical trials as well as commercial supply needs;
- we will likely need to conduct additional work on chemistry, manufacturing and controls, or CMC, in relation to the production of the cell line for CTX-009 to support later-stage clinical trials and to meet commercial supply needs;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We have experienced, and may in the future experience challenges with our third party manufacturers that could have an adverse impact on the development of our product candidates. For example, the expected timing of submission of our IND for our product candidate CTX-8371 was shifted to mid-2022 due to delays at our outside manufacturer for that candidate.

We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Risks related to intellectual property

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, resulting in termination of our access to such intellectual property or increase our financial or other obligations to our licensors.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. Such licenses include those with ABL Bio Inc. with respect to our CTX-009 product candidate and with Adimab, LLC, with respect to our CTX-471 product candidate. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, or we otherwise are unable to maintain our licenses for our product candidates, we may be unable to successfully develop and commercialize the affected product candidates.

Risks related to our work with third parties



We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for CTX-009, CTX-471, CTX-8371 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize CTX-009, CTX-471, CTX-8371 and any current or future product candidates we develop and our business could be materially harmed.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as current good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, including cGCP, or requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and cGCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our cGCP-compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our current or future product candidates. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and cGCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. Further, under certain circumstances, these third parties may unilaterally terminate their agreements with us. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, including on account of the COVID-19 pandemic, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLP and cGCP, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Risks related to our business

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, marketing, sales, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for CTX-009, CTX-471, CTX-8371 and any other current or future product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize CTX-009, CTX-471, CTX-8371 and any current or future product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize CTX-009, CTX-471, CTX-8371 and any current or future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	
10.1*	Research and Development Collaboration and License Agreement, dated November 30, 2018, between TRIGR Therapeutics, Inc. and ABL Bio Inc.	
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	
32.1**	Certification of Principal 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**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	
101.INS	Inline XBRL Instance Document – the instance document does not appear in Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document	
101.SCH	Inline XBRL Taxonomy Extension Schema Document	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

^{**} These exhibits are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act or the Exchange Act, except as otherwise stated in such filing.



SIGNATURES

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

	Company	/ Name
Date: August 16, 2021	By:	/s/ Thomas Schuetz
		Thomas Schuetz, MD
		Co-Founder and Chief Executive Officer
Date: August 16, 2021	By:	/s/ Vered Bisker-Leib
		Vered Bisker-Leib, PhD
		President and Chief Operating Officer
Date: August 16, 2021	By:	/s/ Neil Lerner
		Neil Lerner, CPA
		Vice President - Finance

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

RESEARCH AND DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT – ABL 001

THIS RESEARCH AND DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT-ABL 001 (including the schedules and appendix hereto, this "Agreement"), effective as of November 30, 2018 (the "Effective Date"), is between:

TRIGR Therapeutics Inc., a company organized and existing under the laws of Delaware, USA, with a principal place of business at 53 Carrington, Irvine CA 92620, USA ("**TRIGR**"); and

ABL Bio Inc., a company organized and existing under the laws of the Republic of Korea, with a principal place of business at 2nd Floor, 16 Daewangpangyo-ro 712 Beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do 13488, Republic of Korea (**"ABL"**).

TRIGR and ABL are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, TRIGR is a biotechnology company focused on the development and commercialization of antibodies and other therapeutic products;

WHEREAS, ABL is a pharmaceutical company engaged in the research and development of products useful in the treatment or prevention of human diseases and conditions;

WHEREAS, TRIGR and ABL wish to collaborate in the development and commercialization of the Product (hereinafter defined) as contemplated herein; and

WHEREAS, TRIGR and ABL desire to work together, calling on their respective areas of expertise, in order to effectuate the foregoing under the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1-DEFINITIONS

For purposes of this Agreement, the following capitalized terms, whether used in the singular or plural, shall have the following meanings:

1.1 "ABL Data" means reports, records, data and other information that are Controlled by ABL and/or its Affiliates, as of the Effective Date or at any other time during the Term, and which result from the Research Program or are otherwise necessary or useful in Exploiting the Product.

1.2 "ABL Indemnitee" has the meaning set forth in Section 12.1.

1.3 "ABL Intellectual Property" means, collectively, ABL Know-How and ABL Patents, and ABL's rights in any Joint Intellectual Property.

1.4 "ABL Know-How" means Information and Inventions Controlled by ABL and/or its Affiliates as of the Effective Date or during the Ten n, arising under the Research Program or otherwise necessary or useful in Exploiting the Product, including without limitation, ABL Data. The ABL Know-How excludes any Information contained within an ABL Patent.

1.5 "ABL Materials" means all inventory of the Product in any form and all other materials necessary for the Exploitation of the Product discovered or developed in the Research Program.

1.6 "ABL Patents" means (a) the Antibody-Specific Patents, (b) the Background Patents and (c) ABL's interest in any Joint Patents, in each of cases (a) - (c) on or after the Effective Date. The ABL Patents as of the Effective Date are set forth on Schedule 1, which will be updated from time to time by ABL.

1.7 "Affiliate" means, with respect to any entity, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such entity. For this purpose, "control" means the ownership of more than fifty percent (50%) of the voting securities entitled to elect the directors or management of the entity, or the actual power to elect or direct the management or policies of the entity, whether by law, contract or otherwise. In any country where the local law does not permit foreign equity participation of more than fifty percent (50%), then an "Affiliate" includes any company in which an entity owns or controls or is owned or controlled by, directly or indirectly, the maximum percentage of outstanding stock or voting rights permitted by local law.

1.8 "Antibody-Specific Patents" means the composition of matter and method of use Patents for the Product.

1.9 "Applicable Law" means all statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority applicable to the Parties' performance of their activities under this Agreement, all as amended from time to time, together with any associated rules, regulations, and compliance guidance promulgated thereunder.

1.10 **"Background Patents"** means any Patents on the Effective Date or at any time during the Term (other than Joint Patents) that claim or cover the making, having made, using, selling, offering for sale and/or importing of the Product or are otherwise necessary or useful in Exploiting the Product. For clarity, the Antibody-Specific Patents shall be excluded from Background Patents.

1.11 **"BLA"** means a biologics license application required to be submitted to and approved by the FDA to obtain authorization to manufacture the Product for commercialization in the United States pursuant to section 351 of the Public Health Service Act and 21 CFR § 601.2.

1.12 "C.F.R" means the U.S. Code of Federal Regulations.

1.13 "Claim" has the meaning set forth in Section 12.1.

1.14 **"Commercialization" or "Commercialize"** means any and all activities directed to the offering for sale and sale of the Product, including, (i) activities directed to marketing, promoting, detailing, distributing, manufacturing, importing, selling and offering to sell such Product, (ii) interacting with regulatory authorities regarding any of the foregoing and (iii) seeking pricing approvals and reimbursement approvals for such Product. When used as a verb, "Commercialize" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

1.15 **"Confidential Information"** means all non-public or proprietary Information disclosed by a Party to the other Party under this Agreement, without regard as to whether any of such Information is marked " confidential " or " proprietary," or disclosed in oral, written, graphic, or electronic form. Confidential Information shall include the terms and conditions of this Agreement.

1.16 **"Control**" means, with respect to any Information, Patent, trademark or other intellectual property right, ownership or possession by a Party, or, where expressly provided, its Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense thereto without violating the terms of any agreement or other arrangement with, or necessitating the consent of or any additional payment to, any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license or sublicense.

1.17 "Disclosing Party" has the meaning set forth in Section 9.1.

1.18 "Dispute" has the meaning set forth in Section 11.2.

1.19 **"Exploit" or "Exploitation"** means to research, make, have made, import, export, distribute, use, have used, sell, have sold, or offer for sale, including to develop, manufacture, commercialize, register, modify, enhance, improve or otherwise dispose of. **"FDA"** means the U.S. Food and Drug Administration.

1.20 **"First Commercial Sale"** means the first sale, transfer or disposition for value of a Product by or on behalf of TRIGR or any of its Affiliates or sublicensees in a country to a Third Party in the Territory, where Regulatory Approval (including pricing approval) of the Product has been obtained. For the avoidance of doubt, First Commercial Sale does not include any transfer or disposition of any Product for use in a clinical trial or other development activity, for promotional use (including samples) or to any named patients or for compassionate use purposes in the Territory.

1.21 **"Force Majeure"** means any event beyond the reasonable control of the affected Party including, but not limited to, embargoes; war or acts of war, including terrorism; insurrections, riots, or civil unrest; strikes, lockouts or other labor disturbances; epidemics, fire, floods, earthquakes or other acts of nature; and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances).



1.22 "Governmental Authority" means any multi-national, federal, state, local. municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.23 **"IND"** means an investigational new drug application required to be submitted to the FDA prior to commencing any clinical studies necessary to demonstrate safety and efficacy of a new drug or new biological drug pursuant to 21 CFR Part 312.

1.24 "indemnitee" means an ABL Indemnitee or TRIGR Indemnitee, as the context may require.

1.25 **"Information"** means information, inventions, concepts, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, techniques, designs , drawings, correspondence, computer programs, documents, apparatus, results, strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Governmental Authority or patent office, data, including pharmacological, toxicological, non- clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, patent and *legal* data, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed , whether or not patentable.

1.26 "Inventions" means any and all inventions, discoveries and developments, whether or not patentable, made, conceived and/or reduced to practice in the course of performance of this Agreement whether made, conceived and/or reduced to practice solely by, or on behalf of TRIGR, ABL, the Parties jointly, or any Affiliate of the same.

1.27 "Joint Intellectual Property" means, collectively, Joint Know-How and Joint Patents.

1.28 "Joint Inventions" has the meaning set forth in Section 7.1(b).

1.29 "Joint Know-How" means all Information and Inventions jointly created by TRIGR or its Affiliates and ABL or any of its Affiliates under this Agreement and during the Term arising under the Research Program or otherwise necessary or useful to Exploit the Product. Joint Know-How excludes any Information or Inventions contained within a Joint Patent.

1.30 "Joint Patents" means all Patents covering or claiming any invention that is a Joint Invention necessary or useful for Exploitation of any Product.

1.31 **"Korean Government Program"** means the clinical research program for the Product currently being conducted by National OncoVenture and/or other government agencies in South Korea in conjunction with ABL, as amended from time to time.

1.32 "Losses" has the meaning set forth in Section 12.1.

1.33 "Net Sales" means the gross amount received by TRIGR, its Affiliates, and their sublicensees on account of sales of Product to Third Parties in the Territory, less the following

deductions to the extent not separately invoiced, to and paid by, the Third Party: (i) sales and excise taxes and duties paid or allowed by the selling party and any other governmental charges imposed upon the production, importation, use or sale of such Product; (ii) customary trade, quantity and cash discounts allowed on Product; (iii) allowances or credits to customers on account of rejection or return of Product or on account of retroactive price reductions affecting such Product; (iv) freight and insurance costs; (v) rebates, chargebacks and other amounts paid on sale or dispensing of Product;

(vi) the book cost of devices or systems used for delivering Product into the patient where Product when sold is a combination of the active pharmaceutical ingredient and the device or system; and (vii) bad debt, all as incurred by TRIGR, its Affiliates, and their sublicense es in the ordinary course of business in type and amount consistent with good industry practice and determined in accordance with generally accepted accounting principles consistently applied. For the avoidance of doubt, for each Product the Net Sales shall be calculated only once for the first sale of such Product by TRIGR, its Affiliates and their sublicensees, as the case may be, to a Third Party which is neither an Affiliate or sublicensee of TRIGR. A sale of Products by TRIGR, its Affiliate or their sublicensees to a wholesaler or distributor shall be regarded as the first sale of Product to the patient in which case the first sale shall be the sale to such hospital, pharmacy, physician, retailer or other entity. Net Sales of Product or of sales of Product or of sales of Product in a particular country for which the obligation to pay royalties has expired on or before the date of such sales. Net Sales of Products constituting combination products shall be calculated based on the ratio of the market values of the individual products included in such combination products.

1.34 **"Oncology Product"** means the Product used for indications in the field of oncology. The Oncology Product excludes the Ophthalmology Product.

1.35 **"Ophthalmology Product"** means the Product used for indications in the field of ophthalmology. The Ophthalmology Product excludes the Oncology Product.

1.36 **"Patents"** means all: (a) patents, including any utility or design patent; (b) patent applications, including provisionals, substitutions, divisionals, continuations, continuations in- part or renewals; (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (d) other patents or patent applications claiming priority directly or indirectly to (i) any such specified patent or patent application specified in (a) through (c), or (ii) any patent or patent application from which a patent or patent application specified in (a) through (c) claim direct or indirect priority; (e) inventor's certificates; (f) other rights issued from a Governmental Authority similar to any of the foregoing specified in (a) through (e); and (g) in each of (a) through (f), only if such patent, patent application or other right arises in the Territory.

1.37 **"Person"** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

I.38 "Phase I" means the first clinical investigations in which the Product is first introduced into humans in compliance with applicable regulatory requirements for the principal purpose

of gathering data to make a preliminary determination of safety, tolerability, pharmacokinetics, and pharmacological effects in healthy individuals or patients such as the clinical studies described in 21 C.F.R. § 312.21(a). Phase I includes both Phase Ia and Phase Ib and is the first of three phases conducted to gather data and information to determine whether the Product would meet the criteria for marketing authorization.

1.39 **"Phase II"** means the second phase of clinical investigations, which are conducted after preliminary safety data are obtained from a Phase I studies, to evaluate the effectiveness and safety of the Product and to obtain sufficient data and information to support the design and conduct of one or more Phase III clinical studies, in compliance with applicable regulatory requirements, such as the clinical studies described in 21 C.F.R. § 312.21(b). Phase II includes both Phase IIa and Phase IIb studies and is the second of three phases conducted to gather data and information to determine whether the Product would meet the criteria for marketing authorization.

I .40 **"Phase III"** means the third phase of clinical investigations, which are intended to be pivotal clinical studies designed to demonstrate the safety and effectiveness of the Product in order to prepare a marketing application and obtain authorization from the applicable Regulatory Authority to commercialize the Product, such as clinical studies described in 21 C.F.R. § 312.21(c). Phase III studies may include one or more pivotal studies.

1.41 "Product" means the anti-VEGFxD114 bispecific antibody referred to as ABL001.

1.42 "Product Infringement" has the meaning set forth in Section 7.4(b).

1.43 "Receiving Party" has the meaning set forth in Section 9.1.

1.44 **"Regulatory Approval"** means all approvals (including supplement, amendment, or pre- and post-approval), licenses, registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other Governmental Authority, that are necessary for the commercialization of the Product in the Territory.

1.45 **"Regulatory Authority"** means any applicable Governmental Authority involved in granting Regulatory Approval and any other applicable Governmental Authority having jurisdiction over the development or commercialization of the Product in the Territory.

1.46 **"Regulatory Materials"** means all regulatory applications, submissions, notifications, registrations, Regulatory Approvals or other submissions, including any written correspondence or meeting minutes, made to, made with, or received from a Regulatory Authority in the Territory that are necessary or reasonably desirable in order to develop, manufacture, market, sell or otherwise commercialize a Product in the Territory.

1.47 "Research Program" means the pre-clinical and clinical research program for the discovery, development and selection the Product, including the Korean Government Program.

1.48 **"Royalty Term"** means, on a country-by-country basis, the period commencing on the First Commercial Sale of a Product in such country in the Territory and continuing until the later to occur of [***].

1.49 "Sole Inventions" has the meaning set forth in Section 7.1(a).

1.50 **"Sublicensing Revenue"** means all value, payment or compensation of any type or kind, other than royalties on Net Sales, received by TRIGR and its Affiliates from or through sublicensees for the licensing, cross-licensing or other authorized use of the license or rights granted herein by ABL to the ABL Patents and ABL Know How. Sublicensing Revenue shall include, without limitation, all fees, milestone payments, cash equivalents, equities, securities, equipment, property, rights or anything else of value received by TRIGR and its Affiliates as sublicensing consideration from or for the benefit of any sublicensee (other than royalties on Net Sales).

1.51 "Term" has the meaning set forth in Section 10.1.

1.52 **"Territory"** means all countries in the world except (i) the Republic of Korea (for the Oncology Product) and (ii) the Republic of Korea and Japan (for the Ophthalmology Product).

1.53 "Third Party" means a Person other than ABL and TRIGR and their respective Affiliates.

1.54 "Third Party License" has the meaning set forth in Section 6.5(a).

1.55 "Third Party Payments" has the meaning set forth in Section 6.5(a).

1.56 "TRIGR Indemnitee" has the meaning set forth in Section 12.2.

1.57 **"Valid Claim"** means (a) a claim of an issued and unexpired Patent included within the ABL Patents or Joint Patents, to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final order, from which no further appeal can be taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer; or (b) a claim of any patent application (where such claim was filed in good faith) within the ABL Patents or Joint Patents, to the extent such claim has not been canceled, withdrawn, abandoned or pending for more than ten (10) years from its earliest priority date.

ARTICLE 2 -LICENSE

2.1 License Grant to TRIGR. Subject to the terms and conditions of this Agreement, ABL hereby grants to TRIGR and its Affiliates a royalty- bearing, exclusive (even as to ABL) license, with the right to sublicense (through one or more multiple tiers) in, to and under the ABL Patents and ABL Know How to exploit the Product in the Territory. All sublicenses shall survive termination of this Agreement provided such sublicenses are not in breach (taking into account any applicable cure period provided in such sublicense). During the Term, neither ABL nor any of its Affiliates will, directly or indirectly, undertake or partner with any Third Party to develop or commercialize any therapeutic product competitive with the Product.

2.2 Sublicense Grant to TRIGR. Subject to the terms and conditions of this Agreement, ABL hereby grants to TRIGR and its Affiliates a royalty- free, non-exclusive freely assignable license, with the right to sublicense (through one or more multiple tiers) in, to and under the KR Patent No. 1411740, KR Patent No. 1718764, and their families, and any patents or patent applications claiming priority to any of the foregoing, to exploit the Product in the Territory (the "Sublicensed Patents"), which ABL has licensed from Prestige Bio Pharmaceuticals Co. Ltd. under a license agreement dated October 31, 2018 (the "Prestige License"). ABL represents and warrants to TRIGR that (i) the Prestige License permits ABL to grants the rights to the Sublicensed Patents as contemplated hereunder for the Exploitation of the Product, (ii) all payments required to be made by ABL under the Prestige License have been made on a timely basis and (iii) TRIGR will have no obligations relating to the Prestige License, except that TRIGR agrees that the practice of the Sublicensed Patents by TRIGR, its sublicensee Patents are excluded from ABL Patents. ABL agrees not to terminate, amend, modify or waive any provisions of the Prestige License without the prior written consent of TRIGR.

2.3 No Modifications. TRIGR is not permitted to modify the Product including, but not limited to, making monoclonal or any bispecific antibodies with/from the Product.

2.4 **BINEX Agreement.** TRIGR acknowledges that ABL entered into an agreement with BINEX Co., Ltd. ("**BINEX**") dated March 2, 2016, as amended by that certain Amendment dated Oct 18th, 2018, attached hereto as <u>Exhibit A</u> (the "**BINEX Agreement**"). TRIGR acknowledges and agrees that under the BINEX Agreement ABL has granted BINEX a priority right to manufacture the Avastin Dll4 bispecific antibody (ABL001) component of the Product, subject to the terms and conditions set forth therein. Following the execution of this Agreement, ABL shall use reasonable and good faith efforts to have TRIGR and BINEX reach an agreement for mutual interests, under which BINEX shall have rights and obligations related to the first right to manufacture as set forth in BINEX Agreement.

ARTICLE 3- RESEARCH AND DEVELOPMENT

3.1 Roles and Responsibilities.

(a) **Development and Commercialization Activities.** Subject to the cost-sharing and revenue sharing mechanics described below, (i) ABL shall be responsible for designing and conducting Phase I clinical studies for the Oncology Product subject to the direction and oversight of the JRDC as described in Section 3.3 below and (ii) TRIGR shall be responsible thereafter for the clinical development and commercialization of the Oncology Product starting from Phase II, it being understood by the Parties that ABL is conducting the Phase Ib studies for the Oncology Product. TRIGR shall be responsible for all phases of the preclinical/clinical development and commercialization of the Ophthalmology Product.

(b) Cost and Expenses for the Oncology Product.

(i) ABL's Expense. ABL shall be responsible for [***].

(ii) TRIGR's Expense. Except as set forth in clause (i) above, TRIGR shall be responsible for [***].

(c) Cost and Expenses for the Ophthalmology Product. [***].

3.2 **Transfer of Know-How and Materials.** On request made by TRIGR from time to time during the Term, ABL will transfer to TRIGR (a) the ABL Materials and (b) copies (in electronic or other mutually agreed upon format) of ABL Data (including without limitation all ABL Data arising from the Korean Government Program) and all other ABL Know-How as promptly as possible and within thirty (30) days from the receipt of TRIGR's request. In addition, ABL will provide reasonable assistance, including providing translations and making its personnel reasonably available for meetings or teleconferences to answer questions and provide technical support to TRIGR with respect to the use of the ABL Know How and ABL Materials in accordance with the license granted to TRIGR hereunder. Any translation costs relating to the ABL Know-How will be paid for by ABL.

3.3 Joint Research and Development Committee. The Parties hereby establish the joint research and development committee ("JRDC"), which shall consist of six (6) members, with each Party designating three (3) of its representatives as the members of the JRDC. The names of the initial members of the JRDC are as set forth in the JRDC Chart attached hereto as Schedule 2. Each Party may replace its representative on the JRDC at any time, upon written notice to the other Party. A Patty may designate a substitute employee to temporarily attend and perform the functions of such Party's designee

at any meeting of the JRDC. The JRDC will have oversight and final decision-making responsibility for (i) the Phase I clinical development for the

Oncology Product including Phase IB (the "Phase I Period") and (ii) for the first Phase II clinical study for the Oncology Product (the "Phase II Period" and, together with the Phase I Period, the "Initial Development Period"). TRIGR will be actively involved on a day to day basis in the planning and design for the Phase IB study for the Product, including document review and interactions with third parties involved in the development of the Product. Without limiting the foregoing, the JRDC shall perform the following :functions: (i) serve as a forum for discussion and communication regarding the overall strategy for research and development Period; (ii) review and monitor research and development activities during the Initial Development Period and (iii) determine the research and development plan for the Oncology Product for the Initial Development Period and any amendments thereto. JRDC meetings shall occur at least

quarterly during the Initial Development Period (or with such greater frequency as is otherwise requested by any JRDC member). All decisions of the JRDC shall be subject to the agreement of all its members and any matters not agreed upon by the JRDC shall be finally decided upon by the chief executive officers of the Parties by mutual agreement , who together shall use reasonable and good faith efforts to reach a decision by consensus within thirty (30) days after the date such matter is referred to them; provided, however, that during the Phase I Period ABL shall have the final decision making authority in case of disagreement and that during the Phase II Period TRIGR shall have the final decision making authority in case of disagreement.

3.4 Abandonment by TRIGR.

(a) TRIGR may abandon the clinical studies for the Product only if the principal reason for TRIGR's abandonment of the clinical studies is that TRIGR was unable to get acceptable clinical data for the Product, despite making commercially reasonable efforts in good faith to do so.

(b) In such case of abandonment by TRIGR under (a), ABL may, at its discretion, request to step in and take over the clinical studies and other development activities of the Product, at its own costs and expenses. TRIGR shall, upon ABL's request, (i) provide ABL all data and information related to the clinical development program of the Product and (ii) return to ABL all rights and licenses granted under this Agreement (including rights granted by ABL to TRIGR under Articles 2 and 7). For the data and information controlled by TRIGR and provided to ABL hereunder, the Parties shall in good faith negotiate a license to make them available to ABL on commercially reasonable terms.

(c) In the event that ABL exercise its discretion set forth in (b), the Parties are considered to have reached a mutual agreement on termination of this Agreement.

3.5 Abandonment by ABL.

In the event that ABL does not pursue the research and development of the Product during the Phase I Period in accordance with the direction of the JRDC (or if the JRDC fails to provide such direction) then, TRIGR may, at its discretion, request to step in and take over these research and development activities for the Product and ABL shall, upon TRIGR's request, provide all ABL Materials, ABL Data and ABL Know-How related to the research development of such Product to TRIGR as contemplated by Section 3.2.

In case TRIGR takes over the research and development activities for the Product as contemplated above, (i) TRIGR shall have the right to retain CROs or other third parties to assist with the research and development of the Product at TRIGR's discretion (and to share ABL Materials, ABL Data and ABL Know-How with such third parties for this purpose), (ii) TRIGR shall be responsible for all costs and expenses, including third party costs and expenses, relating to the research and development activities for the Product, and (iii) notwithstanding anything to the contrary in this Agreement, all milestone

and royalty payment obligations and ABL's share of Upfront Revenue that would otherwise be payable to ABL here under in respect of such Product shall be reduced by fifty percent (50%).

¹⁰

ARTICLE 4 - REVENUE SHARING

4.1 Sharing of Sublicensing Revenue. When TRIGR receives any Sublicensing Revenue in respect of the Product under any sublicense thereof, TRIGR shall pay a percentage thereof to ABL as set forth below regardless of when such sublicense is entered into: [***].

(a) **TRIGR Reporting Obligations.** From and after the commencement of Phase II clinical trials, TRIGR shall update ABL on developments related to the clinical activities for the Product no less than once every twelve (12) calendar months. In addition, promptly following the execution of any sublicense for the Product, TRIGR shall report to ABL the name of sublicensee, date of contract, payment and/or royalty terms and conditions (a **"Sublicensing Report").** And after First Commercial Sale, TRIGR shall submit to ABL quarterly royalty reports within forty-five (45) days of March

31, June 30, September 30, and December 31 of each year (each, a **"Royalty Report")** for the Product, together with the royalty payment for such quarter. Each Royalty Report shall cover TRIGR's (and each Affiliate's and sublicensee's) most recently completed calendar quarter and shall show:

(i) the date of commercial launch in each country in the Territory;

- (ii) gross sales, deductions, and Net Sales during the most recently completed calendar quarter and the royalties, in US dollars, payable with respect thereto;
- (iii) the number of each type of Product sold;
- (iv) the method used to calculate the royalties; and
- (v) the exchange rates used.

If no sales of Products have been made by TRIGR, its Affiliates or sublicensees during any reporting period, TRIGR shall so report. (b) Records &

Audits.

(i) TRIGR shall keep, and shall require its Affiliates and sublicensees to keep, complete and accurate records of all Products sold under this Agreement. Such records shall be retained by TRIGR for at least three (3) years following a given reporting period.

(ii) TRIGR shall keep, and shall requires its Affiliates and sublicensees to keep, complete and accurate books and records used in the determination of all Net Sales, payments and deliveries of the Products to third parties for a period of three (3) years following a given reporting period. Upon thirty (30) days'

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prior notice to TRIGR all records shall be made available by TRIGR to ABL during normal business hours for inspection at the expense of ABL by ABL's Internal Audit Department or by a Certified Public Accountant selected by ABL and reasonably acceptable to TRIGR and in compliance with the other terms of this Agreement for the sole purpose of verifying the accuracy of the royalty reports, sublicensing report, and other payments hereunder. TRIGR shall provide all books and records necessary for the inspecting party to determine Net

Sales and calculate payments due to ABL under this Agreement. Such inspector shall not disclose to ABL any information other than information relating to the accuracy of reports and payments made under this Agreement or other compliance issues. If any such inspection shows an under reporting and underpayment more than five percent (5%) for any twelve-month (12-month) period, and such

underpayment is not disputed by TRIGR in good faith, then TRIGR shall pay the cost of the audit as well as any additional sum that would have been payable to ABL had the TRIGR reported correctly, plus an interest charge at a rate of ten percent (10%) per year (pro-rated for any shorter period). Such interest shall be calculated from the date the correct payment was due to ABL up to the date when such payment

is made by TRIGR. For any undisputed underpayment not more than five percent (5%) for any twelve-month (12-month) period, TRIGR shall pay the difference within thirty (30) days without interest charge or inspection cost. ABL may conduct such inspections no more than once per calendar year.

(c) **Due Diligence.** TRIGR shall make commercially reasonable efforts to develop and commercialize the Product subject to Section 3.4(a). In case TRIGR delays developments for a reasonable reason, TRIGR shall inform ABL of delays and the reason of delays in developments. If TRIGR delays development for more than a year without reasonable reason, whether or not this delay has been notified to ABL, this shall be considered abandonment as stipulated in Section 3.4(a) unless TRIGR makes an extension request in writing to ABL prior to the end of such one-year period, in which case such a delay shall be considered abandonment as stipulated in Section 3.4(a) only if TRIGR delays development for more than eighteen (18) months (instead of one year).

ARTICLE 5- REGULATORY MATTERS

5.1 **Regulatory Matters.** During the Phase I Period (as defined in Section 3.3), all communications with Regulatory Authorities shall be the responsibility of ABL subject to the direction, involvement and oversight of the JRDC as described in Section 3.3. Thereafter, all communications with Regulatory Authorities shall be the responsibility of TRIGR. All costs relating to the foregoing shall be allocated between the Parties in accordance with Section 3.1(b). All Regulatory Materials shall be owned by TRIGR, including all INDs, BLAs and comparable regulatory filings in non-US

jurisdictions. For the avoidance of doubt, except for the allocation of costs described above, ABL shall not after the Phase I Period assume any liability or obligation for any regulatory application, filing, or approval necessary to develop or commercialize the Product required by any country in the Territory.



ARTICLE 6-PAYMENT

6.1 **General.** TRIGR shall pay Initial Payments, Development Milestone, Commercial Milestone, and Royalty to ABL as stipulated in the Appendix to this Agreement and this Article 6. Any milestone or royalty payment is made in the recognition of the value of the Product at the time of payment, such that, once made, such-payment is final.

6.2 **Royalties.** TRIGR shall pay the running royalties to ABL on Net Sales of the Product as consideration for the rights granted to TRIGR under Section 2.1 of this Agreement. Subject to Sections 6.3 and 6.4 below, and only during the applicable Royalty Term, TRIGR shall pay to ABL the royalty as described below. Any tax required to be withheld by TRIGR, its Affiliates or any sublicensee under the laws of any foreign country from any royalty or other payments due to ABL hereunder shall be promptly and timely paid by TRIGR for and on behalf of ABL to the appropriate governmental authority, and TRIGR shall furnish ABL with proof of payment of such tax together with official or other appropriate evidence issued by the applicable government authority. Any such tax actually paid on ABL's behalf shall be deducted from royalty payments or other payments due ABL. The

remittance of royalties payable on sales outside the United States shall be payable to ABL in United States Dollar equivalents at the official rate of exchange of the currency of the country from which the royalties are payable, as quoted in the *Wall Street Journal* for the last business day of the

calendar quarter in which the royalties me payable. If the transfer of or the conversion into the United States Dollar equivalents of any such remittance in any such instance is not lawful or possible, the payment of such part of the royalties as is necessary shall be made by the deposit thereof, in the currency of the country where the sale was made on which the royalty was based to the credit and account of ABL or its nominee in any commercial bank or trust company of ABL's choice located in that country, prompt written notice of which shall be given by ABL to TRIGR.

Subject to Sections 6.3 and 6.4 below, and only during the applicable Royalty Term, TRIGR shall pay to ABL a royalty on Net Sales of each Product calculated as follows on a per Product basis: [***].

6.3 Royalty Term. Royalties under Section 6.2 shall be payable on Net Sales for the Product beginning upon the First Commercial Sale of the Product in the Territory until the expiration of the Royalty Term.

6.4 **Sublicensing Revenue.** In addition to the payment set forth in Section 6.1 and royalties stipulated in Section 6.2, TRIGR shall pay to ABL a portion of any Sublicensing Revenue for the Product as set forth in Section 4.1.

6.5 Offset for Third Party Licenses and Excessive COGS.

(a) <u>Third Party Licenses</u>. If it is necessary for TRIGR to enter into an agreement with one or more Third Parties pursuant to which TRIGR licenses one or more Patents (including any license granted in settlement of any litigation as contemplated under Section 7.5) from such



Third Parties in order to Exploit the Product in the Territory, TRIGR will have the right, at its sole discretion, to negotiate and obtain a license under such Patents (each, a **"Third Party License").** A Third Party License will be deemed "necessary" under this Section 6.5(a) if, in the absence of a license under such Third Party Patents, the Exploitation of any Product would, in TRIGR's good faith assessment, infringe such Third Party Patents. Except as set forth in Section 6.5(b), or to the extent of any Claim for which ABL provides indemnification under Section 12.2, or as the Parties may otherwise agree in writing, TRIGR shall bear any payments associated with any royalties or other payments paid or payable to any Third Party for such Third Party License (collectively, the **"Third Party Payments").**

(b) TRIGR may credit up to fifty percent (50%) of the amount of any Third Party Payments paid by TRIGR under a Third Party License deemed "necessary" pursuant to Section 6.5(a) during any calendar quarter against the royalties and other payments payable to ABL under t this Article 6 in respect of the same calendar quarter; provided, (i) in no event will the royalties payable to ABL for such calendar quarter be reduced by more than fifty percent (50%) and (ii) any remaining creditable amount may be credited by TRIGR in subsequent calendar quarters.

6.6 **Royalty Statement.** Within thirty (30) days following the end of each calendar quarter, TRIGR shall provide ABL with a written report containing the following information for the calendar quarter: an accounting of the number of units and prices for the Products sold, by Product; the amount of gross sales of the Products in the Territory; an itemized calculation of Net Sales in the Territory showing deductions provided for in the definition of "Net Sales"; the application of any other reductions or corrections made in accordance with this Article 6; and calculation of the royalty payment due on such Net Sales, as adjusted. At the same time it provides the royalty statement, TRIGR shall pay ABL the corresponding amount for the applicable calendar quarter.

6.7 **Corrections.** In the event that either Party determines that the calculation of Net Sales for a calendar quarter deviates from the amounts previously reported to ABL for any reason (such as, on account of additional amounts collected or Product returns), TRIGR and ABL shall reasonably cooperate to reconcile any such deviations to the extent necessary under applicable legal or financial reporting requirements.

6.8 Late Payments. In the event Initial Payments, Development Milestones, Commercial Milestones, Royalty to ABL as stipulated in the Appendix to this Agreement and this Article 6 are not received by ABL when due, TRIGR shall pay to ABL interest charges at a rate of ten (10%) percent per year, calculated from when the relevant amount was due and payable. Such interest shall be calculated from the date payment was due until received by ABL. In case TRIGR delays payments for a reasonable reason, TRIGR shall inform ABL, in writing of such delays and the reason of delays in payments. If ABL agrees to provide TRIGR an additional period to make the payments, then such interest charges shall accrue and be payable from the end of this additional period.

ARTICLE 7- INTELLECTUAL PROPERTY MATTERS

7.1 Ownership of Inventions.

(a) **Sole Inventions.** Subject to the licenses granted hereunder, each Party shall own any and all inventions made or conceived solely by its own employees, agents, or independent contractors in the course of conducting any activities under this Agreement, together with all intellectual property rights therein (the **"Sole Inventions").**

(b) **Joint Inventions.** The Parties shall jointly own and shall have an equal, undivided right, title and interest in and to and be free to use and commercially exploit any and all inventions that are made or conceived jointly by employees, agents or independent contractors of both Parties in the course of conducting any activities under this Agreement, together with all intellectual property rights therein (the **"Joint Inventions"**). Each Party will have the right to practice, license, assign, enforce and otherwise exploit Joint Inventions, only after obtaining prior written approval of any other Party to practice, license, assign, enforce or otherwise exploit Joint Inventions; provided, however, for the avoidance of doubt that ABL's rights in any Joint Patents are included in the license grant set forth in Article 2.

7.2 Disclosure of Inventions.

(a) **Sole Inventions.** Each Party shall promptly disclose to the other Parties of its Sole Inventions and all Information relating to such inventions to the extent necessary for the use of such Invention in the Exploitation of the Research Program and Product.

(b) Joint Inventions. Each Party shall promptly disclose to the other Parties any Joint Inventions and all Information relating to such inventions to the extent necessary for the use of such Invention in the Exploitation of the Research Program and Product.

7.3 Prosecution of Patents.

(a) **ABL Patents and Joint Patents.** Beginning on the Effective Date, and except as otherwise provided in this Section 7.3, ABL shall have the sole right and authority during the Term to control the preparation, filing, prosecution and maintenance (including any oppositions, cancellations, interferences, reissue proceedings, derivation proceedings, or reexaminations) (collectively, **"Prosecution" or "Prosecute")** of the ABL Patents and any Patents claiming Joint Inventions at ABL's sole expense.

ABL shall use commercially reasonable efforts to file divisional applications with respect to the ABL Patents (including the Background Patents) and Joint Patents to create Antibody-Specific Patents with respect to the ABL Patents being Prosecuted by ABL. ABL shall keep TRIGR informed as to material developments with respect to the Prosecution and maintenance of the ABL Patents (including the Background Patent Rights) and Joint Patents that may reasonably be expected to result in Antibody-Specific Patents. At such time as Antibody-Specific Patents are filed by ABL, then TRIGR shall have fifteen (15) business days after written notice from ABL to elect, but not the obligation, to Prosecute such Antibody-Specific Patents, and if TRIGR timely elects to Prosecute such. Antibody-Specific Patents, then TRIGR shall be responsible for all costs and expenses relating to the Prosecution of such Antibody-Specific Patents.

In addition, and without limiting the foregoing, TRIGR has the right, exercisable by written notice to ABL at any time after the first BLA (or equivalent thereof outside the US) for the Product has been submitted, to assume Prosecution of the ABL Patents and any Patents claiming Joint Inventions, in which case TRIGR shall be responsible for all costs and expenses relating to the Prosecution thereof from and after such exercise.

(b) **Cooperation**. ABL shall reasonably consult with TRIGR regarding (i) the patent filing strategy for the ABL Patent Rights and the Joint Patents prior to Prosecution thereof, (ii) plans for filings to create Antibody-Specific Patents and (iii) the Prosecution of the ABL Patents and the Joint Patents, in each case by providing TRIGR a Reasonable Opportunity (as defined below) to review and comment on all proposed submissions to any patent office before submission. ABL shall, in its reasonable judgment and to the extent practicable, consider in good faith and reasonably incorporate TRIGR's comments concerning such documents and materials with respect to the Product that ABL receives from TRIGR. For the purpose of this Agreement, "Reasonable Opportunity" means that a Party shall receive from the prosecuting party or its patent counsel true copies of all documents relating to the prosecution of patent applications and patents within the relevant patent rights as soon as reasonably practical after the prosecuting party has prepared or received such documents and materials, together with any documents submitted by the prosecuting party to or received by such prosecution gravity from a patent office with respect to such Prosecution. All communications among the Parties relating to the preparation, filing, maintenance or prosecution of the ABL Patents and Joint Patents, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information and subject to the confidentiality provisions of Article 9.

(c) **Step-In Right.** If ABL declines to Prosecute or maintain any ABL Patents, Joint Patents or Antibody-Specific Patents, elects to allow any ABL Patents, Joint Patents or Antibody-Specific Patents before all appeals within the respective patent office have been exhausted (each, an "Abandoned Patent Right"), then:

(i) ABL shall provide TRIGR with reasonable notice of such decision so as to permit TRIGR to decide whether to Prosecute such Abandoned Patent Rights and to take any necessary action (which notice shall, to the extent reasonably feasible for ABL, be given no later than thirty (30) days prior to the next deadline for any action that may be taken with respect to such Abandoned Patent Right with the U.S. Patent & Trademark Office (or any foreign patent office).

(ii) TRIGR, at its sole expense, may assume control of the filing, prosecution and/or maintenance of such Abandoned Patent Rights.

(iii) TRIGR shall have the right to transfer the responsibility for such Prosecution of such Abandoned Patent Rights to patent counsel (outside or internal) of its choice.

(iv) ABL shall use commercially reasonable efforts to assist and cooperate with TRIGR's reasonable requests to support Prosecution of any such Abandoned Patent Rights.

7.4 Enforcement against Third Parties.

(a) **Notification.** Each Party shall promptly notify the other Party in writing of any existing, alleged or threatened infringement of the ABL Patents or Joint Patents in the Territory of which it becomes aware, and shall provide all Information in such Party's possession or control demonstrating such infringement.

(b) **Infringement Action.** TRIGR shall have the right, but not the obligation, to bring suit or take any other appropriate action against any Third Party engaged in any existing, alleged or threatened infringement of any ABL Patent or Joint Patent related to Exploiting the Products in the Territory during the Term (a **"Product Infringement")**, and shall at all times keep ABL informed as to the status thereof. TRIGR may, at its own expense, institute suit against any such infringer or alleged infringer and control and defend and settle such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 7.4(d). ABL shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at TRIGR's expense. TRIGR shall not enter into any settlement of any claim described in this Section 7.4(b) that admits to the invalidity or unenforceability of the ABL Patents or Joint Patents, incurs any financial liability on the part of ABL or requires an admission of liability, wrongdoing or fault on the part of ABL without ABL's prior written consent, in each case, such consent not to be unreasonably withheld.

(c) In addition, if TRIGR elects not to enforce any patent within the ABL Patents or Joint Patents, then it shall so notify ABL in writing within one (1) months of receiving notice that a Product Infringement exists (or such shorter period as may be necessary to prevent exhaustion of a statute of limitations (or laches) applicable to such Product Infringement). With respect to any enforcement by ABL pursuant to this Section 7.4(c), ABL may, in its sole judgment, and at its own expense, take steps to enforce any such patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover any damages, awards or settlements resulting there from, subject to Section 7.4(d). TRIGR shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at ABL's expense. ABL shall not enter into any settlement of any claim described in this Section 7.4(c) that admits to the invalidity or unenforceability of the ABL Patents or Joint Patents or incurs any financial liability on the part of TRIGR or requires an admission of liability, wrongdoing or fault on the part of TRIGR without TRIGR's prior written consent, in each case, such consent not to be unreasonably withheld.

(d) **Allocation of Proceeds.** If TRIGR recovers monetary damages from any Third Party under Section 7.4(b) or Section 7.4(c), or any royalties from a license agreement with a Third Party related to any alleged Product Infringement, whether such damages or royalties result from the infringement of the ABL Patents or Joint Patents, such

recovery shall be allocated first to the reimbursement of any expenses incurred by TRIGR in such litigation, action or license, and any remaining amounts shall be retained by TRIGR and treated as Net Sales for purposes of the royalties due to ABL under this Agreement. If ABL recovers monetary damages from any Third Party under Section 7.4(c), or any royalties from a license agreement with a Third Party related to any alleged Product Infringement, whether such damages or royalties result from the infringement of the ABL Patents or Joint Patents, such recovery shall be retained by ABL.

(e) **Enforcement of Joint Inventions.** Each Party will notify the other Party in writing prior to commencing any enforcement action of intellectual property rights in Joint Inventions against any Third Party after the Term. Any enforcement or defense of any intellectual property rights involving Joint Intellectual Property that is mutually undertaken by both Parties pursuant to this Section 7.4(e) requires separate agreement between the Parties. If either Party provides the other Party written notice of its decision not to participate in an enforcement action of intellectual property rights in any Joint intellectual Property and the other proceeds with such action, the proceeding Party has no obligation to account to the non-participating Party for any amounts collected.

7.5 Infringement of Third Party Rights.

(a) **Notice.** If any Product Exploited hereunder by TRIGR becomes the subject of a claim or assertion of infringement of a Third Party's Patent granted in the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action.

(b) **Defense.** TRIGR shall have the right, but not the obligation, to defend any such Third Party claim or assertion of infringement described in Section 7.5(a) above, at TRIGR's expense. TRIGR may, at its own expense, control and defend and settle such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 7.4(d). ABL shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at TRIGR's expense. TRIGR shall not enter into any settlement of any claim described in this Section 7.5(b) that admits to the invalidity or unenforceability of the ABL Patents or Joint Patents, incurs any financial liability on the part of ABL or requires an admission of liability, wrongdoing or fault on the part of ABL without ABL's prior written consent, in each case, such consent not to be unreasonably withheld. The foregoing is without limitation to the rights of TRIGR under Section 6.5 (Third Party Licenses) and Article 12 (Indemnification).

(c) In addition, if TRIGR elects not to defend any such Third Party claim or assertion of infringement described in Section 7.5(a) above, then it shall so notify ABL in writing within one (1) month of receiving notice that such Third Party claim exists. Following such notice, ABL may, at its own expense, control and defend and settle such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 7.4(d). TRIGR shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at ABL's expense. ABL shall not enter into any settlement of any claim described in this Section 7.5(c) that admits to the invalidity or unenforceability of the ABL Patents or Joint Patents, incurs any financial liability on the part of TRIGR or requires an

admission of liability, wrongdoing or fault on the part of TRIGR without TRIGR's prior written consent, in each case, such consent not to be unreasonably withheld. The foregoing is without limitation to the rights of TRIGR under Section 6.5 (Third Party Licenses) and Article 12 (Indemnification).

ARTICLE 8- REPRESENTATIONS AND WARRANTIES

8.1 Mutual. Each of the Parties hereby represents and warrants to the other Party as of the Effective Date and covenants that:

(a) **Organization**. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite corporate power and authority to execute, deliver and perform this Agreement.

(b) Binding Agreement. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. (c)

Authorization. The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary

corporate action and do not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or any order, writ, judgment, injunction, decree, determination, or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party.

(d) **No Further Approval.** It is not aware of any government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law, currently in effect, necessary for, or in connection with, the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements.

(e) **No Inconsistent Obligations.** Neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

(f) **Transparency Reporting.** Each Party shall be responsible for tracking and reporting transfers of value initiated and controlled by its and its Affiliates' employees, contractors and agents pursuant to the requirements of the marketing reporting laws of any Governmental Authority in the Territory.

8.2 ABL. In addition, ABL represents and warrants to TRIGR as of the Effective Date and covenants that:

(a) ABL has all rights necessary to grant the licenses under the ABL Intellectual Property, Sublicensed Patents and other rights that it grants to TRIGR in this Agreement, including without limitation to the ABL Data (and, in particular, the ABL Data

arising from the Korean Government Program). Neither the shareholders nor the employees, consultant or agents of ABL nor any other Person (other than ABL) has any rights to the ABL Intellectual Property, the ABL Materials or the Product (and any such rights previously held by any of them have been assigned to ABL).

(b) As of the Effective Date, the Patents set forth in Schedule I represent all ABL Patents that ABL or any of its Affiliates Controls that claim or disclose any Invention discovered or developed in the Research Program or necessary or useful for the Exploitation of the Products in the Territory. ABL is the sole and exclusive owner of the entire right, title and interest in the ABL Patents free of any encumbrance, lien or claim of ownership by any Third Party.

(c) The ABL Patents are being diligently prosecuted in the Territory in accordance with Applicable Law. The ABL Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.

(d) The ABL Know-How has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality and no breach of such confidentiality has been committed by any Third Party.

(e) No claim or litigation, other than claims that have been withdrawn and settled by entering into the Prestige License, has been brought or threatened by any Person alleging, and there is no claim, whether or not asserted that: (i) any of the ABL Patents is invalid or unenforceable, (ii) the ABL Intellectual Property, or the disclosing, copying, making, assigning, or licensing of the ABL Intellectual Property, violates, infringes, or otherwise conflicts or interferes with, or would violate, infringe, or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person; or (iii) any intellectual property or proprietary right of any Person is related to the Exploitation of the Products, as of the Effective Date.

(f) ABL owns all right, title and interest in and to the ABL Know-How to be provided hereunder, and all such information is true, complete and correct in all material respects and what it purports to be.

8.3 **Compliance with Applicable Laws.** In addition, each Party covenants that in performing its obligations under this Agreement, or any ancillary agreements (if any), such Party shall comply with all Applicable Laws, including any applicable anti-corruption or anti-bribery laws or regulation, of any Governmental Authority with jurisdiction over the activities performed by such Party or its Affiliates in furtherance of its rights or obligations hereunder.

8.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 8, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT OR AS TO THE VALIDITY OF ANY PATENTS IN THE TERRITORY.

ARTICLE 9- CONFIDENTIALITY

9.1 **Nondisclosure.** Each Party agrees that, during the Term and for a period of ten (10) years thereafter, a Party (the **"Receiving Party")** receiving Confidential Information of the other Party (the **"Disclosing Party")** shall (a) maintain in confidence such Confidential Information using at least the level of care that the Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but not less than reasonable care), (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Section 9.1 shall not create or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary in the foregoing, the obligations of confidential Information remains a trade secret under Applicable Law.

9.2 Exceptions. The obligations in Section 9.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent evidence:

(a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party here under;

(b) is rightfully known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's Knowledge, is not bound by a similar duty of confidentiality or restriction on its use;

(d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates, generally known to the public, either before or after it is disclosed to the Receiving Party;

(e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or access to Confidential Information belonging to the Disclosing Party; or

(f) is the subject of written permission to disclose provided by the Disclosing Party.

9.3 Authorized Disclosure. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances:

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

(b) filing Regulatory Materials in order to obtain or maintain Regulatory Approvals;

(c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

(d) complying with Applicable Laws or court or administrative orders as long as the Disclosing Party has a reasonable advance opportunity to pursue a protective order;

(e) to its Affiliates, sublicensees, subcontractors or prospective subcontractors, payors, consultants, agents and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive (except for the duration of such restrictions, which shall be no less than five (5) years) than those set forth in this Article 9; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 9.3(e) to treat such Confidential Information as required under this Article 9; or

(f) to its actual or prospective investors, acquirers, merger-partners, and to any investment advisors, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in this Article 9 (except for the duration of such restrictions, which shall be no less than three (3) years); provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 9.3(f) to treat such Confidential Information as required under this Article 9.

If and whenever any Confidential Information is disclosed in accordance with this Section 9.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clauses (a) through (d) of this Section 9.3, it shall, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure and shall be jointly and severally liable for any breach of this Article 9 by such Person.

9.4 **Terms of this Agreement.** The Parties acknowledge that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of both Parties.

9.5 **Publicity.** Except as necessary to comply with any Applicable Law, each Party agrees not to issue any other press release or other public statement disclosing any information relating to this Agreement or the transactions contemplated here by that contains information not previously publicly disclosed in accordance with this Section 9.5 without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed.

9.6 **Publication.** Each Party shall submit to the other Party for its review any proposed academic, scientific or medical abstract, poster, publication or public presentation (substantially in final form) that is related to the Research Program or any Product

("Publication") at least forty-five (45) days before submission for publication or presentation. The publishing Party will reasonably consider comments submitted by the reviewing Party during the forty-five (45)-day period and delete any of the reviewing Party's Confidential Information identified therein. In addition, the publishing Party agrees to delay submission for at least thirty (30) days after the forty-five (45)-day period if the reviewing Party demonstrates reasonable need for such extension for the preparation and filing of patent applications on subject matter described in the publication. Each Party will comply with standard academic practice regarding authorship of scientific publications and recognition of other parties in any publication governed by this Section 9.6, including International Committee of Medical Journal Editors standards regarding authorship and

contributions. All Publications will be subject to the prior written approval by (a) the JRDC with respect to Publications relating to the Initial Development Period and (b) thereafter, by TRIGR.

9.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 9. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 9.

ARTICLE 10 - TERM AND TERMINATION

10. **Term.** This Agreement shall become effective as of the Effective Date and shall continue in full force and effect until the expiration of this Agreement as described in this Section 10.1, unless earlier terminated pursuant to this Article 10 (the **"Term")**. This Agreement shall expire as follows:

(a) on a country-by-country basis, upon the expiration of the Royalty Term with respect to each Product in the Territory, as applicable; or

(b) in its entirety, upon the expiration of the Royalty Term with respect to the last Product commercialized in the Territory.

Upon expiration of this Agreement, the licenses and other rights granted to TRIGR and its Affiliates under this Agreement shall be fully paid-up, irrevocable and non-exclusive only to the extent such licenses and other rights relates the Exploitation of the Product.

10.2 Termination on Mutual Agreement. This Agreement may be terminated by the operation of 3.4(c) or by mutual written consent of both Parties.

10.3 **Termination by ABL.** ABL will have the right to terminate this Agreement upon delivery of written notice to TRIGR in the event of any material breach by TRIGR of any terms and conditions of this Agreement, provided, however, that such termination will not be effective if such breach has been cured within ninety (90) days after written notice thereof is given by ABL to TRIGR specifying in reasonable detail the nature of the alleged breach; provided further, however, that to the extent such material breach involves the material undisputed failure to make a payment when due, such breach must be cured within thirty (30)

days after written notice thereof is given by ABL to TRIGR; provided further, however, that if the material breach is not reasonably capable of being cured within the ninety (90)-day cure period, and if TRIGR (a) proposes within such ninety (90)-day period a written plan, reasonably acceptable to ABL, to cure such breach, (b) obtains the prior written consent from ABL for such written cure plan, and (c) makes good faith efforts to cure such default and to implement such written cure plan, then, until the first anniversary of notice of termination, ABL may not terminate this Agreement for so long as TRIGR is diligently pursuing such cure in accordance with such plan.

10.4 Termination by TRIGR. TRIGR may terminate this Agreement as follows:

TRIGR will have the right to terminate this Agreement upon delivery of written notice to ABL in the event of any material breach by ABL of any terms and conditions of this Agreement; provided, however, that such termination will not be effective if such breach has been cured within ninety (90) days after written notice thereof is given by TRIGR to ABL specifying the nature of the alleged breach, however, that if such breach is not reasonably capable of being cured within the ninety (90)-day cure period, and if ABL (a) proposes within such ninety (90)-day period a written plan, reasonably

acceptable to TRIGR, to cure such breach, (b) obtains the prior written consent from TRIGR for such written cure plan, and (c) makes good faith efforts to cure such default and to implement such written cure plan, then, until the first anniversary of receipt of notice of termination, TRIGR may not terminate this Agreement for so long as ABL is diligently pursuing such cure in accordance with such plan.

10.5 **Termination for Insolvency.** ABL or TRIGR may terminate this Agreement if, at any time, ABL (in the case of a proposed termination by TRIGR) or TRIGR (in the case of a proposed termination by ABL) shall (a) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) propose a written agreement of composition or extension of its debts, (c) be served with an involuntary petition against

it, filed in any insolvency proceeding, and such petition has not been dismissed within sixty (60) days after the filing thereof, (d) propose or be a party to any dissolution or liquidation, (e) make an assignment for the benefit of its creditors or (f) admit in writing its inability gene rally to meet its obligations as they fall due in the general course.

10.6 **Effects of Termination in General.** All of the following effects of termination are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and shall not be construed to limit any such rights or remedies. Upon a termination of this Agreement by ABL pursuant to Section 10.3 or 10.5 or by TRIGR pursuant to Section 10.4 or 10.5 (or by mutual agreement under Section 10.2):

(a) Notwithstanding anything contained in this Agreement to the contrary, all rights and licenses granted herein to TRIGR shall terminate and TRIGR shall cease any and all development and commercialization activities with respect to the Research Program and Products; and

(b) All payment obligations hereunder shall terminate, other than those that are accrued and unpaid as of the effective date of such termination.

Notwithstanding the foregoing, no termination of this Agreement shall be construed as a termination of any sublicense hereunder, and thereafter each sublicensee shall be considered a direct licensee of ABL with respect to the rights licensed to TRIGR hereunder and sublicensed to the sublicensee by TRIGR; provided that (i) such sublicensee is then in full compliance with all terms and conditions of its sublicense, and (ii) such sublicensee agrees in writing to assume all applicable obligations of TRIGR under this Agreement.

10.7 **Remedies.** Notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation. Each Party shall be free, pursuant to Article 11, to seek, without restriction as to the number of times it may seek, damages, expenses and remedies that may be available to it under Applicable Law or in equity and

shall be entitled to offset the amount of any damages and expenses obtained against the other Party in a final determination under Section 11.3, against any amounts otherwise due to such other Party under this Agreement.

10.8 **Survival.** The following provisions shall survive any expiration or termination of this Agreement for the period of time specified therein (or, if no such period is specified, indefinitely): Section 4.2 (Records and Audits); Section 6.8 (Late Payment); Article 7 (Intellectual Property Matters); Article 8 (Representations and Warranties); Article 9 (Confidentiality); Article 10 (Term and Termination); Article 11 (Governing Law and Dispute Resolution); Article 12 (Indemnification); and Article 13 (Miscellaneous) except Section 13.3 (Assignment).

ARTICLE 11- GOVERNING LAW AND DISPUTE RESOLUTION

11.1 **Governing Law.** This Agreement shall be interpreted and construed in accordance with the laws of Singapore without reference to any conflicts of laws principles, but the scope and validity of any patent or patent application shall be governed by the applicable laws of the country of the patent or patent application.

11.2 **Dispute Resolution.** In the event of a dispute, controversy or claim or relating to the Agreement ("Dispute"), the Parties shall refer such dispute to the executive officers for attempted resolution by good faith negotiations within thirty (30) calendar days after such referral is made. If the executive officers are unable to resolve such Dispute in a timely manner, which shall in no case be more than thirty (30) calendar days after the matter was referred to them, the matter shall be resolved through arbitration in accordance with the arbitration provisions set forth in Section 11.3, upon notice by a Party to the other Party specifically requesting such arbitration.

11.3 Arbitration.

(a) If the Parties do not resolve a dispute as provided in Section 11.2, and a Party wishes to pursue the matter, each such dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (or its successor entity) in accordance with its Rules. Judgment on the arbitration award may be entered in any court having jurisdiction thereof.

(b) The arbitration shall be decided by a tribunal of three (3) arbitrators, in irrespective of the amount in controversy. Each Party shall nominate one arbitrator, and the third, who shall act as presiding arbitrator, shall be nominated by the two-party nominated arbitrators within thirty (30) days of the second arbitrator's appointment. The seat, or legal place of arbitration, shall be Singapore, and the language of the arbitration, including all proceedings and communications shall be English.

(c) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award any damages proscribed by Section 12.3 hereof.

(d) Except to the extent necessary to confirm, vacate, or enforce an award, or as may be required by Applicable Law, or as needed or the preparation or presentation of claim or defense in the arbitration, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations.

11.4 **Preliminary Injunctions.** Notwithstanding anything in Section 11.2 or elsewhere in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.

11.5 **Confidentiality.** Any and all activities conducted under Article 11, including any and all proceedings and decisions under Section 11.3, shall be deemed Confidential Information of each of the respective Party who owns or Controls such Confidential Information, and shall be subject to Article 9.

ARTICLE 12- INDEMNIFICATION

12.1 **Indemnification by TRIGR.** TRIGR hereby agrees to defend, indemnify and hold harmless ABL and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "**ABL Indemnitee**") from and against any and all claims, suits. actions, demands, liabilities, expenses and/or loss, including reasonable legal expenses and attorneys' fees (collectively, the "**Losses**"), to which any ABL Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "**Claim**") to the extent such Losses arise directly or indirectly out of: (a) the breach by TRIGR of any warranty, representation, covenant or agreement made by TRIGR in this Agreement or

(b) the negligence, gross negligence or willful misconduct of TRIGR or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (a) and (b) above, to the extent such Losses arise directly or indirectly from (i) the negligence, gross negligence or willful

misconduct of any ABL Indemnitee or (ii) the breach by ABL of any warranty, representation, covenant or agreement made by ABL in this Agreement.

12.2 **Indemnification by ABL.** ABL hereby agrees to defend, indemnify and hold harmless TRIGR and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an **"TRIGR Indemnitee")** from and against any and all Losses to which any TRIGR Indemnitee may become subject as a result of any Claim to the extent such Losses arise directly or indirectly out of: (a) the breach by ABL of any warranty, representation, covenant or agreement made by ABL in this Agreement; (b) the negligence or willful misconduct of ABL or any of its Affiliates or other licensees, or any officer, director , employee, agent or representative thereof; or (c) the infringement of a Third Party's Patents in the Territory; except, with respect to each of subsections (a), (b) and (c) above, to the extent such Losses arise directly or indirectly from the (i) negligence, gross negligence or willful misconduct of any TRIGR Indemnitee or (ii) the breach by TRIGR of any warranty, representation, covenant or agreement made by TRIGR in this Agreement.

12.3 Limitation of Liability. EXCEPT FOR A PARTY'S OBLIGATIONS SET FORTH IN THIS ARTICLE 12, AND ANY BREACH OF ARTICLE 10 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 13 - MISCELLANEOUS

13.1 **Correspondence.** Any notice or payment required to be given to either Party under this Agreement shall be deemed to have been properly given and effective (a) on the date of delivery if delivered in person, (b) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other Party, or (c) upon confirmation by recognized national overnight courier , confirmed facsimile transmission, or confirmed electronic mail, to the following addresses or facsimile numbers of the Parties.

If to TRIGR:

George

Uy

CEO & Founder TRIGR Therapeutics, Inc. 53 Carrington Irvine CA 92620 USA Phone: 001 949 648 07 05 e-mail: guy@trigrrx.com

If to ABL:

Sang Hoon Lee CEO & Founder ABL Bio, Inc.

#16 Daewangpangyo-ro 712beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13488, Republic of Korea Phone: 82-10-4104-0861 e-mail: sang.lee@ablbio.com

With a copy to Mikyung Chang Senior manager ABL Bio, Inc. #16 Daewangpangyo-ro 712beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13488, Republic of Korea Phone: 82-10-5515-4238 e-mail: mikyung.chang@ablbio.com

13.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists for more than ninety (90) days, then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure.

13.3 **Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder to any Third Party without the other Party's prior written consent; provided however that TRIGR may assign this Agreement and its rights and/or obligations hereunder including with respect to the Sublicensed Patents without the prior written consent of ABL to any of its Affiliates or in connection with any merger, consolidation or sale of all or substantially all of the assets of TRIGR that relate to this Agreement. Any other assignment by TRIGR shall require the prior written consent of ABL, which shall not be unreasonably withheld, delayed or conditioned (it being understood that ABL may not withhold such consent if the assignee has at least substantially comparable development capabilities for the Product as TRIGR). Any assignee permitted hereunder shall, in writing to the other Party, expressly assume performance of all of the assigning Party's rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 13.3 shall be null, void and of no legal effect.

13.4 **Rights Survive ABL Bankruptcy.** All rights and licenses granted under or pursuant to any section of this Agreement are intended to survive any bankruptcy of ABL and are, and shall otherwise be deemed to be, for purposes of Section 365(11) of the U.S. Bankruptcy Code (and comparable provisions under the laws of other jurisdictions), licenses of rights to " intellectual property" as defined under Section 10 I (35 A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their

respective rights and elections under the U.S. Bankruptcy Code (and comparable provisions under the laws of other jurisdictions). Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

13.5 **Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

13.6 **Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided here in are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

13.7 **Further Assurance.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

13.8 **Relationship of the Parties**. It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of that Party and not of the other Party and all expenses and obligations incurred by reason of such employment shall be for the account and expense of such Party.

13.9 **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.

13.10 **Construction**. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provision.

13.11 Entire Agreement. This Agreement, including the Schedules and Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and the Schedules or Exhibits to this Agreement, unless otherwise expressly stated to the contrary in such Schedule or Exhibit or subsequent ancillary agreement, the terms contained in this Agreement shall control.

13.12 **Headings.** The headings of each Section, Article, Schedule and Exhibit in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained therein.

<Signature page follows.> IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

TRIGR THERAPEUTICS. INC.

By: /s/ George Uy Name: George Uy Title: CEO

ABL BIO INC.

By: /s/ Sang Hoon Lee Name: Sang Hoon Lee Title: CEO

<Signature Page of Research and Development Collaboration and License Agreement ABL 00l>

Appendix. Payments

1. ABL001

1.1 Initial Payment (Upfront). Initial payments shall be as follows: [***].

1.2 **Development Milestones.** Development Milestones payable to ABL by TRIGR shall accrue upon the achievement of the events set forth below on a Region by Region basis where indicated. TRIGR shall promptly notify ABL in writing following the achievement by TRIGR of each milestone event described in this Section 1.3. With the receipt of such notice by TRIGR, ABL shall submit to TRIGR an invoice for the corresponding milestone payment in the applicable amount, and TRIGR shall remit each milestone payment to ABL within thirty (30) days after TRIGR's receipt of the applicable invoice from ABL. The event described below includes all cases achieved by the Parties, its Affiliates and sublicensees. The obligation of Milestone Payments arises when each milestone event (four milestones) is achieved, on a Region by Region basis where indicated. Each Milestone Payment shall be payable only once (even if, for example, there is more than one Phase III or Phase III study).

The following milestones are payable on achievement for the Product in the oncology field: [***].

Further, the following milestones are payable on achievement for the Product in the ophthalmology field: [***].

1.3 **Commercial Milestones.** Commercial Milestones payable by TRIGR to ABL shall accrue upon the achievement of the events set forth below. TRIGR shall promptly notify ABL in writing following the achievement by TRIGR of each milestone event described as below the table. With the receipt of such notice by TRIGR, ABL shall submit to TRIGR an invoice for the corresponding milestone payment in the applicable amount, and TRIGR shall remit each milestone payment to ABL within thirty (30) days after TRIGR's receipt of the applicable invoice from ABL. The event described below includes all cases achieved by the Parties, its Affiliates and sublicensees. The obligation of Milestone Payments arises when each milestone event is achieved. Each Milestone Payment shall be payable only once.

The following milestones are payable on achievement for the Product in the oncology field: [***].

In addition, the following milestones are payable on achievement for the Product in the ophthalmology field: [***].

ABL PATENTS

✓ "Patents" has the meaning set forth in Section 1.36. The Patents below constitute the ABL Patents as of the Effective Date.

✓ Patents based on provisional applications currently pending or registered are included ABL Patents. Novel monoclonal

antibody binding specifically to dll4 and use thereof

Country	Application No.	Filing Date	Patent No.	Issue Date
CN	2013-80035510	2013-07-02	104428319	2018-03-09
CN	2016-10937490	2013-07-02		
US	<u>14/412419</u>	2013-07-02	9598483	2017-03-21
JP	<u>2015 -520051</u>	2013-07-02	5982698	2016-08-12
KR	<u>10 -2013 -0071261</u>	2013-06-20	10-1535341	2015-07-02
EP	<u>2013 -813 388</u>	2013-07-02		

Novel double-targeting protein that specifically binds to DLL4 and VEGF, and use thereof

Country	Application No.	Filing Date	Patent No.	Issue Date
RU	20160104057	2014-07-08	2648154	2018-03-22
JP	2016 -525275	2014-07-08	6283411	2018-02-02
KR	<u>10-2014-0085332</u>	2014-07-08	10-1673389	2016-11-01
AU	<u>2014-28798 4</u>	2014-07-08	2014287984	2017-01-05
US	14/903077	2014-07-08		
EP	<u>2014-823338</u>	2014-07-08		
CN	<u>2014-80049434</u>	2014-07-08		
CA	<u>2917402</u>	2014-07-08		

JRDC CHART

TRIGR ABL

George Uy Sang Hoon Lee Miranda Toledano Weon-Kyoo You [To be designated by TRIGR](*) Jaeho Jung

(*)If TRIGR does not designate this additional representative or such representative is otherwise unavailable to participate in JRDC meetings and/or decisions, Mr. George Uy is entitled to act on behalf of TRIGR at the JRDC on behalf of such representative.

BINEX AGREEMENT

[Omitted]

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas Schuetz, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Compass Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by 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 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.

By:

Date: August 16, 2021

/s/ Thomas Schuetz

Thomas Schuetz Principal Executive Officer

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vered Bisker-Leib, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Compass Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by 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 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 16, 2021

By: /s/ Vered Bisker-Leib

Vered Bisker-Leib Principal Financial and 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 Compass Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of 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 result of operations of the Company.

By:

Date: August 16, 2021

/s/ Thomas Schuetz

Principal 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 Compass Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of 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 result of operations of the Company.

Date: August 16, 2021

By: /s/ Vered Bisker-Leib Vered Bisker-Leib Principal Financial and Accounting Officer