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

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2021

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36721

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**Coherus BioSciences, Inc.**

*(Exact name of registrant as specified in its charter)*

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

27-3615821  
(I.R.S. Employer Identification No.)

333 Twin Dolphin Drive, Suite 600  
Redwood City, California 94065  
(650) 649-3530

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CHRS	The Nasdaq Global Market

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

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

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

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

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

As of April 30, 2021, 75,752,478 shares of the registrant's common stock were outstanding.

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**COHERUS BIOSCIENCES, INC.**  
**FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2021**  
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## CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts contained in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by words such as “aim,” “anticipate,” “assume,” “attempt,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “seek,” “should,” “strive,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- whether we will be able to continue to maintain or increase sales for UDENYCA® (pegfilgrastim-cbqv) in the United States;
- our expectations regarding our ability to develop and commercialize our toripalimab drug candidates in the United States and Canada and whether the trial results, data package or biologics license application (“BLA”) will be sufficient to support the regulatory approvals;
- our expectations regarding our ability to develop and commercialize our bevacizumab (Avastin®) biosimilar candidate in the United States and Canada, including the anticipated three-way pharmacokinetic study, the planned additional analytical similarity characterizations and our plans to submit a 351(k) BLA to the U.S. Food and Drug Administration (“FDA”);
- whether our CHS-1420 (our adalimumab (Humira®) biosimilar candidate) trial results, data package or BLA will be sufficient to support domestic or global regulatory approvals;
- whether our ranibizumab (Lucentis®) biosimilar candidate partner, Bioeq AG (“Bioeq”), will be able to file a BLA and obtain regulatory approval in the United States or if we will be able successfully initiate sales of Bioeq’s biosimilar candidate upon such approval;
- our ability to maintain regulatory approval for UDENYCA® and our ability to obtain and maintain regulatory approval of our product candidates;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to manufacture our product candidates in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;
- our reliance on third-party contract manufacturers to supply our product candidates for us;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our financial performance, including, but not limited to, future performance of our gross margins, research and development expenses and selling and general administrative expenses;
- the implementation of strategic plans for our business and products;

- the initiation, timing, progress and results of future preclinical and clinical studies and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- our expectations regarding the scope or enforceability of third-party intellectual property rights, or the applicability of such rights to our product candidates;
- the cost, timing and outcomes of litigation involving our product candidates;
- our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;
- the benefits of the use of our product candidates;
- the rate and degree of market acceptance of our current or any future product candidates;
- our ability to compete with companies currently producing the reference products, including Neulasta®, Avastin®, Humira® and Lucentis®;
- developments and projections relating to our competitors and our industry; and
- the potential impact of COVID-19 on our business and prospects.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and discussed elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

**PART I. FINANCIAL INFORMATION**

**ITEM 1. Unaudited Condensed Consolidated Financial Statements**

**Coherus BioSciences, Inc.  
Condensed Consolidated Balance Sheets  
(in thousands)  
(unaudited)**

	March 31, 2021 (unaudited)	December 31, 2020 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 259,489	\$ 541,158
Investments in marketable securities	140,014	—
Trade receivables, net	140,410	157,046
Inventory	51,613	44,233
Prepaid manufacturing	15,385	19,429
Other prepaid and other assets	10,350	5,613
Total current assets	617,261	767,479
Property and equipment, net	9,670	10,108
Inventory, non-current	52,065	47,956
Intangible assets	2,620	2,620
Goodwill	943	943
Other assets, non-current	10,744	12,543
Total assets	<u>\$ 693,303</u>	<u>\$ 841,649</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 15,482	\$ 15,201
Accrued rebates, fees and reserve	78,202	81,529
Accrued compensation	12,090	22,244
Accrued and other current liabilities	44,840	26,679
Convertible notes due 2022 - current	80,240	—
Convertible notes due 2022 - related parties, current	26,747	—
Total current liabilities	257,601	145,653
Convertible notes due 2022	—	79,885
Convertible notes due 2022 - related parties	—	26,628
Convertible notes due 2026	223,341	223,029
Term loan	74,696	74,481
Lease liabilities, non-current	9,244	9,948
Other liabilities, non-current	750	1,051
Total liabilities	<u>565,632</u>	<u>560,675</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock (\$0.0001 par value; Shares authorized: 5,000,000; No shares issued and outstanding as of March 31, 2021 and December 31, 2020)	—	—
Common stock (\$0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 73,122,908 and 72,513,348 at March 31, 2021 and December 31, 2020, respectively)	7	7
Additional paid-in capital	1,063,672	1,043,991
Accumulated other comprehensive loss	(307)	(270)
Accumulated deficit	(935,701)	(762,754)
Total stockholders' equity	<u>127,671</u>	<u>280,974</u>
Total liabilities and stockholders' equity	<u>\$ 693,303</u>	<u>\$ 841,649</u>

(1) The consolidated balance sheet as of December 31, 2020 has been derived from the audited consolidated balance sheet included in the Company's 2020 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2021.

See accompanying notes.

**Coherus BioSciences, Inc.**  
**Condensed Consolidated Statements of Operations**  
**(in thousands, except share and per share data)**  
**(unaudited)**

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Net product revenue	\$ 83,034	\$ 116,180
Operating expenses:		
Cost of goods sold	7,511	6,855
Research and development	203,492	33,107
Selling, general and administrative	39,391	35,350
Total operating expenses	250,394	75,312
(Loss) income from operations	(167,360)	40,868
Interest expense (includes related party expense of \$631 and \$620 for the three months ended March 31, 2021 and 2020, respectively)	(5,648)	(4,431)
Other income, net	61	68
Net (loss) income before income taxes	(172,947)	36,505
Income tax provision	—	933
Net (loss) income	<u>\$ (172,947)</u>	<u>\$ 35,572</u>
Net (loss) income per share:		
Basic	\$ (2.37)	\$ 0.50
Diluted	\$ (2.37)	\$ 0.48
Weighted-average number of shares used in computing net (loss) income per share:		
Basic	72,832,953	70,662,185
Diluted	72,832,953	74,416,554

See accompanying notes.

**Coherus BioSciences, Inc.**  
**Condensed Consolidated Statements of Comprehensive (Loss) Income**  
**(in thousands)**  
**(unaudited)**

	Three Months Ended	
	March 31,	
	2021	2020
Net (loss) income	\$ (172,947)	\$ 35,572
Other comprehensive (loss) income:		
Unrealized loss on available-for-sale securities, net of tax	(37)	—
Foreign currency translation adjustments, net of tax	—	608
Comprehensive (loss) income	<u>\$ (172,984)</u>	<u>\$ 36,180</u>

See accompanying notes.

**Coherus BioSciences, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**(in thousands, except share and per share data)**  
**(unaudited)**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2020	72,513,348	\$ 7	\$1,043,991	\$ (270)	\$ (762,754)	\$ 280,974
Issuance of common stock upon exercise of stock options	451,883	—	4,429	—	—	4,429
Issuance of common stock upon vesting of restricted stock units (RSUs)	252,846	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(95,169)	—	(1,730)	—	—	(1,730)
Stock-based compensation expense	—	—	16,982	—	—	16,982
Unrealized loss on marketable securities	—	—	—	(37)	—	(37)
Cumulative translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	—	(172,947)	(172,947)
Balances at March 31, 2021	73,122,908	\$ 7	\$1,063,672	\$ (307)	\$ (935,701)	\$ 127,671

See accompanying notes.



**Coherus BioSciences, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**(in thousands, except share and per share data)**  
**(unaudited)**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	70,366,661	\$ 7	\$1,000,763	\$ (558)	\$ (894,998)	\$ 105,214
Issuance of common stock upon exercise of stock options	421,850	—	4,438	—	—	4,438
Issuance of common stock upon vesting of restricted stock units (RSUs)	10,000	—	—	—	—	—
Issuance of common stock upon 2019 bonus payout	134,099	—	2,378	—	—	2,378
Taxes paid related to net share settlement of bonus payout in RSUs	(49,616)	—	(880)	—	—	(880)
Stock-based compensation expense	—	—	9,945	—	—	9,945
Cumulative translation adjustment	—	—	—	608	—	608
Net income	—	—	—	—	35,572	35,572
Balances at March 31, 2020	70,882,994	\$ 7	\$1,016,644	\$ 50	\$ (859,426)	\$ 157,275

See accompanying notes.

**Coherus BioSciences, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
**(in thousands)**  
**(unaudited)**

	Three Months Ended	
	March 31,	
	2021	2020
<b>Operating activities</b>		
Net (loss) income	\$ (172,947)	\$ 35,572
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	849	607
Stock-based compensation expense	16,884	9,555
Write off of prepaid manufacturing services related to the termination of CHS-2020	3,210	—
Non-cash accretion of discount on marketable securities	279	—
Non-cash interest expense from amortization of debt discount	1,001	627
Non-cash operating lease expense	526	510
Upfront license fee payment to Shanghai Junshi Biosciences Ltd. ("Junshi Biosciences")	145,000	—
Other non-cash adjustments	173	636
Changes in operating assets and liabilities:		
Trade receivables, net	16,663	(25,626)
Inventory	(11,378)	(9,608)
Prepaid manufacturing	2,109	(3,100)
Other prepaid, current and non-current assets	(4,621)	(1,788)
Accounts payable	203	(4,959)
Accrued rebates, fees and reserve	(3,327)	15,037
Accrued compensation	(10,154)	(5,632)
Accrued and other current and non-current liabilities	16,897	1,646
Net cash provided by operating activities	<u>1,367</u>	<u>13,477</u>
<b>Investing activities</b>		
Purchases of property and equipment	(145)	(1,783)
Proceeds from disposal of property and equipment	—	167
Purchases of investments in marketable securities	(140,330)	—
Upfront license fee payment to Junshi Biosciences	(145,000)	—
Net cash used in investing activities	<u>(285,475)</u>	<u>(1,616)</u>
<b>Financing activities</b>		
Proceeds from issuance of common stock upon exercise of stock options	4,329	4,803
Taxes paid related to net share settlement of RSUs	(1,730)	(880)
Other immaterial financing activities	(160)	—
Net cash provided by financing activities	<u>2,439</u>	<u>3,923</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(281,669)	15,784
Cash, cash equivalents and restricted cash at beginning of period	541,598	177,908
Cash, cash equivalents and restricted cash at end of period	<u>\$ 259,929</u>	<u>\$ 193,692</u>
<b>Supplemental disclosure of cash flow information</b>		
Unpaid upfront license fee to Innovent included in Accounts Payable as of March 31, 2020	\$ —	\$ 5,000
Non-cash bonus payment settled in common stock	\$ —	\$ 1,498
Right-of-use assets obtained in exchange for lease obligations related to operating leases	\$ —	\$ 1,388
Right-of-use assets obtained in exchange for lease obligations related to finance leases	\$ 212	\$ 257

See accompanying notes.

**Coherus BioSciences, Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

**1. Organization and Summary of Significant Accounting Policies**

**Organization**

Coherus BioSciences, Inc. (the “Company” or “Coherus”) is a commercial-stage biotherapeutics company focused on the biosimilar and immuno-oncology market primarily in the United States. The Company’s headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company’s product pipeline comprise four drugs, CHS-1420 (an adalimumab (Humira) biosimilar), a ranibizumab (Lucentis) biosimilar in-licensed for U.S. and Canadian commercial rights from Bioeq AG, a bevacizumab (Avastin) biosimilar in-licensed for U.S. commercial rights from Innovent Biologics (Suzhou) Co., Ltd. and toripalimab, an anti-PD-1 antibody being developed in collaboration with Shanghai Junshi Biosciences Co., Ltd.

The Company commercializes UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, in the United States.

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements include the accounts of Coherus and its wholly-owned subsidiaries. Unless otherwise specified, references to the Company are references to Coherus and its consolidated subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the Securities Act of 1933, as amended (the “Securities Act”). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring accruals that the Company believes are necessary to fairly state the financial position and the results of the Company’s operations and cash flows for interim periods in accordance with U.S. GAAP. Interim-period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on February 25, 2021.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgements, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. Accounting estimates and judgements are inherently uncertain and the actual results could differ from these estimates.

### Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets which, in aggregate, represent the amount reported in the condensed consolidated statements of cash flows (in thousands):

	March 31, 2021	March 31, 2020
Cash and cash equivalents at beginning of period	\$ 541,158	177,668
Restricted cash - non-current at beginning of period	440	240
Total cash, cash equivalents and restricted cash at beginning of period	<u>\$ 541,598</u>	<u>177,908</u>
Cash and cash equivalents at end of period	\$ 259,489	\$ 193,252
Restricted cash - non-current at end of period	440	440
Total cash, cash equivalents and restricted cash at end of period	<u>\$ 259,929</u>	<u>\$ 193,692</u>

Restricted cash – non-current consists of deposits for letter of credits that the Company has provided to secure its obligations under certain facility and other leases.

### Investments in Marketable Securities

Investments in marketable securities primarily consist of corporate debt obligations and commercial paper. Management determines the appropriate classification of investments in marketable securities at the time of purchase based upon management's intent with regards to such investment and reevaluates such designation as of each balance sheet date. The Company's investment policy requires that it only invests in highly-rated securities and limit its exposure to any single issuer. All investments in debt marketable securities are held as "available-for-sale" and are carried at the estimated fair value as determined based upon quoted market prices or pricing models for similar securities.

The Company classifies investments in marketable securities as short-term when they have remaining contractual maturities of one year or less from the balance sheet date. Unrealized gains and losses are reported as a component of accumulated comprehensive income (loss), with the exception of unrealized losses believed to be related to credit losses, which, if any, are recognized in earnings in the period the impairment occurs. Impairment assessments are made at the individual security level each reporting period. When the fair value of an investment is less than its cost at the balance sheet date, a determination is made as to whether the impairment is related to a credit loss and, if it is, the portion of the impairment relating to credit loss is recorded as an allowance through net income. Realized gains and losses and declines in value, if any, on available-for-sale securities are included in other income, net, based on the specific identification method.

### Trade Receivables

Trade receivables are recorded net of allowances for chargebacks, chargeback prepayments, cash discounts for prompt payment and credit losses. The Company estimates an allowance for expected credit losses by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The corresponding expense for the credit loss allowance is reflected in selling, general and administrative expenses. The credit loss allowance was immaterial as of March 31, 2021.

## Recent Accounting Pronouncements

The following are the recent accounting pronouncements adopted by the Company in 2021:

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new guidance removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. It also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. This guidance is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company adopted this guidance as of January 1, 2021. The adoption did not have a material impact on the Company's condensed consolidated financial statements.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company adopted this guidance as of January 1, 2021. The adoption did not have a material impact on the Company's condensed consolidated financial statements.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or that no material effect is expected on the condensed consolidated financial statements as a result of future adoption.

## 2. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amounts of certain of the Company's financial instruments, including cash, cash equivalents, restricted cash, investments in marketable securities, accounts receivable, accounts payable and other current liabilities approximate their fair value due to their short maturities. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting guidance describes a fair value hierarchy based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable. These levels of inputs are the following:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The Company's financial instruments consist of Level 1 and Level 2 assets, and Level 3 liabilities. Where quoted prices are available in an active market, securities are classified as Level 1. Level 1 assets consist of highly liquid money market funds that are included in cash and cash equivalents, and restricted cash. There were no unrealized gains and losses in the Company's investments in these money market funds.

When quoted market prices are not available for the specific security, then the Company estimates the fair value by using quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount

the future amounts to a present value using market-based observable inputs obtained from various third party data providers, including but not limited to, benchmark yields, interest rate curves, reported trades, broker/dealer quotes and market reference data. Level 2 assets consist of corporate notes and commercial paper. Level 2 inputs for the valuations are limited to quoted prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3. Level 3 liabilities consist of the contingent consideration.

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows (in thousands):

	Fair Value Measurements March 31, 2021			
	Total	Level 1	Level 2	Level 3
<b>Financial Assets:</b>				
Money market funds	\$ 241,115	\$ 241,115	\$ —	\$ —
Restricted cash (money market funds)	440	440	—	—
Corporate notes and Commercial paper	157,033	—	157,033	—
<b>Total financial assets</b>	<b>\$ 398,588</b>	<b>\$ 241,555</b>	<b>\$ 157,033</b>	<b>\$ —</b>
<b>Financial Liabilities:</b>				
Contingent consideration	\$ 102	\$ —	\$ —	\$ 102

	Fair Value Measurements December 31, 2020			
	Total	Level 1	Level 2	Level 3
<b>Financial Assets:</b>				
Money market funds	\$ 538,673	\$ 538,673	\$ —	\$ —
Restricted cash (money market funds)	440	440	—	—
<b>Total financial assets</b>	<b>\$ 539,113</b>	<b>\$ 539,113</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Financial Liabilities:</b>				
Contingent consideration	\$ 102	\$ —	\$ —	\$ 102

Cash equivalents, marketable securities and restricted cash, consisted of the following (in thousands):

	March 31, 2021			
	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	\$ 241,115	\$ —	\$ —	\$ 241,115
Corporate notes and commercial paper	17,019	—	—	17,019
Classified as cash equivalents	\$ 258,134	\$ —	\$ —	\$ 258,134
Corporate notes and Commercial paper	\$ 140,051	\$ —	\$ (37)	\$ 140,014
Classified as marketable securities	\$ 140,051	\$ —	\$ (37)	\$ 140,014
Money market funds	\$ 440	\$ —	\$ —	\$ 440
Classified as restricted cash	\$ 440	\$ —	\$ —	\$ 440

	December 31, 2020			Fair Value
	Cost	Unrealized Gain	Unrealized (Loss)	
Money market funds	\$ 538,673	\$ —	\$ —	\$ 538,673
Classified as cash equivalents	\$ 538,673	\$ —	\$ —	\$ 538,673
Money market funds	\$ 440	\$ —	\$ —	\$ 440
Classified as restricted cash	\$ 440	\$ —	\$ —	\$ 440

As of March 31, 2021, the remaining contractual maturities of available-for-sale securities were less than one year. The average maturity of investments in available-for-sale marketable securities as of March 31, 2021 was approximately 9 months. The realized gains or losses on marketable securities for the periods presented were immaterial. None of the Company's investments in marketable securities has been in an unrealized loss position for more than one year. The Company determined that it has the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery and there is no indication of default on interest or principal payments for any of its debt securities, thus there has been no recognition of credit losses in the three months ended March 31, 2021 and 2020.

#### 1.5% Convertible Notes due 2026

The estimated fair value of the 1.5% Convertible Notes due 2026, which the Company issued in April 2020 (see Note 7) is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices observed in market trading. The market for trading of the Convertible Notes due 2026 is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs. The estimated fair value of the Convertible Notes due 2026 was approximately \$246.7 million (par value \$230.0 million) as of March 31, 2021.

#### 8.2% Convertible Notes due 2022

The estimated fair value of the 8.2% Convertible Senior Notes due 2022, which the Company issued in February 2016 (see Note 7) is based on an income approach. The estimated fair value was approximately \$112.0 million (par value \$100.0 million) as of March 31, 2021 and represents a Level 3 valuation. When determining the estimated fair value of the Company's long-term debt, the Company uses a single factor binomial lattice model, which incorporates the terms and conditions of the convertible notes and market based risk measurement that are indirectly observable, such as credit risk. The lattice model produces an estimated fair value based on changes in the price of the underlying common shares price over successive periods of time. An estimated yield based on market data is used to discount straight debt cash flows.

#### Term Loan

The principal amount outstanding under the Company's Term Loan (see Note 7) of \$75 million as of March 31, 2021 is subject to variable interest rate, which is based on a fixed percentage plus three month LIBOR ("LIBOR"), and as such, the Company believes the carrying amount of these obligations approximates fair value.

### 3. Inventory

Inventory consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Raw Materials	\$ 3,727	\$ 5,205
Work in process	61,644	43,952
Finished goods	38,307	43,032
Total	<u>\$ 103,678</u>	<u>\$ 92,189</u>

Balance sheet classifications (in thousands):

	March 31, 2021	December 31, 2020
Inventory	\$ 51,613	\$ 44,233
Inventory, non-current	52,065	47,956
Total	<u>\$ 103,678</u>	<u>\$ 92,189</u>

Inventory expected to be sold more than twelve months from the balance sheet date is classified as inventory, non-current on the condensed consolidated balance sheets. As of March 31, 2021 and December 31, 2020, the non-current portion of inventory consisted of raw materials and a portion of work in process.

Prepaid manufacturing of \$15.4 million as of March 31, 2021 includes prepayments of \$7.5 million to a contract manufacturing organization ("CMO") for manufacturing services for UDENYCA®, which the Company expects to be converted into inventory within the next twelve months; and prepayments of \$7.9 million to various CMOs for other research and development pipeline programs. Prepaid manufacturing of \$19.4 million as of December 31, 2020 included prepayments of \$8.9 million to a CMO for manufacturing services for UDENYCA®; and prepayments of \$10.5 million to various CMOs for other research and development pipeline programs.

Other Assets, non-current of \$10.7 million on the condensed consolidated balance sheet as of March 31, 2021 primarily includes \$9.4 million of operating lease right-of-use assets. Other Assets, non-current of \$12.5 million on the consolidated balance sheet as of December 31, 2020 primarily includes \$10.0 million of operating lease right-of-use assets and prepayments of \$1.3 million made to a CMO for manufacturing services for UDENYCA®.

In February 2021, the Company announced the discontinuation of the development of CHS-2020, a biosimilar of Eylea® as part of a realignment of research and development resources toward other development programs. As part of the discontinuation, the Company wrote-off prepaid manufacturing services not deemed to have any probable future benefits resulting in the recognition of an impairment charge of \$3.2 million within research and development expenses on the Company's condensed consolidated statement of operations. Additionally, the Company recognized an expense of \$8.3 million within research and development expenses on our condensed consolidated statement of operations in connection with the cancellation of open purchase orders with various vendors related to CHS-2020 development.



#### 4. Balance Sheet Components

##### Property and Equipment, Net

Property and equipment, net are as follows (in thousands):

	March 31, 2021	December 31, 2020
Machinery and equipment	\$ 13,739	\$ 13,301
Computer equipment and software	3,996	3,996
Furniture and fixtures	1,274	1,268
Leasehold improvements	5,898	5,830
Finance lease right of use assets	2,032	1,451
Construction in progress	10	312
Total property and equipment	<u>26,949</u>	<u>26,158</u>
Accumulated depreciation and amortization	<u>(17,279)</u>	<u>(16,050)</u>
Property and equipment, net	<u>\$ 9,670</u>	<u>\$ 10,108</u>

Total depreciation and amortization expense was \$0.8 million and \$0.6 million for the three months ended March 31, 2021 and 2020, respectively.

##### Accrued and Other Current Liabilities

Accrued and other current liabilities are summarized as follows (in thousands):

	March 31, 2021	December 31, 2020
Accrued clinical and manufacturing	\$ 30,608	\$ 11,365
Accrued other	10,944	12,182
Lease liabilities, current	<u>3,288</u>	<u>3,132</u>
Total Accrued and other current liabilities	<u>\$ 44,840</u>	<u>\$ 26,679</u>

#### 5. Revenue

The Company recorded net product revenue of \$83.0 million and \$116.2 million during the three months ended March 31, 2021 and 2020, respectively.

Revenue by significant customer was as follows:

	Three Months Ended	
	March 31, 2021 Percent of Total	March 31, 2020 Percent of Total
McKesson Corporation	39 %	41 %
AmeriSource-Bergen Corporation	38 %	35 %
Cardinal Health, Inc.	21 %	22 %
Others	2 %	2 %
Total revenue	<u>100 %</u>	<u>100 %</u>

## Product Sales Discounts and Allowances

The activities and ending reserve balances for each significant category of discounts and allowances, which constitute variable consideration, were as follows (in thousands):

	Three Months Ended March 31, 2021			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balance at December 31, 2020	\$ 40,580	\$ 54,058	\$ 28,760	\$ 123,398
Provision related to sales made in:				
Current period	114,670	30,233	25,130	170,033
Prior period	(2,316)	(1,888)	(823)	(5,027)
Payments and customer credits issued	(123,441)	(27,373)	(26,157)	(176,971)
Balance at March 31, 2021	\$ 29,493	\$ 55,030	\$ 26,910	\$ 111,433

	Three Months Ended March 31, 2020			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balance at December 31, 2019	\$ 35,159	\$ 27,494	\$ 24,494	\$ 87,147
Provision related to sales made in:				
Current period	102,652	29,456	29,384	161,492
Prior period	152	4,937	(4,051)	1,038
Payments and customer credits issued	(105,612)	(20,240)	(24,646)	(150,498)
Balance at March 31, 2020	\$ 32,351	\$ 41,647	\$ 25,181	\$ 99,179

Government and other chargebacks payable to our direct customers and discounts for prompt payment are recorded as a reduction in trade receivables, and the remaining reserve balances are classified as current liabilities in the accompanying unaudited condensed consolidated balance sheets.

## 6. License Agreements

### Shanghai Junshi Biosciences, Co., Ltd.

On February 1, 2021, the Company entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Junshi Biosciences for the co-development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody, in the United States and Canada.

Under the terms of the Collaboration Agreement, the Company paid \$150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, options in these territories to Junshi Biosciences' anti-TIGIT antibody and next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. The Company will have the right to conduct all commercial activities of toripalimab in the United States and Canada. The Company will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate \$380.0 million in one-time payments for the achievement of various milestones, including up to \$290.0 million for attainment of certain sales thresholds. If the Company exercises its options, it will be obligated to pay an option exercise fee for each of the anti-TIGIT antibody and the IL-2 cytokine of \$35.0 million per program. Additionally, for each exercised option, the Company will be obligated to pay Junshi Biosciences an 18% royalty on net sales and up to an aggregate \$255.0 million for the achievement of various milestones, including up to \$170.0 million for attainment of certain sales thresholds. Under the Collaboration Agreement, the Company retains the right to collaborate in the

development of toripalimab and the other licensed compounds and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The Company recorded research and development expense of \$145.0 million during the three months ended March 31, 2021, related to an upfront payment for exclusive rights to toripalimab in the United States and Canada. The Company had entered into a Right of First Negotiation agreement with Junshi Biosciences and paid a fee of \$5.0 million which was fully expensed as research and development expense in the fourth quarter of 2020. The Right of First Negotiation fees was fully credited against the total upfront license fee obligation under the collaboration agreement. As of March 31, 2021, the Company did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences.

The additional milestone payments, option fees for additional anti-TIGIT antibodies and the IL-2 cytokines and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved, option fees will be incurred or when royalties are due.

In connection with the Collaboration Agreement, the Company entered into a stock purchase agreement (the "Stock Purchase Agreement") with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in the Company. Pursuant to the Stock Purchase Agreement, on April 16, 2021, the Company issued 2,491,988 unregistered shares of its common stock to Junshi Biosciences, at a price per share of \$20.0643, for an aggregate value of approximately \$50.0 million cash, which was received in April 2021 by the Company. Under the terms of the Stock Purchase Agreement, Junshi Biosciences is not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two years period following its effective date. The Collaboration Agreement and the Stock Purchase Agreement were negotiated concurrently and were therefore evaluated as a single agreement. The Company used the "Finnerty" and "Asian put" valuation models and determined the fair value for the discount for lack of marketability ("DLOM") to be \$9.0 million. The fair value of the DLOM will be included as an offset against the research and development expense in the condensed consolidated statement of operations for the three months ending June 30, 2021.

#### **Innovent Biologics (Suzhou) Co., Ltd.**

On January 13, 2020, the Company entered into a license agreement (the "License Agreement") with Innovent Biologics (Suzhou) Co., Ltd. ("Innovent") for the development and commercialization of a biosimilar version of bevacizumab (Avastin®) in any dosage form and presentations ("bevacizumab Licensed Product") in the United States and Canada (the "Territory"). Under the License Agreement, Innovent granted to the Company an exclusive, royalty-bearing license to develop and commercialize the bevacizumab Licensed Product in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Avastin®. Under the License Agreement, the Company also acquired an option to develop and commercialize Innovent's biosimilar version of rituximab (Rituxan®) in any dosage form and presentations (the "rituximab Licensed Product" and together with the bevacizumab Licensed Product, the "Innovent Licensed Products") in the Territory. Subject to the terms of the License Agreement, the Company may exercise its option within 12 months of its receipt of certain regulatory materials from Innovent. Following the Company's option exercise, Innovent's biosimilar version of rituximab would be deemed an Innovent Licensed Product for all purposes of the License Agreement and Innovent would grant to the Company an exclusive, royalty-bearing license to develop and commercialize Innovent's biosimilar version of rituximab in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Rituxan®.

Innovent will supply the Innovent Licensed Products to the Company in accordance with a manufacturing and supply agreement to be executed by the parties. Under the License Agreement, the Company acquired the right to require Innovent to perform technology transfer for the manufacturing of the Innovent Licensed Products in the Territory and, upon completion of such technology transfer, the Company will have the exclusive right to manufacture the Innovent Licensed Products in the Territory.

Under the License Agreement, the Company committed to pay Innovent a \$5.0 million upfront payment and an aggregate of up to \$40.0 million in milestone payments in connection with the achievement of certain development,

regulatory and sales milestones with respect to the bevacizumab Licensed Product and, if the Company's option is exercised, an aggregate of up to \$40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the rituximab Licensed Product. The Company will share a percentage of net sales of Innovent Licensed Products with Innovent in the mid-teens to low twenty percent range. If the Company exercises its option to acquire Innovent's biosimilar version of rituximab (Rituxan®), it would be required to pay a fee of \$5.0 million. Subject to the terms of the License Agreement, if the Company requests Innovent to perform technology transfer for the manufacturing of the Innovent Licensed Products, it would be required to pay up to \$10.0 million for fees related thereto. The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The Company recorded research and development expense of \$5.0 million during the three months ended March 31, 2020, related to an upfront payment for the bevacizumab Licensed Product. As of March 31, 2021, the Company did not have any outstanding milestone or royalty payment obligations to Innovent.

The additional milestone payments, option fee for licensing of rituximab (Rituxan®), manufacturing technology transfer fee and royalties are contingent upon future events and, therefore, will be recorded when such payments become probable.

## **7. Convertible Notes and Term Loan**

### **1.5% Convertible Senior Subordinated Notes due 2026**

In April 2020, the Company issued and sold \$230.0 million aggregate principal amount of its 1.5% Convertible Senior Subordinated notes due 2026 (the "2026 Convertible Notes") in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The net proceeds from the offering were \$222.2 million after deducting initial purchasers' fees and offering expenses. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to the Company's designated senior indebtedness (as defined in the indenture for the 2026 Convertible Notes) and structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted.

At any time before the close of business on the second scheduled trading day immediately before the maturity date, noteholders may convert their 2026 Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per \$1,000 principal amount of the 2026 Convertible Notes, which represents an initial conversion price of approximately \$19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of \$14.815 per share of the Company's common stock on the Nasdaq Global Market on April 14, 2020. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a "make-whole fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, the Company will, in certain circumstances, increase the conversion rate for a specified period of time for noteholders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at the Company's election before maturity. If a "fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, noteholders may require the Company to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

The 2026 Convertible Notes have customary provisions relating to the occurrence of "events of default" (as defined in the Indenture for the 2026 Convertible Notes). The occurrence of such events of default could result in the acceleration of all amounts due under the 2026 Convertible Notes.

As of March 31, 2021, the Company was in full compliance with these covenants and there were no events of default under the 2026 Convertible Notes.

The 2026 Convertible Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and ASC 815-40, *Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or non-bifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. The Company determined that the 2026 Convertible Notes do contain embedded features indexed to its own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt were recorded as a liability on the condensed consolidated balance sheet.

#### *Capped Call Transactions*

In connection with the pricing of the 2026 Convertible Notes, the Company also paid \$18.2 million to enter into privately negotiated capped call transactions with one or a combination of the initial purchasers, their respective affiliates and other financial institutions (the "option counterparties"). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the 2026 Convertible Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the 2026 Convertible Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the 2026 Convertible Notes. The cap price of the capped call transactions will initially be \$25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of the Company's common stock of \$14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions.

The capped call transactions are accounted for as separate transactions from the 2026 Convertible Notes and classified as equity instruments. Therefore, the total \$18.2 million capped call premium paid was recorded as a reduction to additional paid-in capital in the condensed consolidated balance sheets. The capped calls will not be subsequently re-measured as long as the conditions for equity classification continue to be met.

The Company incurred \$0.9 million of debt issuance costs relating to the issuance of the 2026 Convertible Notes, which were recorded as a reduction to the notes on the condensed consolidated balance sheet. The debt issuance costs are being amortized and recognized as additional interest expense over the six-year contractual term of the notes using the effective interest rate method.

The following table summarizes components of the 2026 Convertible Notes (in thousands):

	March 31, 2021	December 31, 2020
Principal amount of the 2026 Convertible Notes	\$ 230,000	\$ 230,000
Unamortized debt discount and debt issuance costs	(6,659)	(6,971)
Total 2026 Convertible Notes	<u>\$ 223,341</u>	<u>\$ 223,029</u>

If the 2026 Convertible Notes were to be converted on March 31, 2021, the holders of the 2026 Convertible Notes would receive common shares with an aggregate value of \$174.5 million based on the Company's closing stock price of \$14.61 as of March 31, 2021.

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The following table presents the components of interest expense related to 2026 Convertible Notes (in thousands):

	Three Months Ended March 31,	
	2021	2020
Stated coupon interest	\$ 863	\$ —
Accretion of debt discount and debt issuance costs	312	—
Total interest expense	<u>\$ 1,175</u>	<u>\$ —</u>

The remaining unamortized debt discount and debt offering costs related to the Company's 2026 Convertible Notes of approximately \$6.7 million as of March 31, 2021, will be amortized using the effective interest rate over the remaining term of the 2026 Convertible Notes of 5 years. The annual effective interest rate is 2.11% for the 2026 Convertible Notes.

Future payments on the 2026 Convertible Notes as of March 31, 2021 are as follows (in thousands):

<u>Year ending December 31,</u>	
Remainder of 2021	\$ 3,450
2022	3,450
2023	3,450
2024	3,450
2025 and beyond	<u>235,175</u>
Total minimum payments	248,975
Less amount representing interest	<u>(18,975)</u>
2026 Convertible Notes, principal amount	230,000
Less debt discount and debt issuance costs on 2026 Convertible Notes	<u>(6,659)</u>
Net carrying amount of 2026 Convertible Notes	<u>\$ 223,341</u>

### 8.2% Convertible Notes due 2022

On February 29, 2016, the Company issued and sold \$100.0 million aggregate principal amount of its 8.2% Convertible Senior Notes (the "2022 Convertible Notes"). The 2022 Convertible Notes constitute general, senior unsubordinated obligations of the Company and are guaranteed by certain subsidiaries of the Company. The 2022 Convertible Notes bear interest at a fixed coupon rate of 8.2% per annum payable quarterly in arrears on March 31, June 30, September 30 and December 31 of each year, which commenced on March 31, 2016, and mature on March 31, 2022, unless earlier converted, redeemed or repurchased. The 2022 Convertible Notes also bear a premium of 9% of their principal amount, which is payable when the 2022 Convertible Notes mature or are repurchased or redeemed by the Company.

The 2022 Convertible Notes were issued to Healthcare Royalty Partners III, L.P., for \$75.0 million in aggregate principal amount, and to three related party investors, KKR Biosimilar L.P., MX II Associates LLC, and KMG Capital Partners, LLC, for \$20.0 million, \$4.0 million, and \$1.0 million, respectively, in aggregate principal amount.

The 2022 Convertible Notes are convertible at the option of the holder at any time prior to the close of business on the business day immediately preceding March 31, 2022 at the initial conversion rate of 44.7387 shares of common stock per \$1,000 principal amount of 2022 Convertible Notes, which is equivalent to an initial conversion price of approximately \$22.35 per share, and is subject to adjustment in certain events. Upon conversion of the 2022 Convertible Notes by a holder, the holder will receive shares of the Company's common stock together, if applicable, with cash in lieu of any fractional share.

The 2022 Convertible Notes are redeemable in whole, and not in part, at the Company's option with effect from March 31, 2020, if the last reported sale price per share of common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which the Company sends notice of such redemption to the holders of the 2022 Convertible Notes. At maturity or redemption, if not earlier converted, the Company will pay 109% of the principal amount of the 2022 Convertible Notes maturing or being redeemed, together with accrued and unpaid interest, in cash.

The 2022 Convertible Notes contain customary negative covenants and events of default, the occurrence of which could result in the acceleration of all amounts due under the 2022 Convertible Note. As of March 31, 2021, the Company was in full compliance with these covenants and there were no events of default under the 2022 Convertible Notes.

The 2022 Convertible Notes are accounted for in accordance with ASC 470-20. Pursuant to ASC 470-20, the Company evaluated the features embedded in the 2022 Convertible Notes and concluded that the embedded features are not required to be bifurcated and accounted for separately from the host debt instrument.

On April 13, 2020, the Company entered into an amendment (the "Second Amendment") to the 2022 Convertible Note Purchase Agreement, dated as of February 29, 2016 (the "Note Purchase Agreement"), which amended the definition of Restricted Payment to exclude any payment (including a premium) to a counterparty under a "Permitted Bond Hedge Transaction" (as defined in the Note Purchase Agreement). The Second Amendment also added to the Note Purchase Agreement a definition of "Permitted Bond Hedge Transaction", with such definition including any capped call option (or substantively equivalent derivative transaction) relating to the Company's common stock purchased by it in connection with any issuance of indebtedness or convertible indebtedness.

The following table summarizes components of the 2022 Convertible Notes (in thousands):

	March 31, 2021	December 31, 2020
Principal amount of the 2022 Convertible Notes	\$ 81,750	\$ 81,750
Unamortized debt discount and debt issuance costs	(1,510)	(1,865)
2022 Convertible Notes	\$ 80,240	\$ 79,885
Principal amount of the 2022 Convertible Notes - related parties	\$ 27,250	\$ 27,250
Unamortized debt discount and debt issuance costs - related parties	(503)	(622)
2022 Convertible Notes - related parties	\$ 26,747	\$ 26,628
Total 2022 Convertible Notes	<u>\$ 106,987</u>	<u>\$ 106,513</u>

The 2022 Convertible notes and the 2022 Convertible Notes – related parties were classified in current liabilities as of March 31, 2021 and in non-current liabilities as of December 31, 2020 on the condensed consolidated balance sheets. If the 2022 Convertible Notes were to be converted on March 31, 2021, the holders of the 2022 Convertible Notes would receive common shares with an aggregate value of \$65.4 million based on the Company's closing stock price of \$14.61.



The following table presents the components of interest expense (in thousands):

	Three Months Ended	
	March 31,	
	2021	2020
Stated coupon interest	\$ 1,538	\$ 1,538
Accretion of debt discount and debt issuance costs	356	324
Interest expense	\$ 1,894	\$ 1,862
Stated coupon interest - related parties	\$ 512	\$ 512
Accretion of debt discount and debt issuance costs - related parties	119	108
Interest expense - related parties	\$ 631	\$ 620
Total interest expense	<u>\$ 2,525</u>	<u>\$ 2,482</u>

The remaining unamortized debt discount and debt offering costs related to the 2022 Convertible Notes of approximately \$2.0 million as of March 31, 2021, will be amortized using the effective interest rate over the remaining term of the 2022 Convertible Notes of one year. The annual effective interest rate is 9.48% for the 2022 Convertible Notes.

Future payments on the 2022 Convertible Notes as of March 31, 2021 are as follows (in thousands):

<u>Year ending December 31,</u>	
Remainder of 2021	\$ 6,150
2022	111,050
Total minimum payments	117,200
Less amount representing interest	(8,200)
2022 Convertible Notes, principal amount	109,000
Less debt discount and debt issuance costs on 2022 Convertible Notes	(2,013)
Net carrying amount of 2022 Convertible Notes	<u>\$ 106,987</u>

#### Term Loan

On January 7, 2019 (“the “Term Loan Closing Date”), the Company entered into a credit agreement (the “Term Loan”) with affiliates of Healthcare Royalty Partners (together, the “Lender”). The Term Loan consists of a six-year term loan facility for an aggregate principal amount of \$75.0 million (the “Borrowings”). The obligations of the Company under the loan documents are guaranteed by the Company’s material domestic U.S. subsidiaries.

The Borrowings under the Term Loan bear interest through maturity at 6.75% per annum plus three-month LIBOR. Interest is payable quarterly in arrears. The Company adopted the prospective method to account for future cash payments. Under the prospective method, the effective interest rate is not constant, and any change in the expected cash flows is recognized prospectively as an adjustment to the effective yield. As of March 31, 2021, the effective interest rate is 10.47%.

The Company is required to pay principal on the Borrowings in equal quarterly installments beginning on the fourth anniversary of the Term Loan Closing Date (or, if consolidated net sales of UDENYCA® in the fiscal year ending December 31, 2021 are less than \$375.0 million, beginning on the third anniversary of the Term Loan Closing Date), with the outstanding balance to be repaid on January 7, 2025, the maturity date.

The Company is also required to make mandatory prepayments of the Borrowings under the Term Loan, subject to specified exceptions, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events including the occurrence of a change in control.



If all or any of the Borrowings are prepaid or required to be prepaid under the Term Loan, then the Company shall pay, in addition to such prepayment, a prepayment premium equal to (i) with respect to any prepayment paid or required to be paid on or prior to the third anniversary of the credit agreement closing date, 5.00% of the Borrowings prepaid or required to be prepaid, plus all required interest payments that would have been due on the Borrowings prepaid or required to be prepaid through and including the three year anniversary of the term loan closing date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the term loan closing date but on or prior to the four year anniversary of the term loan closing date, 5.00% of the Borrowings prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after the fourth anniversary of the term loan closing date but on or prior to the fifth anniversary of the term loan closing date, 2.50% of the Borrowings prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 1.25% of the Borrowings prepaid or required to be prepaid.

In connection with the Term Loan, the Company paid a fee to the Lender of \$1.1 million at closing in the form of an original issue discount. Upon the prepayment or maturity of the Borrowings (or upon the date such prepayment or repayment is required to be paid), it is required to pay an additional exit fee in an amount equal to 4.00% of the total principal amount of the Borrowings.

The obligations under the Term Loan are secured by a lien on substantially all of the Company's and its Guarantors' tangible and intangible property, including intellectual property. The Term Loan contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, restrict the ability of the Company and its subsidiaries to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, or in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA® must not be lower than \$150.0 million for each fiscal year after the fiscal year ending December 31, 2020. A failure to comply with these covenants could permit the Lender under the Term Loan to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

On April 13, 2020, the Company entered into an amendment to the Term Loan, which amended the Term Loan's indebtedness covenant such that the Company could incur Convertible Bond Indebtedness (as defined in the credit agreement governing the Term Loan) in an amount not to exceed the greater of \$230.0 million or 20% of the Company's market capitalization.

As of March 31, 2021, the Company was in full compliance with these covenants and there were no events of default under the Term Loan.

The following table summarizes information about the components of the Term Loan (in thousands):

	March 31, 2021	December 31, 2020
Principal amount of the Term Loan	\$ 75,000	\$ 75,000
Unamortized debt discount and debt issuance costs	(304)	(519)
Term Loan	<u>\$ 74,696</u>	<u>\$ 74,481</u>

The following table presents the components of interest expense (in thousands):

	Three Months Ended March 31,	
	2021	2020
Stated coupon interest	\$ 1,734	\$ 1,754
Accretion of debt discount and debt issuance costs	215	195
Interest expense	<u>\$ 1,949</u>	<u>\$ 1,949</u>

The remaining unamortized debt discount and debt offering costs related to the Term Loan of approximately \$0.3 million as of March 31, 2021, will be amortized using the effective rate over the remaining term of the Term Loan of 3.75 years.

Future payments on the Term Loan as of March 31, 2021 are as follows (in thousands):

<u>Year ending December 31,</u>	
Remainder of 2021	\$ 5,299
2022	7,034
2023	39,187
2024	36,073
2025	11,348
Total minimum payments	98,941
Less amount representing interest	(20,941)
Term Loan, gross	78,000
Less debt discount and debt issuance costs on Term Loan	(3,304)
Net carrying amount of Term Loan	<u>\$ 74,696</u>

## 8. Commitments and Contingencies

### Purchase Commitments

The Company entered into agreements with a vendor to secure raw materials and a CMO to manufacture its commercial supply of UDENYCA<sup>®</sup>. As of March 31, 2021, the Company's contractual obligations under the terms of the agreements are as follows (in thousands):

<u>Years ending December 31,</u>	
Remainder of 2021	\$ 34,204
2022	15,946
2023	9,753
2024	600
Total obligations	<u>\$ 60,503</u>

The Company enters into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and contract manufacturing organizations for the manufacture of clinical trial materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for products or services that the Company had received as of the effective date of the termination and any applicable cancellation fees.

### Guarantees and Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company would assess the likelihood of any adverse judgments or related claims, as well as ranges of probable losses. In the cases where the Company believes that a reasonably possible or probable loss exists, it will disclose the facts and circumstances of the claims, including an estimate range, if possible.

## 9. Leases

In July 2015, the Company entered into the office space for its corporate headquarters in Redwood City, California under an operating lease agreement, which has been subject to amendments to secure additional space such that the total headquarters leased space is approximately 47,789 square feet. The lease agreement, provides for certain limited rent abatement and contains annual scheduled rent increases over the lease term. The lease terminates in September 2024 and contains a one-time option to extend the lease term for five years.

The Company also leases laboratory facilities in Camarillo, California. In October 2019, the Company entered into a new laboratory facility lease ("New Camarillo Lease") of approximately 25,017 square feet in a new location in Camarillo, California as the current Camarillo leases terminated in June 2020 and December 2020. The New Camarillo Lease provides for certain limited rent abatement and annual scheduled rent increases over the lease term. The lease commenced in January 2020 and terminates in May 2027, and contains a one-time option to extend the lease term for five years.

The Company determined that the above facility leases were operating leases. The options to extend the lease terms for these leases were not included as part of the right-of-use asset or lease liability as the Company was not reasonably certain it would exercise those options.

In 2019, the Company entered into a vehicle lease agreement, pursuant to which it currently leases approximately 50 vehicles. Delivery of the vehicles commenced during the first quarter of 2020. The term of each leased vehicle commences upon the delivery of the vehicle and is for a period of 36 months. The vehicles leased under this arrangement were classified as finance leases.

In determining the present value of the lease payments, the Company used the incremental borrowing rate based on the information available on January 1, 2019 (adoption date of ASC 842) for the leases that commenced prior to that date. For all other leases, the Company used the incremental borrowing rate on the lease commencement or the lease modification date, as applicable.

The supplemental information related to Company's leases is as follows (in thousands):

		March 31, 2021	December 31, 2020
<b>Assets</b>	<b>Balance Sheet Classification</b>		
Operating lease	Other assets, non-current	\$ 9,430	\$ 9,956
Finance lease	Property and equipment, net	1,508	1,451
Total leased assets		<u>\$ 10,938</u>	<u>\$ 11,407</u>
<b>Liabilities</b>	<b>Balance Sheet Classification</b>	March 31, 2021	December 31, 2020
Operating lease liabilities, current	Accrued and other current liabilities	\$ 2,651	\$ 2,573
Operating lease liabilities, non-current	Lease liabilities, non-current	8,375	9,073
Total operating lease liabilities		<u>\$ 11,026</u>	<u>\$ 11,646</u>
Finance lease liabilities, current	Accrued and other current liabilities	\$ 637	\$ 560
Finance lease liabilities, non-current	Lease liabilities, non-current	869	875
Total finance lease liabilities		<u>\$ 1,506</u>	<u>\$ 1,435</u>

Operating lease costs were \$0.8 million for each of the three months ended March 31, 2021 and 2020. Cash paid for amounts included in the measurement of the operating lease liabilities for the three months ended March 31, 2021 and 2020 was \$0.9 million and \$0.8 million, respectively, and was included in net cash used in operating activities in the

condensed consolidated statements of cash flows. Finance lease costs and cash paid for amounts included in the measurement of finance lease liabilities were immaterial during the three months ended March 31, 2021 and 2020.

As of March 31, 2021, the maturities of the operating and finance lease liabilities were as follows (in thousands):

Years ending December 31,	Operating leases	Finance leases
Remainder of 2021	\$ 2,572	\$ 530
2022	3,293	700
2023	3,438	360
2024	2,889	16
2025 and beyond	700	—
Total lease payments	12,892	1,606
Less imputed interest	(1,866)	(100)
Lease liabilities	\$ 11,026	\$ 1,506

As of March 31, 2021 and December 31, 2020, the weighted average remaining lease term for operating leases was 3.8 years and 4.1 years, respectively. The weighted average discount rate used to determine the operating lease liabilities was 8.1% as of March 31, 2021 and December 31, 2020. The weighted average remaining lease term for finance leases was 2.3 years as of March 31, 2021 and 2.4 years as of December 31, 2020. The weighted average discount rate used to determine the finance lease liabilities was 5.8% as of March 31, 2021 and December 31, 2020.

#### 10. Stock-Based Compensation

The following table summarizes the classification of stock-based compensation expense in our condensed consolidated statements of income related to options and restricted stock units granted to employees and nonemployees (in thousands):

	Three Months Ended	
	March 31,	
	2021	2020
Cost of goods sold (1)	\$ 191	\$ 45
Research and development	6,432	3,590
Selling, general and administrative	10,261	5,920
Stock-based compensation expense	\$ 16,884	\$ 9,555
Capitalized stock-based compensation expense into inventory at March 31	\$ 289	\$ 434

(1) Stock-based compensation capitalized into inventory is recognized as cost of goods sold when the related product is sold.

#### 11. Net Income (loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Diluted net income per share was computed by dividing the net income by the weighted average number of common shares outstanding for the period plus any diluted potential common shares outstanding for the period determined using the treasury stock method for options, RSUs and ESPP and using the if-converted method for the convertible notes. Since the Company was in a net loss position for the three months ended March 31, 2021, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive for that period.

The following table sets forth the computation of the basic and diluted net income per share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2021	2020
<b>Basic net (loss) income per share</b>		
<b>Numerator:</b>		
Net (loss) income	\$ (172,947)	\$ 35,572
<b>Denominator:</b>		
Weighted-average common shares outstanding	72,832,953	70,662,185
Basic net (loss) income per share	\$ (2.37)	\$ 0.50
<b>Diluted net income (loss) per share</b>		
<b>Numerator:</b>		
Net (loss) income	\$ (172,947)	\$ 35,572
<b>Denominator:</b>		
Denominator for basic net (loss) income per share	72,832,953	70,662,185
<b>Add effect of potential dilutive securities:</b>		
Stock options, including purchases from contributions to ESPP	—	3,666,137
Restricted stock units	—	88,232
Denominator for diluted net (loss) income per share	72,832,953	74,416,554
Diluted net (loss) income per share	\$ (2.37)	\$ 0.48

The following outstanding dilutive potential shares were excluded from the calculation of diluted net income per share due to their anti-dilutive effect:

	Three Months Ended March 31,	
	2021	2020
Stock options, including purchases from contributions to ESPP	19,889,972	8,862,891
Restricted stock units	1,691,310	4,135
Shares issuable upon conversion of 2022 Convertible Notes	4,473,871	4,473,871
Shares issuable upon conversion of 2026 Convertible Notes	11,942,152	—
<b>Total</b>	<b>37,997,305</b>	<b>13,340,897</b>

## 12. Income Taxes

There was no income tax expense for the three months ended March 31, 2021 due to a projected tax loss for 2021 and the tax effect of the valuation allowance against such loss for the year. Income tax expense of 0.9 million for the three months ended March 31, 2020, primarily related to state taxes in jurisdictions outside of California, for which the Company has a limited operating history. Income tax provision during the interim periods is based on applying an estimated annual effective income tax rate to year to date income, plus any significant unusual or infrequently occurring items, which are recorded in the interim period. The Company maintains a full valuation allowance against its net deferred tax assets due to its history of losses.

## 13. Related Party Transactions

### Convertible Notes

In February 2016, the Company issued Convertible Notes to certain related parties (certain companies affiliated with members of the Company's board of directors), for an aggregate principal amount of \$25.0 million (see Note 7).

### **Consulting services**

In October 2020, the Company entered into a consulting agreement with Lanfear advisors owned by Mr. Jonathan Lanfear who is the brother of Dennis Lanfear, our President, Chief Executive Officer and Chairman of our Board of Directors. Mr. Jonathan Lanfear provided consulting services with respect to the Collaboration Agreement executed with Junshi Biosciences in February 2021 (See Note 6). In addition to the hourly consulting fee paid to Lanfear advisors under the consulting agreement, the Company granted fully vested stock options to purchase 65,000 shares of common stock with an exercise price of \$17.60 per share to Mr. Jonathan Lanfear in February 2021 upon the execution of the Collaboration Agreement with Junshi Biosciences. The Company recognized a cash consulting expense of \$0.2 million and stock based compensation expense of \$0.8 million with respect to these consulting services during the three months ended March 31, 2021. Total liabilities recognized in Accounts payable and Accrued liabilities in the condensed consolidated balance sheets with respect to these services were \$30,094 and \$286,640 as of March 31, 2021 and December 31, 2020, respectively.

## **ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Annual Report on Form 10-K filed with the SEC on February 25, 2021. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended "Exchange Act". These forward-looking statements are subject to risks and uncertainties, including those discussed in the section titled "Risk Factors," set forth in Part II – Other Information, Item 1A below and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.*

### **Overview**

We are a commercial-stage biopharmaceutical company with a mission to increase patient access to cost-effective medicines that can have a major impact on their lives and to deliver significant savings to the health care system. Our first product, UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta®, a long-acting granulocyte-colony stimulating factor, was launched commercially in the United States in January 2019. Biosimilars are a class of protein-based therapeutics with high similarity to approved originator products on the basis of various structural and biologic properties, as well as in terms of safety and efficacy. We have become a leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production, clinical-regulatory development and commercialization. In addition to UDENYCA®, we have a product candidate pipeline that includes biosimilars of Humira®, Avastin® and Lucentis®.

We are investing cash flows generated by our commercial biosimilars business to build a leading immuno-oncology franchise in the United States and Canada. In February 2021, we in-licensed Junshi Biosciences' toripalimab, a novel anti-PD-1 antibody, which was first approved in 2018 for second-line treatment of melanoma in China, where it is marketed by Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences"). Toripalimab has been extensively evaluated in late-stage clinical trials for the treatment of multiple tumor types. We and Junshi Biosciences initiated a rolling submission of the biologic license application ("BLA") to the United States Food and Drug Administration ("FDA") in March 2021 for the treatment of third-line nasopharyngeal carcinoma, an indication for which the FDA has granted toripalimab Breakthrough Therapy Designation. Within the next several years, we and Junshi Biosciences anticipate submitting BLAs for multiple additional indications for rare and highly prevalent tumor types, including non-small cell lung cancer. We have also acquired options to license two pipeline immuno-oncology product candidates from Junshi Biosciences, an anti-TIGIT antibody and a next-generation engineered IL-2 cytokine, which we plan to evaluate in combination with toripalimab.

With our UDENYCA commercialization efforts, we have built a strong, oncology-focused commercial capability in the United States. We expect to leverage this commercial capability as we build our immuno-oncology franchise if toripalimab and potential combination product candidates are approved.

Our pipeline includes the following product candidates:

### **Oncology Pipeline**

- Toripalimab, an anti-PD-1 antibody being developed in collaboration with Junshi Biosciences, a leading Chinese biotechnology company. More than thirty company-sponsored clinical studies covering more than fifteen indications have been conducted globally, including in China and the United States, on toripalimab. On December 17, 2018, toripalimab obtained a conditional approval from the National Medical Products Administration of China ("NMPA") for the second-line treatment of patients with unresectable or

metastatic melanoma, making it the first Chinese domestic anti-PD-1 monoclonal antibody to obtain marketing approval in China. In December 2020, toripalimab was included in the National Reimbursement Drug List (“NRDL”) for the treatment of melanoma by the China National Healthcare Security Administration (“NHSA”). In February 2021, the supplemental new drug application (“NDA”) for toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic nasopharyngeal carcinoma was accepted by the NMPA. Also in February 2021, the NMPA granted a conditional approval to toripalimab for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma (“NPC”) after failure of at least two lines of prior systemic therapy. In April 2021, NMPA granted a conditional approval to toripalimab for the treatment of patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

In the United States, toripalimab was granted the Breakthrough Therapy designation for the treatment of recurrent/metastatic nasopharyngeal carcinoma by the FDA in September 2020. The FDA has also granted toripalimab Fast Track designation for the treatment of mucosal melanoma and orphan drug designations for treatment of nasopharyngeal carcinoma, mucosal melanoma and soft tissue sarcoma.

We initiated a rolling submission of toripalimab Biologics License Application (“BLA”) to the FDA for recurrent/metastatic nasopharyngeal carcinoma in March 2021. In addition to nasopharyngeal carcinoma, we and Junshi Biosciences plan to submit BLAs to the FDA for toripalimab within the next two years for the treatment of several rare and highly prevalent cancers, including non-small cell lung cancer.

- UDENYCA® (pegfilgrastim-cbqv). We are continuing to develop additional presentations of UDENYCA®.
- Bevacizumab (Avastin) biosimilar and option to license rituximab (Rituxan®) biosimilar. On January 13, 2020, we entered into a license agreement with Innovent Biologics (Suzhou) Co., Ltd. (“Innovent,” and with respect to the license agreement with Innovent, the “Innovent Agreement”) for the development and commercialization of a biosimilar version of bevacizumab (Avastin) in any dosage form and presentations (“bevacizumab Licensed Product”) in the United States and Canada. Under the Innovent Agreement, Innovent granted us an exclusive, royalty-bearing license to develop and commercialize the bevacizumab Licensed Product for the prevention or amelioration of any human diseases and conditions as included in the label of Avastin. We also acquired an option for twelve months to develop and commercialize Innovent’s biosimilar version of rituximab (Rituxan®) in any dosage form and presentations in the United States and Canada.

We are performing a three-way pharmacokinetic (“PK”) study using Avastin drug products from the United States, Avastin drug products from China and Innovent’s biosimilar to bevacizumab, as well additional analytical similarity exercises prior to submitting a BLA for a biosimilar product candidate, or a 351(k) BLA, to the FDA.

### ***Immunology Pipeline***

- CHS-1420 (our adalimumab (Humira) biosimilar candidate). We are developing CHS-1420, an anti-TNF product candidate, as an adalimumab (Humira) biosimilar. In the fourth quarter of 2020, we submitted the 351(k) BLA, which was accepted for review by the FDA in February 2021. The user fee goal date is in December 2021. If approved, we anticipate we would be able to launch CHS-1420 in the United States on or after July 1, 2023, in accordance with settlement and license agreements with AbbVie Inc. (“AbbVie”) that grants us global, non-exclusive license rights under AbbVie’s intellectual property to commercialize CHS-1420.



### ***Ophthalmology Pipeline***

- Ranibizumab (Lucentis) Biosimilar. On November 4, 2019, we entered into a license agreement with Bioeq IP AG (now Bioeq AG or “Bioeq”) for the commercialization of a biosimilar version of ranibizumab (Lucentis) in certain dosage forms in both a vial and pre-filled syringe presentation. Under this agreement, Bioeq granted to us an exclusive royalty-bearing license to commercialize Bioeq’s biosimilar to ranibizumab in the field of ophthalmology (and any other approved labelled indication) in the United States.

The Bioeq ranibizumab biosimilar candidate demonstrated similar binding and bioactivity as Lucentis (ranibizumab) and met its primary endpoint in a wet age-related macular degeneration (“wet AMD”) Phase 3 study. At the request of a national European health authority addressed to Bioeq’s drug substance contract manufacturer, the manufacturer moved a piece of processing equipment to a different location within the same site after the production of the Bioeq ranibizumab biosimilar candidate qualification batches was completed. The FDA requested additional manufacturing data for the equipment in its new location in the context of its review of the 351(k) BLA. As a result, Bioeq decided to withdraw its 351(k) BLA for this candidate and provide the requested data. During the first quarter of 2021, Bioeq received positive pre-BLA filing feedback from the FDA on the requested manufacturing data, and the FDA indicated support of Bioeq’s current plans to proceed with the resubmission of its 351(k) BLA. Bioeq has indicated that it expects to resubmit the BLA in mid-2021.

### ***Small Molecule Pipeline***

- CHS-131 (our oral, small-molecule drug candidate). CHS-131 is a novel, potential first-in-class, once-daily oral drug candidate for non-alcoholic steatohepatitis (“NASH”) and other metabolic conditions. In February 2020, we announced that we are seeking strategic alternatives to finance this program externally.

### ***COVID-19 Update***

As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies. See “Risk Factors”. These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA®’s market position or increase its penetration against all Neulasta’s dosage forms, and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth. Until the COVID-19 pandemic is controlled, we expect it may continue to adversely impact our sales growth.

While the long-term economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and could negatively affect our liquidity and the liquidity and stability of markets for our common stock and our convertible notes. In addition, a recession, further market correction or depression resulting from the spread of COVID-19 could materially affect our business and the value of our notes and our common stock.

### **Financial Operations Overview**

#### ***Revenue***

We recorded net product revenue of \$83.0 million and \$116.2 million during the three months ended March 31, 2021 and 2020, respectively.

### **Cost of Goods Sold**

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with UDENYCA®. A portion of the costs of producing UDENYCA® sold to date was expensed as research and development prior to the FDA approval of UDENYCA® and therefore it is not reflected in the cost of goods sold.

On May 2, 2019, we settled a trade secret action brought by Amgen Inc. and Amgen USA Inc. (collectively "Amgen"). As a result, the cost of goods sold reflects a mid-single digit royalty on net product revenue, which began on July 1, 2019. The royalty cost will continue for five years per the terms of the settlement agreement.

### **Research and Development Expense**

Research and development expense represents costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. We currently track research and development costs incurred on a product candidate basis only for external research and development expenses. Our external research and development expense consists primarily of:

- expense incurred under agreements with consultants, third-party contract research organizations ("CROs"), and investigative sites where a substantial portion of our preclinical studies and all of our clinical trials are conducted;
- costs of acquiring originator comparator materials and manufacturing preclinical study and clinical trial supplies and other materials from contract manufacturing organizations ("CMOs"), and related costs associated with release and stability testing;
- costs associated with manufacturing process development activities; and
- upfront and milestone payments related to licensing and collaboration agreements.

Internal costs are associated with activities performed by our research and development organization and generally benefit multiple programs. These costs are not separately allocated by product candidate. Unallocated, internal research and development costs consist primarily of:

- personnel-related expense, which includes salaries, benefits and stock-based compensation; and
- facilities and other allocated expense, which includes direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment, laboratory and other supplies.

The largest component of our total operating expense has historically been our investment in research and development activities, including the clinical development and manufacturing process development of our product candidates. We received regulatory approval for UDENYCA® and as a result, all of our manufacturing costs for this product are capitalized as inventory and subsequently expensed as costs of goods sold when the inventory is sold.

We consider regulatory approval of product candidates to be uncertain, and any products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. We expense manufacturing costs as incurred for product candidates prior to regulatory approval as research and development expense. If, and when, regulatory approval of a product candidate is obtained, we will begin capitalizing manufacturing costs related to the approved product into inventory.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming. Furthermore, in the past, we have entered into collaborations with third parties to participate in the development and commercialization of our product candidates, and we may enter into additional collaborations in the future. In situations in which third parties have substantial influence over the development activities for product candidates, the estimated completion dates are not fully under our control. For example, our partners in licensed territories may exert considerable influence on the regulatory filing process globally. Therefore, we cannot forecast with any degree of certainty the duration and completion costs of these or other current or future clinical trials of our product candidates. We may never succeed in achieving regulatory approval for any of our pipeline product candidates. In addition, we may enter into other collaboration arrangements for our other product candidates, which could affect our development plans or capital requirements.

### ***Selling, General and Administrative Expense***

Selling, general and administrative expense consists primarily of personnel costs, allocated facilities costs and other expense for outside professional services, including legal, insurance, human resources, outside marketing, advertising, audit and accounting services, as well as costs associated with establishing commercial capabilities in support of the commercialization of UDENYCA<sup>®</sup>. Personnel costs consist of salaries, benefits and stock-based compensation.

### ***Interest Expense***

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and debt issuance costs associated with our various outstanding debt agreements.

### ***Other Income, Net***

Other income, net consists primarily of interest earned from our investments in marketable securities and foreign exchange gains and losses resulting from currency fluctuations.

### **Significant Transactions**

#### **License Agreement with Junshi Biosciences**

On February 1, 2021, we entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Junshi Biosciences for the co-development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody in the United States and Canada (the "Collaboration").

Under the terms of the Collaboration Agreement, we paid \$150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, options in these territories to Junshi Biosciences' anti-TIGIT antibody and next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. We will have the right to conduct all commercial activities of toripalimab in the United States and Canada. We will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate \$380.0 million in one-time payments for the achievement of various milestones, including up to \$290.0 million for attainment of certain sales thresholds. If we exercise our options, we will be obligated to pay an option exercise fee for each of the anti-TIGIT antibody and the IL-2 cytokine of \$35.0 million per program. Additionally, for each exercised option, we will be obligated to pay Junshi Biosciences an 18% royalty on net sales and up to an aggregate \$255.0 million for the achievement of various milestones, including up to \$170.0 million for attainment of certain sales thresholds. Under the Collaboration Agreement, we retain the right to collaborate in the development of toripalimab and the other licensed compounds, and will pay for a portion of these co-development activities up to a maximum of \$25.0 million per licensed compound per year. We accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. We recorded research and development expense of \$145.0 million during the three months ended March 31,

2021, related to an upfront payment for exclusive rights to toripalimab in the United States and Canada. We had entered into a Right of First Negotiation agreement with Junshi Biosciences and paid a fee of \$5 million which was fully expensed as research and development expense in the fourth quarter of 2020. The Right of First Negotiation fees was fully credited against the total upfront license fee obligation under the collaboration agreement. As of March 31, 2021 we did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences.

The additional milestone payments, option fees for additional anti-TIGIT antibodies and the IL-2 cytokines and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved, option fees will be incurred or when royalties are due.

In connection with the Collaboration Agreement, we entered into a stock purchase agreement (the "Stock Purchase Agreement") with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in the Company. Pursuant to the Stock Purchase Agreement, on April 16, 2021, we issued 2,491,988 unregistered shares of our common stock to Junshi Biosciences, at a price per share of \$20.0643, for an aggregate value of approximately \$50.0 million cash, which was received in April 2021 by us. Under the terms of the Stock Purchase Agreement, Junshi Biosciences is not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two years period following its effective date. The Collaboration Agreement and the Stock Purchase Agreement were negotiated concurrently and were therefore evaluated as a single agreement. We used the "Finnerty" and "Asian put" valuation models and determined the fair value for the discount for lack of marketability ("DLOM") to be \$9.0 million at the date the shares were issued. The fair value of the DLOM is attributable to the Collaboration Agreement and will be included as an offset against the research and development expense in the condensed consolidated statement of operations for the three months ending June 30, 2021.

#### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make judgements, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue and expenses, and related disclosures. As appropriate, we periodically evaluate our critical accounting policies and estimates. Our estimates are based on historical experience and on various other factors that we believed to be reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Accounting estimates and judgements are inherently uncertain and actual results could differ from these estimates.

There have been no significant changes to our accounting policies during the three months ended March 31, 2021, as compared to the significant accounting policies described in our Annual Report on Form 10-K filed with the SEC on February 25, 2021. We believe that the accounting policies discussed in the Annual Report are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

#### **Recent Accounting Pronouncements**

For a description of the expected impact of recent accounting pronouncements, see "Note 1. Organization and Summary of Significant Accounting Policies" in the "Notes to Condensed Consolidated Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

**Results of Operations****Comparison of Three Months Ended March 31, 2021 and 2020***Net Revenue*

	Three Months Ended March 31,		Change
	2021	2020 (in thousands)	
Net product revenue	\$ 83,034	\$ 116,180	\$ (33,146)

Net product revenue for the three months ended March 31, 2021 and 2020 was 83.0 million and \$116.2 million, respectively, a decrease of \$33.1 million. This decrease was primarily due to a decrease in the number of units of UDENYCA® sold and an increase in discounts and allowances incurred during the three months ended March 31, 2021.

We expect net product revenue and market penetration to rise in the second half of 2021, assuming the COVID-19 pandemic recedes and treatment patterns normalize, and subject to pricing trends in the overall pegfilgrastim market.

*Cost of goods sold*

	Three Months Ended March 31,		Change
	2021	2020 (in thousands)	
Cost of goods sold	\$ 7,511	\$ 6,855	\$ 656
Gross margin	91 %	94 %	(3)%

The cost of goods sold was \$7.5 million and \$6.9 million for the three months ended March 31, 2021 and 2020, respectively, an increase of \$0.7 million. Cost of goods sold consists primarily of third-party manufacturing, distribution, overhead costs associated with the sale of UDENYCA® and a mid-single digit royalty cost on net product revenue to Amgen, which began on July 1, 2019 and will continue for five years. A portion of the manufacturing costs for inventory were incurred prior to the regulatory approval of UDENYCA® and, therefore, were expensed as research and development costs when incurred. The cost basis of product sold that was expensed prior to approval, was approximately \$3.3 million and \$5.6 million for the three months ended March 31, 2021 and 2020, respectively. Had such inventories been valued at acquisition cost, it would have resulted in corresponding increases in cost of goods sold and corresponding decreases in gross margin during such periods. We have utilized all of the remaining inventory expensed prior to approval of UDENYCA® as of March 31, 2021 and estimate that the cost of goods sold as a percentage of net product revenue will be in the range of a high single digit to low double digit percentage from the second quarter of 2021, including the mid-single digit royalty cost on net product revenue.

We expect our gross margin to moderately decrease during the remainder of 2021 as a result of decreasing net revenue per unit sold in response to competitive pressure and higher cost of goods sold due to the depletion in the first quarter of the inventory manufactured and fully expensed prior to the regulatory approval of UDENYCA®.

*Research and Development Expense*

	Three Months Ended March 31,		Change
	2021	2020 (in thousands)	
Research and development	\$ 203,492	\$ 33,107	\$ 170,385

Research and development expense for the three months ended March 31, 2021 was \$203.5 million compared to \$33.1 million for the same period in 2020, an increase of \$170.4 million. The increase in research and development expense was primarily due to the following:

- an upfront license fee of \$145.0 million pursuant to the Collaboration Agreement with Junshi Biosciences in February 2021 as compared to an upfront license fee of \$5.0 million to Innovent in January 2020;
- an increase of \$8.1 million related to the development of additional presentations of UDENYCA®;
- an increase of \$7.6 million in costs related to CHS-2020 primarily attributable to \$11.5 million of costs incurred in the first quarter of 2021 from discontinuation of that program compared to \$3.9 million in development costs incurred in the first quarter of 2020;
- an increase of \$6.6 million related to costs incurred for the continued co-development of toripalimab;
- an increase of \$3.3 million in costs incurred for the continued development of bevacizumab (Avastin) biosimilar product candidate licensed from Innovent in 2020;
- an increase of \$2.8 million in stock-based compensation expense primarily related to the grant of fully vested stock options to certain employees and consultants upon the execution of the Collaboration Agreement with Junshi Biosciences and additional equity awards granted since the first quarter of 2020;
- an increase of \$2.2 million in personnel and consulting costs to advance our research and development programs; and
- an increase of \$0.7 million in costs related to the development of our other biosimilar product candidates.

The increase in research and development expense for the three months ended March 31, 2021 was partially offset by the following:

- a decrease of \$0.7 million in CHS-131 related costs primarily due to discontinuation of the development activities in 2021; and
- a decrease of \$0.6 million in CHS-1420 related costs mainly due to the preparation of our BLA submission and activities related to inspection readiness during 2020.

We expect substantially lower research and development expense in the second quarter and subsequent quarters of 2021 compared to the first quarter of 2021 which included a \$145 million upfront payment to Junshi Biosciences upon the closing of the collaboration agreement.

#### *Selling, General and Administrative Expenses*

	Three Months Ended March 31,		Change
	2021	2020 <i>(in thousands)</i>	
Selling, general and administrative	\$ 39,391	\$ 35,350	\$ 4,041

Selling, general and administrative expense for the three months ended March 31, 2021 was \$39.4 million compared to \$35.4 million for the three months ended March 31, 2020, an increase of \$4.0 million. The increase was primarily due to the following:

- an increase of \$4.3 million in stock-based compensation expense mainly related to the grant of fully vested stock options to certain employees and consultants upon the execution of the collaboration agreement with Junshi Biosciences and additional equity awards granted since the first quarter of 2020;
- a net increase of \$1.6 million for personnel, consulting, professional services, marketing, advertising and other related expenses due to an increase in sales force personnel and related commercial functions to support UDENYCA® sales; and
- an increase of \$0.9 million in facilities, supplies and materials and other infrastructure related expenses to support our commercial infrastructure for UDENYCA®.

The increase in selling, general and administrative expense for the three months ended March 31, 2021 was partially offset by a decrease of \$2.7 million in travel, offsite conference and training related expenses as a result of COVID-19 shelter-in-place restrictions.

We expect selling, general and administrative expense to increase during the remainder of 2021 as a result of anticipated increased commercial activities to support UDENYCA® sales and as a result of initiating our ophthalmology and immuno-oncology commercial activities.

#### *Interest Expense*

	Three Months Ended March 31,		Change
	2021	2020 <i>(in thousands)</i>	
Interest expense	\$ 5,648	\$ 4,431	\$ 1,217

Interest expense for the three months ended March 31, 2021 was \$5.6 million compared to \$4.4 million for the same period in 2020, an increase of \$1.2 million. The increase is primarily due to the interest related to our 2026 convertible notes ("2026 Convertible Notes") that were issued in April 2020.

#### *Income Tax Provision*

	Three Months Ended March 31,		Change
	2021	2020 <i>(in thousands)</i>	
Income tax provision	\$ —	\$ 933	\$ (933)

There was no income tax expense for the three months ended March 31, 2021 due to a projected tax loss for 2021 and the tax effect of the valuation allowance against such loss for the year. Income tax expense of 0.9 million for the three months ended March 31, 2020, primarily related to state taxes in jurisdictions outside of California, for which we have a limited operating history. Income tax provision during the interim periods is based on applying an estimated annual effective income tax rate to year to date income, plus any significant unusual or infrequently occurring items, which are recorded in the interim period. We maintain a full valuation allowance against our net deferred tax assets due to our history of losses.



### *Liquidity and Capital Resources*

Due to our significant research and development expenditures we have generated significant operating losses since our inception. We have funded our operations primarily through equity financing, sales of our convertible preferred stock, sales of UDENYCA® units and issuance of debt.

As of March 31, 2021, we had an accumulated deficit of \$935.7 million, cash and cash equivalents of \$259.5 million and investments in marketable securities of \$140.0 million. We believe that our current available cash, cash equivalents, investments in marketable securities and cash collected from UDENYCA® sales will be sufficient to fund our planned expenditures and meet our obligations for at least the next 12 months following our financial statement issuance date. We may need to raise additional funds in the future; however, there can be no assurance that such efforts will be successful or that, if they are successful, the terms and conditions of such financing will be favorable.

In February 2016, we issued and sold \$100.0 million aggregate principal amount of our 8.2% Convertible Senior Notes due in March 2022 (the "2022 Convertible Notes"). These 2022 Convertible Notes require quarterly interest distributions at a fixed coupon rate of 8.2% until maturity, redemption or conversion, which will be no later than March 31, 2022. If we fail to satisfy certain registration or reporting requirements, then additional interest will accrue on the 2022 Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The holders of the 2022 Convertible Notes are Healthcare Royalty Partners III, L.P. and three of its related entities, which hold \$75.0 million in aggregate principal amount, and three related party investors, KKR Biosimilar L.P., which holds \$20.0 million, MX II Associates LLC, which holds \$4.0 million, and KMG Capital Partners, LLC, which holds \$1.0 million. The 2022 Convertible Notes are convertible into shares of common stock at an initial conversion rate of 44.7387 shares of common stock per \$1,000 principal amount of the 2022 Convertible Notes (equivalent to a conversion price of approximately \$22.35 per share of common stock, representing a 60% premium over the average last reported sale price of our common stock over the 15 trading days preceding the date the 2022 Convertible Notes were issued), subject to adjustment in certain events. Upon conversion of the 2022 Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. After March 31, 2020, the full amount of the 2022 Convertible Notes not previously converted are redeemable for cash at our option if the last reported sale price per share of our common stock exceeds 160% of the conversion price on 20 or more trading days during the 30 consecutive trading days preceding the date on which we send notice of such redemption to the holders of the 2022 Convertible Notes. At maturity or redemption, if not earlier converted, we will pay 109% of the principal amount of the 2022 Convertible Notes, together with accrued and unpaid interest, in cash. In April 2020, we amended the 2022 Convertible Notes purchase agreement in connection with the issuance and sale of our 2026 Convertible Notes (as defined below).

On January 7, 2019 (the "Term Loan Closing Date"), we entered into a credit agreement (the "Term Loan") with affiliates of Healthcare Royalty Partners (together, the "Lender"). The Term Loan consists of a six-year term loan facility for an aggregate principal amount of \$75.0 million (the "Borrowings"). Our obligations under the loan documents are guaranteed by our material domestic U.S. subsidiaries.

The Borrowings under the Term Loan bear interest through maturity at 6.75% per annum plus LIBOR (customarily defined). Interest is payable quarterly in arrears.

We are required to pay principal on the Borrowings in equal quarterly installments beginning on the fourth anniversary of the Term Loan Closing Date (or, if consolidated net sales of UDENYCA® in the fiscal year ending December 31, 2021 are less than \$375.0 million, beginning on the third anniversary of the Term Loan Closing Date, with the outstanding balance to be repaid on January 7, 2025, the maturity date).

We are also required to make mandatory prepayments of the Borrowings under the Term Loan, subject to specified exceptions, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events including the occurrence of a change in control.



If all or any of the Borrowings are prepaid or required to be prepaid under the Term Loan, then we shall pay, in addition to such prepayment, a prepayment premium equal to (i) with respect to any prepayment paid or required to be paid on or prior to the third anniversary of the Term Loan Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, plus all required interest payments that would have been due on the Borrowings prepaid or required to be prepaid through and including the third anniversary of the Term Loan Closing Date, (ii) with respect to any prepayment paid or required to be paid after the third anniversary of the Term Loan Closing Date but on or prior to the fourth anniversary of the Term Loan Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after the fourth anniversary of the Term Loan Closing Date but on or prior to the fifth anniversary of the Term Loan Closing Date, 2.50% of the Borrowings prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 1.25% of the Borrowings prepaid or required to be prepaid.

In connection with the Term Loan, we paid a fee to the Lender of approximately \$1.1 million at closing in the form of an original issue discount. Upon the prepayment or maturity of the Borrowings (or upon the date such prepayment or repayment is required to be paid), we are required to pay an additional exit fee in an amount equal to 4.00% of the total principal amount of the Borrowings.

The obligations under the Term Loan are secured by a lien on substantially all of our and our Guarantors' tangible and intangible property, including intellectual property. The Term Loan contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, restrict our ability and our subsidiaries to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA<sup>®</sup> must not be lower than \$150.0 million for each fiscal year after the year ended December 31, 2020. A failure to comply with these covenants could permit the Lender under the Term Loan to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable. In April 2020, we amended the Term Loan in connection with the issuance and sale of our 2026 Convertible Notes.

In April 2020, we issued and sold \$230 million aggregate principal amount of 1.5% convertible senior subordinated notes due 2026 in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with the pricing of the 2026 Convertible Notes, we entered into privately negotiated capped call transactions with one or more of the initial purchasers or their respective affiliates and/or other financial institutions (the "option counterparties"). The cap price of the capped call transactions will initially be \$25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of our common stock of \$14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to our designated senior indebtedness. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders may convert their 2026 Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per \$1,000 principal amount of 2026 Convertible Notes, which represents an initial conversion price of approximately \$19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of \$14.815 per share of our common stock on the Nasdaq Global Market on April 14, 2020. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a "make-whole fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, we will, in certain circumstances, increase the conversion rate for a specified period of time for holders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at our election before maturity. If a "fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, holders may require us to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable

repurchase date. The net proceeds from the offering were \$222.2 million, net of the initial purchasers' fees and the offering expenses. We used approximately \$18.2 million of the net proceeds to fund the cost of entering into the capped call transactions.

### Summary Statement of Cash Flows

The following table summarizes our cash flows for the periods presented:

	Three Months Ended	
	March 31,	
	2021	2020
	<i>(in thousands)</i>	
Net cash provided by operating activities	\$ 1,367	\$ 13,477
Net cash used in investing activities	(285,475)	(1,616)
Net cash provided by financing activities	2,439	3,923
Net increase in cash, cash equivalents and restricted cash	<u>\$ (281,669)</u>	<u>\$ 15,784</u>

#### *Net cash provided by operating activities*

Cash provided by operating activities was \$1.4 million for the three months ended March 31, 2021, which was primarily due to the following:

- cash outflow from the upfront license fee payment of \$145.0 million to Junshi Biosciences was reclassified to investing activities to provide better alignment between the cash flows and the underlying nature of the transactions;
- a decrease in trade receivables of \$16.7 million primarily due to the timing of payments from our customers;
- an increase in accrued and other current and non-current liabilities of \$16.9 million primarily due to contract manufacturing accruals related to our research and development programs and commercial manufacturing services;
- a decrease in prepaid manufacturing services of \$2.1 million primarily due to prepaid contract manufacturing related to our research and development programs and prepaid commercial manufacturing services; and
- non-cash charges related to stock-based compensation of \$16.9 million and depreciation and amortization of property and equipment of \$0.8 million, write-off of prepaid manufacturing services of \$3.2 million related to the termination of CHS-2020 development, non-cash interest expense from amortization of debt issuance discounts of \$1.0 million, non-cash accretion of discount on marketable securities of \$0.3 million, non-cash operating lease expense of \$0.5 million, other non-cash adjustments of \$0.2 million.

The cash provided by operating activities was partially offset by the following

- net loss of \$172.9 million;
- an increase in inventory of \$11.4 million in order to maintain adequate supplies in order to meet potential future demand for UDENYCA®;
- a decrease in accrued compensation of \$10.2 million primarily due to the settlement of 2020 bonus payout, which was partially offset by an increase in ESPP contributions;

- an increase in other prepaid, current and non-current assets of \$4.6 million primarily due to timing of insurance payments and clinical services; and
- a decrease in accrued rebates, fees and reserve of \$3.3 million as a result of lower sales in the first quarter of 2021.

Cash provided by operating activities was \$13.5 million for the three months ended March 31, 2020, which was primarily due to the following:

- net income of \$35.6 million;
- an increase in accrued rebates, fees and reserve of \$15.0 million as a result of continued growth in UDENYCA<sup>®</sup> sales;
- non-cash charges related to stock-based compensation of \$9.6 million and depreciation and amortization of property and equipment of \$0.6 million, non-cash interest expense from amortization of debt issuance discounts of \$0.6 million, non-cash operating lease expense of \$0.5 million, other non-cash adjustments of \$0.6 million; and
- an increase in accrued and other liabilities of \$1.6 million primarily due to contract manufacturing accruals related to our research and development programs.

The cash provided by operating activities was partially offset by the following:

- an increase in trade receivables of \$25.6 million primarily due to the timing of payment from our customers;
- an increase in inventory of \$9.6 million primarily due to continued growth in UDENYCA<sup>®</sup> sales and to maintain adequate supplies in order to meet the future demand;
- an increase in prepaid manufacturing services of \$3.1 million to secure drug production runs scheduled for 2020;
- an increase in other prepaid and other current and non-current assets of \$1.8 million primarily due to the timing of insurance payments;
- a decrease in accrued compensation of \$5.6 million primarily due to the settlement of 2019 bonus payout, which was partially offset by an increase in ESPP contributions; and
- a decrease in accounts payable of \$5.0 million primarily due to the timing of receiving and processing invoices from our vendors partially offset by the upfront payment due to Innovent under the Innovent Agreement; and

*Net cash used in investing activities*

Cash used in investing activities of \$285.5 million for the three months ended March 31, 2021 was primarily due to upfront license fee payment of \$145.0 million to Junshi Biosciences and purchases of investments in marketable securities of \$140.3 million.

Cash used in investing activities of \$1.6 million for the three months ended March 31, 2020 was primarily due to purchases of property and equipment.

*Net cash provided by financing activities*

Cash provided by financing activities of \$2.4 million for the three months ended March 31, 2021 was primarily due to \$4.3 million proceeds from the exercise of stock options and was partially offset by \$1.7 million in tax payments related to net share settlement of RSUs.

Cash provided by financing activities of \$3.9 million for the three months ended March 31, 2020 was primarily due to \$4.8 million proceeds from the exercise of stock options partially offset by \$0.9 million in tax payments related to net share settlement of bonus payout in RSUs.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

**Contractual Obligations**

As of March 31, 2021, there have been no material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2020.

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

As of March 31, 2021, we had cash and cash equivalents and investments in marketable securities of \$399.5 million consisting of cash, investments in money market funds and investments in marketable securities. A portion of our cash equivalents and investments in marketable securities may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure.

**ITEM 4. Controls and Procedures**

**Evaluation of Effectiveness of Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision of our Chief Executive Officer and our Chief Financial Officer, and evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were, in design and operation, effective.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer, principal financial officer and principal accounting officer, as appropriate, to allow for timely decisions regarding required disclosure.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to

modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**Changes in Internal Control Over Financial Reporting.**

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 pandemic to minimize its impact on the design and operating effectiveness of our internal controls.

**Limitations on Effectiveness of Controls and Procedures**

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

## **PART II – OTHER INFORMATION**

### **ITEM 1. Legal Proceedings**

We are not a party to any material legal proceedings on the date of this report.

### **Item 1A. Risk Factors**

#### **Risk Factor Summary**

*Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q, including our financial statements and related notes thereto, before making investment decisions regarding our common stock.*

- Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic.
- We have a limited operating history in an emerging regulatory environment on which to assess our business and we have a limited history of profitability.
- The commercial success of UDENYCA®, or any future product candidate, will depend upon the degree of market acceptance and adoption by healthcare providers, patients, third-party payers and others in the medical community.
- UDENYCA® and our other product candidates, even if approved, will remain subject to regulatory scrutiny.
- UDENYCA®, or our other biosimilar product candidates, if approved, will face significant competition from the reference products and from other biosimilar products or pharmaceuticals approved for the same indication as

the originator products. Our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.
- If an improved version of an originator product, such as Neulasta, Humira or Lucentis, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.
- We are highly dependent on the services of our key executives and personnel, including our President and Chief Executive Officer, Dennis M. Lanfear, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.
- We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We are subject to a multitude of manufacturing risks. Any adverse developments affecting the manufacturing operations of our biosimilar product candidates could substantially increase our costs and limit supply for our product candidates.
- UDENYCA® or our product candidates may cause undesirable side effects or have other properties that could, as applicable, delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.
- If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.
- We are heavily dependent on the development, clinical success, regulatory approval and commercial success of our product candidates. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

### **Risk Factors**

*Investing in the common stock of a biopharmaceuticals company is a highly speculative undertaking and involves a substantial degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing the Company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.*

## Risks Related to COVID-19

### ***Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic.***

We are subject to risks related to public health crises such as the global pandemic associated with the novel coronavirus and the associated disease (“COVID-19”). In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19, has spread to most countries, and all 50 states within the United States. As a result of the COVID-19 outbreak, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies, including, but not limited to:

- decreased sales of UDENYCA®;
- our ability to maintain or expand the commercial use of UDENYCA® due to, among other factors, healthcare providers, payers and patients not utilizing or adopting UDENYCA® due to resources being strained or otherwise focused on the COVID-19 pandemic and our sales team efficacy in selling UDENYCA® being limited due to such strained resources or other factors such as travel restrictions;
- fewer individuals undertaking or completing cancer treatments, whether due to contracting COVID-19, self-isolating or quarantining to lower the risk of contracting COVID-19 or being unable to access care as a result of healthcare providers tending to COVID-19 patients;
- our third-party contract manufacturers and logistics providers not being able to maintain adequate (in amount and quality) supply to support the commercial sale of UDENYCA® or the clinical development of our product candidates due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays and difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, as well as delays or difficulties in enrolling patients or maintaining enrolled patients in our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines; and
- limitations on our employee resources, and those of our business partners, that would otherwise be focused on the conduct of our business in all aspects, including because of sickness of employees or their families.

These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA®’s market position or increase its penetration against all of Neulasta’s dosage forms, and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth.

Numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Multiple times in 2020, the governor of California, where our headquarters and laboratory facilities are located, issued a “shelter-in-place” order restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions, have resulted in our headquarters closing for certain periods, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Such orders or



restrictions may continue or re-instated, as the case may be, thereby causing additional negative impact on our operations. Further, because the rollout of COVID-19 vaccines has, and could continue to, experience significant delays and suffered from reluctance from eligible individuals to be fully inoculated, the COVID-19 pandemic may last longer than expected and could result in additional outbreaks that prompt additional closings.

While the long-term economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and could negatively affect our liquidity and the liquidity and stability of markets for our common stock and the notes. In addition, a recession, further market correction or depression resulting from the spread of COVID-19 could materially affect our business and the value of our notes and our common stock.

### **Risks Related to Our Financial Condition and Capital Requirements**

***We have a limited operating history in an emerging regulatory environment on which to assess our business and we have a limited history of profitability, which we have not maintained and may not achieve again, and only one product that has been approved, with multiple products still early in development.***

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment. We incurred net losses in each year from our inception in September 2010 through December 31, 2018, including net losses of \$209.4 million for the year ended December 31, 2018 and a net loss of \$172.9 million in the first quarter of 2021. However, while we did generate net income of \$132.2 million and \$89.8 million for the year ended December 31, 2020 and 2019, respectively, it is uncertain that we will be profitable in future periods as research and development is expensive and risky. The amount of our future net losses or net income will depend, in part, on the amount of our future expenditures offset by the amount of future product sales, including sales of UDENYCA or any other products that may receive regulatory approval. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

For example, as of March 31, 2021, we had an accumulated deficit of \$935.7 million. The losses and accumulated deficit were primarily due to the substantial investments we made to identify, develop or license our product candidates, including conducting, among other things, analytical characterization, process development and manufacturing, formulation and clinical studies and providing general and administrative support for these operations.

We anticipate we will incur certain development and pre-commercial expenses for the Lucentis biosimilar candidate, which we licensed from Bioeq in November 2019, for the Avastin biosimilar candidate, which we licensed from Innovent in January 2020, and for toripalimab, the anti-PD-1 antibody we licensed from Junshi Biosciences in 2021. Advancing these candidates through clinical development will be expensive and could result in us continuing to experience future net losses.

If we obtain regulatory approval to market a biosimilar product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payers, and adequate market share for our product candidates which include all product candidates for which we obtained commercial rights, in those markets. However, even if additional product candidates in addition to UDENYCA® gain regulatory approval and are commercialized, we may not remain profitable.

Our expenses will increase substantially if and as we:

- establish a sales, marketing and distribution infrastructure to commercialize UDENYCA® or any of our product candidates for which we may obtain marketing approval;
- make upfront, milestone, royalty or other payments under any license agreements;

- continue our nonclinical and clinical development of our product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- seek to identify, assess, acquire and/or develop other biosimilar product candidates or products that may be complementary to our products;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation, including patent litigation, and Inter Partes Review (“IPR”) proceedings with originator companies or others that may hold patents;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, manufacturing delays, litigation or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies or analyses in order to pursue marketing approval.

Further, the net loss or net income we incur may fluctuate significantly from quarter-to-quarter and year-to-year such that a period-to-period comparison of our results of operations may not be a good indication of our future performance quarter-to-quarter and year-to-year due to factors including the timing of clinical trials, any litigation that we may initiate or that may be initiated against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder.

***We continue to be dependent on the ability to raise funding. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development and commercialization efforts or other operations.***

As of March 31, 2021, our cash and cash equivalents and short-term investments were \$399.5 million. We expect that our existing cash and cash equivalents and cash collected from our UDENYCA® sales will be sufficient to fund our current operations for the foreseeable future. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, license agreements and through recent product sales of UDENYCA®.

However, our operating or investing plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- our ability to continue to successfully commercialize UDENYCA®, and to compete against Neulasta, Neulasta Onpro® and new and existing commercial pegfilgrastim biosimilar products;

- the scope, rate of progress, results and cost of any clinical studies, nonclinical testing and other related activities;
- the cost of manufacturing clinical drug supplies and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any licensing or other arrangements to acquire intellectual property rights that we may establish, including any milestone and royalty payments thereunder;
- the timing of conversion in common shares or repayment in cash of our convertible debt, or the timing of repayment in cash, whether due or not, of our credit facilities; and
- the cost, timing and outcomes of any litigation that we may file against third parties or that may be filed against us by third parties.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute the share ownership of our existing stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

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

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period), such corporation’s ability to use its pre-change net operating loss carryforwards (“NOLs”) and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future (some of which changes are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which

could accelerate or permanently increase state taxes owed. As a result, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

### **Risks Related to Launch and Commercialization of UDENYCA® and our Other Product Candidates**

#### ***We have a limited operating history in an emerging regulatory environment on which to assess our business.***

We are a biotherapeutics company with a limited operating history in an emerging regulatory environment of biosimilar products. Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements, UDENYCA® is our only product approved for commercialization in the United States and E.U., and we have no products approved in any other territories.

Our ability to generate meaningful revenue and remain profitable depends on our ability, alone or with strategic collaboration partners, to successfully market and sell UDENYCA®, and to complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our other product pipeline candidates, which include:

- Toripalimab;
- Bioeq's ranibizumab (Lucentis) biosimilar candidate;
- Innovent's bevacizumab (Avastin) biosimilar candidate;
- CHS-1420 (our adalimumab (Humira) biosimilar candidate); and

We may not be able to continue to generate meaningful revenue from product sales, as this depends heavily on our success in many areas, including but not limited to:

- our ability to continue to successfully commercialize UDENYCA®;
- competing against current and future pegfilgrastim products;
- healthcare providers, payers, and patients adopting our product candidates once approved and launched;
- our ability to procure and commercialize our in-licensed biosimilar candidates;
- obtaining additional regulatory and marketing approvals for product candidates for which we complete clinical studies;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our product candidates as viable treatment options;
- completing nonclinical and clinical development of our product candidates;
- developing and testing of our product formulations;
- attracting, hiring and retaining qualified personnel;
- developing a sustainable and scalable manufacturing process for any approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our product candidates, if approved;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing) new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;

- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- defending against any litigation including patent or trade secret infringement lawsuits, that may be filed against us, or achieving successful outcomes of IPR petitions that we have filed, or may in the future file, against third parties.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medical Agency (the "EMA"), other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining additional regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the number of biosimilar competitors in such markets, the accepted price for the product, the ability to get reimbursement at any price, the nature and degree of competition from originators and other biosimilar companies (including competition from large pharmaceutical companies entering the biosimilar market that may be able to gain advantages in the sale of biosimilar products based on brand recognition and/or existing relationships with customers and payers) and whether we own (or have partnered with) the commercial rights for that territory. If the market for our product candidates (or our share of that market) is not as significant as we expect, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain additional regulatory approval for our products, our business may suffer.

***The commercial success of UDENYCA®, or any future product candidate, will depend upon the degree of market acceptance and adoption by healthcare providers, patients, third-party payers and others in the medical community.***

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of UDENYCA®, or any of our future product candidates, if approved, will depend in part on the medical community, patients and third-party payers accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product, as demonstrated in clinical studies, and potential advantages over competing treatments;
- the prevalence and severity of any side effects and any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience and ease of administration;

- the extent to which our product may be similar to the originator product than competing biosimilar product candidates;
- policies and practices governing the naming of biosimilar product candidates;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payers provide adequate third-party coverage and reimbursement for our product candidates, if approved;
- the price at which we sell our products;
- the actions taken by competitors to delay, restrict or block customer usage of the product; and
- our ability to maintain compliance with regulatory requirements.

Market acceptance of any future product candidates, if approved, will not be fully known until after they are launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar product candidates. Further, continued market acceptance of UDENYCA®, and the market acceptance of any future product candidates that may be approved, depends on our efforts to educate the medical community and third-party payers on the benefits of the product candidates may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If UDENYCA® or any future product candidates that are approved fail to achieve an adequate level of acceptance by physicians, patients, third-party payers and others in the medical community, we will not be able to generate sufficient revenue to sustain profitability.

***The third-party coverage and reimbursement status of UDENYCA® (or our other product candidates, if approved) is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

Pricing, coverage and reimbursement of UDENYCA®, or any of our product candidates, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not continue to be sufficient to recover our development and manufacturing costs, and as a result, we may not be profitable in the future. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payers are essential for most patients to be able to afford expensive treatments such as ours. Sales will depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government authorities, private health insurers and other third-party payers. If coverage and reimbursement are not available, or are available only to limited levels, or become unavailable, we may not be able to successfully commercialize UDENYCA® or any of our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payers, including private and governmental payers such as the Medicare and Medicaid

programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict what third-party payers will decide with respect to the coverage and reimbursement for any newly approved product. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third-party payers. Therefore, coverage and reimbursement for biologics can differ significantly from payer to payer. As a result, the process for obtaining favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained.

Effective January 2019, centers for Medicare and Medicaid Services (“CMS”) assigned a product specific Q-Code to UDENYCA®, which is necessary to allow UDENYCA® to have its own reimbursement rate and average selling price with Medicare or other third-party payers. However, reimbursement is not guaranteed and rates may vary based on product life cycle, site of care, type of payer, coverage decisions, and provider contracts. Furthermore, while a large majority of payers have adopted the Q-Code assigned by CMS for UDENYCA®, there remains uncertainty as to whether such payers will continue to cover and pay providers for the administration and use of the product with each patient or may favor a competing product. If UDENYCA®, or any of our future product candidates, are not covered or adequately reimbursed by third-party payers, including Medicare, then the cost of the relevant product may be absorbed by healthcare providers or charged to patients. If this is the case, our expectations of the pricing we expect to achieve for such product and the related potential revenue, may be significantly diminished.

Outside the U.S., pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Increasing efforts by governmental and third-party payers in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for UDENYCA® or any of our product candidates. While cost containment practices generally benefit biosimilars, severe cost containment practices may adversely affect our product sales. We expect to experience pricing pressures in connection with the sale of UDENYCA® and any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

***UDENYCA® and our other product candidates, even if approved, will remain subject to regulatory scrutiny.***

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers’ facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (“cGMP”), regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA,



original BLA, 351(k) BLA or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. If our product candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We or our collaboration partners could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval is obtained via an accelerated biosimilar approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other possibilities:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the results of the



2020 U.S. Presidential Election may impact our business and industry. Namely, while in power the Trump administration took several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of a new administration are unknown and could materially impact the regulations governing our product candidates.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

#### **Risks Related to Competitive Activity**

***UDENYCA®, or our other biosimilar product candidates, if approved, will face significant competition from the reference products and from other biosimilar products or pharmaceuticals approved for the same indication as the originator products. Our failure to effectively compete may prevent us from achieving significant market penetration and expansion.***

We operate in highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical market have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous

companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced multinational pharmaceutical and biotechnology companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel, marketing resources, and the benefits of mergers and acquisitions.

Specifically, some of the pharmaceutical and biotechnology companies we expect to compete with include: Sandoz International GmbH ("Sandoz"), Amgen Inc. ("Amgen"), Pfizer Inc. ("Pfizer"), Boehringer Ingelheim GmbH ("Boehringer Ingelheim"), Teva Pharmaceutical Industries, Ltd. ("Teva"), and Samsung Bioepis, Ltd. ("Samsung Bioepis"), (a Merck/Biogen/Samsung biosimilar venture), Mylan N.V. ("Mylan"), and Cinfa Biotech S.L. ("Cinfa," a subsidiary of Mundipharma), as well as other smaller companies. We are currently aware that such competitors are engaged in the development and commercialization of biosimilar product candidates to pegfilgrastim (Neulasta), ranibizumab (Lucentis), bevacizumab (Avastin) and adalimumab (Humira).

UDENYCA® faces competition in the United States from Amgen, Mylan (with partner Biocon Ltd.), Sandoz, Pfizer, and may face completion from Amneal Pharmaceuticals, Inc. and Fresenius Medical Care AG & Co. KGaA, companies that announced the development of a pegfilgrastim biosimilar.

Our ranibizumab (Lucentis) biosimilar candidate licensed from Bioeq may face competition in the United States from Genentech (the manufacturer of Lucentis). Biogen with collaborator Samsung Bioepis, and Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG and Bausch + Lomb) have each disclosed the development for a Lucentis biosimilar candidate.

Our bevacizumab (Avastin) biosimilar candidate licensed from Innovent may face competition in the United States from Genentech, Inc. (the manufacturer of Avastin) as well as Amgen and Pfizer, each of which have initiated the commercial launch of an Avastin biosimilar.

Similarly, CHS-1420, our adalimumab (Humira) biosimilar may face competition from AbbVie (the manufacturer of Humira) as well as manufacturers of Humira biosimilars such as Pfizer, Boehringer Ingelheim, Amgen, Sandoz and Samsung Bioepis. There are five adalimumab biosimilar products that have been approved by the FDA in the United States, and Fujifilm and Fresenius have each disclosed development plans for a Humira biosimilar candidate. As a result of number of potential adalimumab (Humira) biosimilar competitors, we may not be able to achieve substantial topline sales for CHS-1420 in the United States, if approved.

These companies may also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates, obtaining FDA and other regulatory approvals of products and marketing and commercializing products once approved.

Additionally, many manufacturers of originator products have increasingly used legislative, regulatory and other means, such as litigation, to delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included:

- settling, or refusing to settle, patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval;
- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications;
- appealing denials of Citizen Petitions in U.S. federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;

- attempting to influence potential market share by conducting medical education with physicians, payers, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from originator products to be trusted as safe and effective alternatives;
- implementing payer market access tactics that benefit their brands at the expense of biosimilars;
- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the U.S. Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes, which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

***UDENYCA® and our other biosimilar product candidates, if approved, could face price competition from other biosimilars of the same reference products for the same indication. This price competition could exceed our capacity to respond, detrimentally affecting our market share and revenue as well as adversely affecting the overall financial health and attractiveness of the market for the biosimilar.***

Competitors in the biosimilar market have the ability to compete on price through payers and their third-party administrators, who exert downward pricing pressure on our price offerings. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share or volume requirements could exceed our capacity to respond in kind and reduce market prices beyond our expectations. Such practices may limit our ability to increase market share and may also impact profitability.

***We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.***

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Biosimilar product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors.

***If other biosimilars of bevacizumab (Avastin), ranibizumab (Lucentis) or adalimumab (Humira), are approved and successfully commercialized before our product candidates for these originator products, our business would suffer.***

We expect other companies to seek approval to manufacture and market biosimilar versions of Avastin, Lucentis or Humira. If other biosimilars of these branded biologics are approved and successfully commercialized before our

biosimilar candidates, we may never achieve meaningful market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer. For instance, Mylan received FDA approval for its pegfilgrastim biosimilar in June 2018, and in July 2018, Mylan initiated the commercialization in the United States of this biosimilar. Furthermore, in September 2018, the European Commission (“EC”) granted marketing authorization to UDENYCA® and to a pegfilgrastim biosimilar candidate from Intas Pharmaceuticals Limited. In November and December 2018, the EC granted marketing authorizations to three additional pegfilgrastim biosimilar candidates from Sandoz, Mylan and Cinfa. In June 2019, the E.U. granted marketing authorization to a pegfilgrastim biosimilar candidate from USV Biologics.

***If an improved version of an originator product, such as Neulasta, Humira or Lucentis, is developed or if the market for the originator product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.***

Originator companies may develop improved versions of a reference product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental BLA submitted to the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biologic product, it may capture a significant share of the collective reference product market in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar product candidates. In addition, the improved product may be protected by additional patent rights that may subject our follow-on biosimilar to claims of infringement.

Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. As new products are approved that compete with the reference product to our biosimilar product candidates, sales of the reference originator product may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share or experience limited market potential for our approved biosimilar products or product candidates, and the value of our product pipeline could be negatively impacted. As a result of the above factors, our business, prospects and financial condition could suffer.

#### **Risks Related to Our Ability to Hire and Retain Highly Qualified Personnel**

***We are highly dependent on the services of our key executives and personnel, including our President and Chief Executive Officer, Dennis M. Lanfear, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.***

We are highly dependent on the principal members of our management and scientific and technical staff. The loss of service of any of our management or key scientific and technical staff could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management, particularly our President and Chief Executive Officer, Mr. Lanfear, and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

We will need to expand and effectively manage our managerial, scientific, operational, financial, commercial and other resources in order to successfully pursue our clinical development and commercialization efforts. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

***We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of March 31, 2021, we had 310 employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

#### **Risks Related to Reliance on Third-Party Vendors**

***We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, good clinical practices (“GCP”), and Good Laboratory Practices (“GLP”), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or GCPs, the data generated in our nonclinical and clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional nonclinical and clinical studies before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with product generated under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be implicated if our CRO or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going nonclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, a transition period is necessary when a new CRO commences work, which can materially impact our ability to meet our desired clinical development timelines. Though we strive to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects and financial condition.

***We rely on third parties, and in some cases a single third party, to manufacture nonclinical, clinical and commercial drug supplies of our product candidates and to store critical components of our product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product candidates or fail to do so at acceptable quality levels or prices.***

We do not currently have the infrastructure or capability internally to manufacture supplies of our product candidates for use in our nonclinical and clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on third party manufacturers to manufacture and supply us with our product candidates for our preclinical and clinical studies as well as to establish commercial supplies of our product candidates. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and we may not be able to achieve such transfer or do so in a timely manner. Moreover, the availability of contract manufacturing services for protein-based therapeutics is highly variable and there are periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we will plan accordingly and generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the U.S. Our failure or the failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our



manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, any contract manufacturer that we engage may need to increase manufacturing capacity. If we are unable to build and stock our product candidates in sufficient quantities to meet the requirements for the launch of these candidates or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

***We are dependent on Bioeq, Innovent and Orox Pharmaceuticals B.V. for the commercialization of our biosimilar product candidates in certain markets and we intend to seek additional commercialization partners for major markets, and the failure to commercialize in those markets could have a material adverse effect on our business and operating results.***

We have an exclusive license from Bioeq to commercialize Bioeq's ranibizumab (Lucentis) biosimilar in the United States. We have an exclusive license from Innovent to develop and commercialize Innovent's bevacizumab (Avastin) biosimilar in the United States and Canada. Our licensors are responsible for supplying us with drug substance and final drug products as well as, in the case of Innovent, the necessary regulatory data to submit a 351(k) BLA for Innovent's bevacizumab candidate in the United States and Canada.

Our exclusive licensee, Orox, is responsible for commercialization of certain of our products and product candidates, including UDENYCA® and CHS-1420, in certain Caribbean and Latin American countries (excluding Brazil, and in the case of UDENYCA®, also excluding Argentina).

Our licenses with Bioeq, Innovent, Orox, or other future license or collaboration agreements, may not be successful. Factors that may affect the success of our licenses and collaborations include, but are not limited to, the following:

- our existing and potential collaboration partners may fail to provide sufficient amounts of commercial products or they may be ineffective in doing so;
- our existing and potential collaboration partners may fail regulatory inspections which may preclude or delay the delivery of commercial products;
- our existing and potential collaboration partners may fail to exercise commercially reasonable efforts to market and sell our products in their respective licensed jurisdictions or they may be ineffective in doing so;
- our existing and potential licensees and collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects;
- our existing and potential licensees and collaboration partners may terminate their licenses or collaborations with us, which could make it difficult for us to attract new partners and/or adversely affect perception of us in the business and financial communities; and
- our existing and potential licensees and collaboration partners may choose to pursue alternative, higher priority programs, which could affect their commitment to us.

Moreover, any disputes with our licensees and collaboration partners will substantially divert the attention of our senior management from other business activities and will require us to incur substantial costs associated with litigation or arbitration proceedings. If we cannot maintain successful license and collaboration arrangements, our business, financial condition and operating results may be adversely affected.

## Risks Related to Manufacturing and Supply Chain

***We are subject to a multitude of manufacturing risks. Any adverse developments affecting the manufacturing operations of our biosimilar product candidates could substantially increase our costs and limit supply for our product candidates.***

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error; and
- equipment failures, labor shortages, natural disasters, power failures and numerous other factors associated with the manufacturing facilities in which our product candidates are produced, and potentially exacerbated by climate change.

Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. For example, we have experienced failures with respect to the manufacturing of certain lots of each of our product candidates resulting in delays prior to our taking corrective action. Additionally, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any adverse developments affecting manufacturing operations for our product candidates, including due to sudden or long-term changes in weather patterns, may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

***We currently engage single suppliers for manufacture, clinical trial services, formulation development and product testing of our product candidates. The loss of any of these suppliers or vendors could materially and adversely affect our business.***

For UDENYCA® and our product candidates, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these products, such as manufacture of the biological substance present in each of the products, manufacture of the final filled and finished presentation of these products, as well as laboratory testing, formulation development and clinical testing of these products. For example, in December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma, Inc. for long-term commercial manufacturing of UDENYCA®. Because we currently have engaged a limited number of back-up suppliers or vendors for these single-sourced services, and although we believe that there are alternate sources that could fulfill these activities, we cannot assure you that identifying and establishing relationships with alternate suppliers and vendors would not result in significant delay in the development of our product candidates. Additionally, we may not be able to enter into arrangements with alternative service providers on commercially reasonable terms or at all. A delay in the development of our product candidates, or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers, could have a material adverse impact on our business.



***We and our collaboration partners and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.***

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners or our contract manufacturers must supply all necessary documentation in support of a 351(k) BLA, original BLA, NDA or MAA on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, inspect or audit the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaboration partners or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a BLA supplement, NDA supplement or MAA variation or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur additional costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

***The structure of complex proteins used in protein-based therapeutics is inherently variable and highly dependent on the processes and conditions used to manufacture them. If we are unable to develop manufacturing processes that achieve a requisite degree of biosimilarity to the originator drug, and within a range of variability considered acceptable by regulatory authorities, we may not be able to obtain regulatory approval for our products.***

Protein-based therapeutics are inherently heterogeneous and their structures are highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots produced within a single facility. The physicochemical complexity and size of biologic therapeutics create significant technical and scientific challenges in the context of their replication as biosimilar products.

The inherent variability in protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to an originator product to support regulatory approval requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein backbone of a therapeutic protein when it is produced in a living cell, is critical to therapeutic efficacy, half-life, efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of an originator molecule in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent glycosylation profiles at scale is challenging and highly dependent on the skill of the cell biologist and process scientist.

There are extraordinary technical challenges in developing complex protein-based therapeutics that not only must achieve an acceptable degree of similarity to the originator molecule in terms of characteristics such as the unique glycosylation pattern, but also the ability to develop manufacturing processes that can replicate the necessary structural characteristics within an acceptable range of variability sufficient to satisfy regulatory authorities.

Given the challenges caused by the inherent variability in protein production, we may not be successful in developing our products if regulators conclude that we have not achieved a sufficient level of biosimilarity to the originator product, or that the processes we use are unable to generate our products within an acceptable range of variability.

#### **Risks Related to Adverse Events**

***UDENYCA® or our product candidates may cause undesirable side effects or have other properties that could, as applicable, delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.***

As with most pharmaceutical products, use of UDENYCA® or our product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which will harm our business. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, prospects and financial condition.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory approval could impact product safety and efficacy.

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our license agreements. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more 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 but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy ("REMS"), plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

If we receive approval for our product candidates, regulatory agencies including the FDA and foreign regulatory agencies, regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

***Adverse events involving an originator product, or other biosimilars of such originator product, may negatively affect our business.***

In the event that use of an originator product, or other biosimilar for such originator product, results in unanticipated side effects or other adverse events, it is likely that our biosimilar product candidate will be viewed comparably and may become subject to the same scrutiny and regulatory sanctions as the originator product or other biosimilar, as applicable. Accordingly, we may become subject to regulatory supervisions, clinical holds, product recalls or other regulatory actions for matters outside of our control that affect the originator product, or other biosimilar, as

applicable, if and until we are able to demonstrate to the satisfaction of our regulators that our biosimilar product candidate is not subject to the same issues leading to the regulatory action as the originator product or other biosimilar, as applicable.

### **Risks Related to Intellectual Property**

***If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.***

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the United States Patent and Trademark Office (“USPTO”) and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. The companies that originated the products for which we intend to introduce biosimilar versions, such as Amgen, AbbVie and Genentech and Regeneron, as well as other competitors (including other companies developing biosimilars) have developed, and are continuing to develop, worldwide patent portfolios of varying sizes and breadth, many of which are in fields relating to our business, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use.

Third parties may assert that we are employing their proprietary technology without authorization. We are aware of third-party patents or patent applications with claims, for example, to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to UDENYCA® and our product candidates, including our in-licensed biosimilar candidates, as well as our pipeline candidates, we cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future biosimilar product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions, which do not require publication of patent applications until 18 months after filing. Moreover, some U.S. patents may issue without any prior publication in cases where the patent applicant does not also make a foreign filing. We may also face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid and/or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving

invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the U.S. District Court for the District of Delaware alleging infringement of one or more claims of Amgen's US patent 8,273,707 (the "'707 patent") under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the U.S. Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, our pending motion to dismiss Amgen's complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the U.S. Magistrate Judge's Report and Recommendation to grant our motion pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging infringement of the '707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit. Amgen and Coherus filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court's judgment in our favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court's dismissal. In a Joint Status Report, dated September 20, 2019, Amgen stated that it does not intend to further appeal the Federal Circuit's decision. On October 11, 2019, we filed a Motion for Attorneys' Fees with the District Court. Amgen filed its Answering Brief in Opposition on November 8, 2019. On November 22, 2019, we filed our Reply Brief with the District Court. On November 30, 2020, the District Court issued an order denying the Company's motion.

On January 24, 2019, we entered into settlement and license agreements with AbbVie, that grant us global, royalty-bearing, non-exclusive license rights under AbbVie's intellectual property to commercialize CHS-1420, our proposed adalimumab (Humira) biosimilar. The global settlements resolve all pending disputes between the parties related to CHS-1420. Under the U.S. settlement, our license period in the United States commences on July 1, 2023.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, IPR, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the E.U. states (including Switzerland) seeking to extend certain patent protection, which, if approved, may interfere with or delay the launch of one or more of our biosimilar products.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. The companies that originated the products for which we intend to introduce biosimilar versions, as well as other competitors (including other biosimilar companies) may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

We do not know whether any of our pending patent applications will result in the issuance of any patents or whether the rights granted under any patents issuing from these applications will prevent any of our competitors from marketing similar products that may be competitive with our own. Moreover, even if we do obtain issued patents, they will not guarantee us the right to use our patented technology for commercialization of our product candidates. Third parties may have blocking patents that could prevent us from commercializing our own products, even if our products use or embody our own, patented inventions.

The validity and enforceability of patents are generally uncertain and involve complex legal and factual questions. Any patents that may issue on our pending applications may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing products similar to ours. Furthermore, our competitors may develop similar or alternative technologies not covered by any patents that may issue to us.



For technologies for which we do not seek patent protection, we may rely on trade secrets to protect our proprietary position. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, advisors, contractors or collaborators. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

***We may be involved in lawsuits or IPR proceedings to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

We may discover that competitors are infringing our issued patents. Expensive and time-consuming litigation may be required to abate such infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if we cannot obtain a license from the prevailing party on commercially reasonable terms. Third parties may request an IPR of our patents in the USPTO. An unfavorable decision may result in the revocation of our patent or a limitation to the scope of the claims of our patents. Our defense of litigation, interference or IPR proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

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

***We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear is a former employee of Amgen. Mr. Lanfear was employed at Amgen during periods when Amgen's operations included

the development and commercialization of Neulasta and Enbrel. Senior members of our commercial team who will be responsible for any launch of our Neulasta biosimilar formerly held positions at Amgen. Our board of directors and scientific advisory board include members that were former employees of Genentech, Amgen and Abbott Laboratories. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

On March 3, 2017, Amgen filed an action against us, KBI Biopharma Inc., our employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint, which was amended, alleged that we engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. The complaint, as amended, sought injunctive relief and monetary damages. On May 2, 2019, we and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but the Company will continue to market UDENYCA® and began paying a mid-single digit royalty to Amgen for five years starting on July 1, 2019.

***If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We are a party to certain non-exclusive intellectual property license agreements with certain vendors (pertaining to mammalian cell lines) and with AbbVie (pertaining to AbbVie's intellectual property related to CHS-1420) that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.

In the event we breach any of our obligations related to such agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.



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

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

We currently have rights to certain intellectual property, through licenses from third parties and under patent applications that we own, to develop our biosimilar product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

***Our ability to market our products in the United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism.***

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262, (the "BPCIA"), created an elaborate and complex patent dispute resolution mechanism for biosimilars that, if we choose to implement it, could prevent us from launching our product candidates in the United States or could substantially delay such launches. However, even if we elect not to implement this mechanism, the launch of our products in the United States could still be prevented or substantially delayed by intellectual property disputes with originator companies that market the reference products on which our biosimilar products are based.

The BPCIA establishes a patent disclosure and briefing process between the biosimilar applicant and the originator that is demanding and time-sensitive. While certain aspects of this process are still being tested in the federal courts, the U.S. Supreme Court, as discussed further below, recently ruled that this process is not mandatory, such that a biosimilar applicant may elect to engage in this process, but is not required to do so. The following is an overview of the patent exchange and patent briefing procedures established by the BPCIA for biosimilar applicants that elect to employ them:

1. Disclosure of the Biosimilar Application. Within 20 days after the FDA publishes a notice that its application has been accepted for review, a 351(k) biosimilar applicant may elect to provide a copy of its application to the originator if it chooses to engage in the BPCIA patent exchange mechanism.
2. Identification of Pertinent Patents. Within 60 days of the date of receipt of the application the originator must identify patents owned or controlled by the originator, which it believes could be asserted against the biosimilar applicant.
3. Statement by the Biosimilar Applicant. Following the receipt of the originator's patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments that the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the originator with a list of patents it believes the brand-name firm could assert against the reference product.

4. Statement by the Originator. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the originator must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.
5. Patent Resolution Negotiations. If the originator provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the discussed patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the brand-name firm must bring an action for patent infringement within 30 days.
6. Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the originator of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the originator may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the originator may identify one patent.
7. Commencement of Patent Litigation. The originator must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the originator's list and all of the patents on the follow-on applicant's list. The follow-on applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.
8. Notice of Commercial Marketing. The BPCIA requires the biosimilar applicant to provide notice to the originator 180 days in advance of its first commercial marketing of its proposed follow-on biologic. The originator is allowed to seek a preliminary injunction blocking such marketing based upon any patents that either party had preliminarily identified, but were not subject to the initial phase of patent litigation. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion. The federal courts have not yet settled the issue as to when, or under what circumstances, the biosimilar applicant must provide the 180 notice of commercial marketing provided in the BPCIA.

On June 12, 2017, the Supreme Court issued its decision in *Amgen v. Sandoz*, holding that (i) the "patent dance" is optional; and (ii) the 180-day pre-marketing notification may be given either before or after receiving FDA approval of the biosimilar product. The Supreme Court declined to rule whether a state injunctive remedy may be available to the originator and remanded that question to the Federal Circuit for further consideration. On December 14, 2017, the Federal Circuit decided that state law claims are preempted by the BPCIA on both field and conflict grounds.

A significant legal risk for a biosimilar applicant that pursues regulatory approval under the 351(k) regulatory approval route, and also elects to engage in the above-described BPCIA patent exchange mechanism, is that the process could result in the initiation of patent infringement litigation prior to FDA approval of a 351(k) application, and such litigation could result in blocking the market entry of the biosimilar product. However, even if biosimilar applicants opt out of the BPCIA patent exchange process, originators will still have the right to assert patent infringement as a basis to enjoin a biosimilar product launch. Thus, whether or not we engage in the BPCIA patent exchange process, there is risk that patent infringement litigation initiated by originators could prevent us indefinitely from launching our biosimilar products.

The legal and strategic considerations weighing for or against a decision to voluntarily engage in the BPCIA patent exchange process are complex and will differ on a product-by-product basis. If we decide to engage in the BPCIA patent exchange process, preparing for and conducting the patent exchange, briefing and negotiation process outlined above will require extraordinarily sophisticated legal counseling and extensive planning, all under extremely tight deadlines. Moreover, it may be difficult for us to secure or retain such legal support if large, well-funded originators have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long-standing relationships with originators.

Under the complex, and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any originator patents that might be asserted against us in this new process, we see substantial risk that the BPCIA process may significantly delay or defeat our ability to market our products in the United States, or may result in us incurring substantial legal settlement costs.

### **Risks Related to the Discovery and Development of Our Product Candidates**

***We are heavily dependent on the development, clinical success, regulatory approval and commercial success of our product candidates. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.***

We invested substantially all of our efforts and financial resources to identify, acquire and develop our product candidates. Our future success is dependent on our ability to develop, obtain regulatory approval for, and then commercialize and obtain adequate third party coverage and reimbursement for one or more of our product candidates. We currently do not have any approved products, other than UDENYCA®.

Our product candidates are in varying stages of development and will require additional clinical development, management of nonclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supplies, commercial organization and significant marketing efforts before we generate any revenue from product sales. For example, CHS-1420 has completed Phase 3 clinical trials or other 351(k) BLA-enabling clinical development, and toripalimab is currently being evaluated in Phase 3 clinical trials. Other than certain PK bridging studies, we have not initiated phase 3 clinical trials for other product candidates in our pipeline. It may be some time before we file for market approval with the relevant regulatory agencies for these product candidates.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we and our existing or future collaboration partners do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We, together with our collaboration partners, generally plan to seek regulatory approval to commercialize our product candidates in the United States, the E.U., and additional foreign countries where we or our partners have commercial rights. To obtain regulatory approval, we and our collaboration partners must comply with numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, and pricing and distribution of our product candidates. Even if we and our collaboration partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. For example, Innovent's bevacizumab (Avastin) biosimilar product candidate has been developed principally in China, and the FDA may not agree that Innovent's clinical development plan, even if successfully completed, will support submission of a 351(k) BLA. If we and our collaboration partners are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

***The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and the regulatory approval requirements for biosimilars are evolving. If we and our collaboration partners are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic and biosimilar products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the EMA and EEA Competent Authorities in the European Economic Area (“EEA”), and by other regulatory authorities in other countries, where regulations differ from country to country. Neither we nor any existing or future collaboration partners are permitted to market our product candidates in the United States until we and our collaboration partners receive approval from the FDA, or in the EEA until we and our collaboration partners receive EC or EEA Competent Authority approvals.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, may take many years following the completion of clinical studies and depends upon numerous factors. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, during FDA’s review of Bioeq’s 351(k) BLA for its ranibizumab (Lucentis) biosimilar, the FDA requested that Bioeq submit additional manufacturing data for the equipment in its new location, leading Bioeq to withdraw its 351(k) BLA for this candidate in order to provide the requested data and resubmit the application thereafter. Neither we nor any collaboration partner has obtained regulatory approval for any of our product candidates, other than UDENYCA®, which has received approval from the FDA and EMA, and toripalimab, which is approved for use in China only, and it is possible that none of our other current or future product candidates will ever obtain additional regulatory approvals.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of an original BLA, an NDA, a biosimilar product application under the 351(k) pathway of the Public Health Service Act (“PHSA”), a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate’s risk-benefit ratio for its proposed indication is acceptable;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of our collaborators or third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This approval process, as well as the unpredictability of the results of clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business. Any delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing.

***If we are not able to demonstrate biosimilarity of our biosimilar product candidates to the satisfaction of regulatory authorities, we will not obtain regulatory approval for commercial sale of our biosimilar product candidates and our future results of operations would be adversely affected.***

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and to commercialize our proposed biosimilar products. To obtain regulatory approval for the commercial sale of these product candidates, we will be required to demonstrate to the satisfaction of regulatory authorities, among other things, that our proposed biosimilar products are highly similar to biological reference products already licensed by the regulatory authority pursuant to marketing applications, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. Each individual jurisdiction may apply different criteria to assess biosimilarity, based on a preponderance of the evidence that can be interpreted subjectively in some cases. In the EEA, the similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy.

It is uncertain if regulatory authorities will grant the full originator label to biosimilar product candidates when they are approved. For example, an infliximab (Remicade) biosimilar molecule was approved in Europe and in the United States for the full originator label but received a much narrower originator label when initially approved in Canada. That infliximab biosimilar only received full label extension in Canada in 2016 after providing additional clinical data. A similar outcome could occur with respect to our product candidates and there is no guarantee that our product candidates will receive a full originator label even after the provision of additional clinical data.

In the event that regulatory authorities require us to conduct additional clinical trials or other lengthy processes, the commercialization of our proposed biosimilar products could be delayed or prevented. Delays in the commercialization of or the inability to obtain regulatory approval for these products could adversely affect our operating results by restricting or significantly delaying our introduction of new biosimilars.

***Clinical drug development involves a lengthy and expensive process and we may encounter substantial delays in our clinical studies or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we or our collaboration partners, or both we and our collaboration partners, as the case may be, must conduct clinical studies to demonstrate the safety and efficacy of the product candidates in humans.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent registration clinical studies. There is a high failure rate for product candidates proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having

progressed through preclinical studies and initial clinical studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Nonclinical and clinical data are also often susceptible to varying interpretations and analyses. We do not know whether any clinical studies we may conduct for our product candidates will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval. Furthermore, biosimilar clinical studies must use originator products as comparators, and such supplies may not be available on a timely basis to support such trials.

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”), and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board (“IRB”), approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug (“IND”), application or amendment or equivalent application or amendment, or an inspection of our clinical study operations or study sites or as a result of adverse events reported during a clinical trial;
- delays in recruiting suitable patients to participate in our clinical studies sponsored by us or our partners;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA’s good clinical practices requirements or applicable regulatory guidelines in other countries;
- delays in patients completing participation in a study or return for post-treatment follow-up, or patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and originator products for use in clinical studies or the inability to do any of the foregoing.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, or conducting our planned clinical trials. Any inability to successfully complete



nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. For example, we altered the manufacturing processes for CHS-1420 and will need to provide data to the FDA and foreign regulatory authorities demonstrating that the change in manufacturing process has not changed the product candidate. If we are unable to make that demonstration to the FDA or comparable foreign regulatory authorities, we could face significant delays or fail to obtain regulatory approval to market the product, which could significantly harm our business.

***The development, manufacture and commercialization of biosimilar products under various global regulatory pathways pose unique risks.***

We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the BPCIA, enacted on March 23, 2010, as part of the ACA. The BPCIA established this abbreviated pathway under section 351(k) of the PHSA. Subsequent to the enactment of the BPCIA, the FDA issued guidance documents regarding the demonstration of biosimilarity and interchangeability as well as the submission and review of biosimilar applications. Moreover, market acceptance of biosimilar products in the United States is unclear. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for originator products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payers and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

We will continue to analyze and incorporate into our biosimilar development plans any final regulations issued by the FDA, pharmacy substitution policies enacted by state governments and other applicable requirements established by relevant authorities. The costs of development and approval, along with the probability of success for our biosimilar product candidates, will be dependent upon the application of any laws and regulations issued by the relevant regulatory authorities.

Biosimilar products may also be subject to extensive originator-controlled patent portfolios and patent infringement litigation, which may delay and could prevent the commercial launch of a product. Moreover, the BPCIA prohibits the FDA from accepting an application for a biosimilar candidate to a reference product within four years of the reference product's licensure by the FDA. In addition, the BPCIA provides innovative biologics with 12 years of exclusivity from the date of their licensure, during which time the FDA cannot approve any application for a biosimilar candidate to the reference product.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are evolving and remain subject to significant uncertainty. Future implementation decisions by the FDA could result in delays in the development or commercialization of our product candidates or increased costs to assure regulatory compliance and could adversely affect our operating results by restricting or significantly delaying our ability to market new biosimilar products. Moreover, the Trump administration previously enacted several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be interpreted and implemented and whether they will be overturned or otherwise modified by the Biden administration, and the extent to which they will impact the FDA's ability to continue implementing the BPCIA and engage in its other regulatory activities under the FDA. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course or if the Biden administration were to implement similar or more severe restrictions, our business may be negatively impacted.

Under current E.U. regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the E.U. until expiration of an eight-year data exclusivity period for the reference (originator) product, measured from

the date of the reference product's initial marketing authorization. Furthermore, once approved, the biosimilar cannot be marketed until expiration of a ten-year period following the initial marketing authorization of the reference product, such ten-year period being extendible to 11 years if the reference product received approval of an additional therapeutic indication, within the first eight years following its initial marketing authorization, representing a significant clinical benefit in comparison with existing therapies.

In Europe, the approval of a biosimilar for marketing is based on an opinion issued by the EMA and a decision issued by the EC. Therefore, the marketing approval will cover the entire EEA. However, substitution of a biosimilar for the originator is a decision that is made at the national level. Additionally, a number of countries do not permit the automatic substitution of biosimilars for the originator product. Therefore, even if we obtain marketing approval for the entire EEA, we may not receive substitution in one or more European nations, thereby restricting our ability to market our products in those jurisdictions.

Other regions, including Canada, Japan and South Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases other countries have either adopted European guidance (Singapore and Malaysia) or are following guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also some areas of non-overlap. Additionally, we cannot predict whether countries that we may wish to market in which do not yet have an established or tested regulatory framework could decide to issue regulations or guidance and/or adopt a more conservative viewpoint than other regions. Therefore, it is possible that even if we obtain agreement from one health authority to an accelerated or optimized development plan, we will need to defer to the most conservative view to ensure global harmonization of the development plan. Also, for regions where regulatory authorities do not yet have sufficient experience in the review and approval of a biosimilar product, these authorities may rely on the approval from another region (e.g., the U.S. or the E.U.), which could delay our approval in that region. Finally, it is possible that some countries will not approve a biosimilar without clinical data from their population or may require that the biosimilar product be manufactured within their region, or some countries may require both.

***If other biosimilars of pegfilgrastim (Neulasta), bevacizumab (Avastin), ranibizumab (Lucentis) or adalimumab (Humira), are determined to be interchangeable and our biosimilar candidates for these originator products are not, our business would suffer.***

The FDA or other relevant regulatory authorities may determine that a proposed biosimilar product is "interchangeable" with a reference product, meaning that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar product candidate and the reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of interchangeability, regulatory authorities may require additional confirmatory information beyond what we plan to initially submit in our applications for approval, such as more in-depth analytical characterization, animal testing or further clinical studies. Provision of sufficient information for approval may prove difficult and expensive.

We cannot predict whether any of our biosimilar product candidates will meet regulatory authority requirements for approval not only as a biosimilar product but also as an interchangeable product in any jurisdiction. Furthermore, legislation governing interchangeability could differ by jurisdiction on a state or national level worldwide.

The labelling of "interchangeability" is important because, in the United States for example, the first biosimilar determined to be interchangeable with a particular reference, or originator, product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that originator product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit



instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). Thus, a determination that another company's product is interchangeable with the originator biologic before we obtain approval of our corresponding biosimilar product candidates may delay the potential determination that our products are interchangeable with the originator product, which could materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

***Failure to obtain regulatory approval in any targeted regulatory jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities.***

We are marketing UDENYCA® in the United States, and subject to product approvals and relevant patent expirations, we intend to market our other biosimilar products in the United States and outside the U.S. on our own or with future collaboration partners. We entered into a distribution agreement with our licensee Orox for the commercialization of biosimilar versions of etanercept (Enbrel), rituximab (Rituxan), adalimumab (Humira) and pegfilgrastim (Neulasta) in certain Caribbean and Latin American countries. We intend to market our biosimilar product candidates in the United States and may seek to partner commercially all biosimilars outside the U.S.

In order to market our products in the E.U., the U.S. and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the centralized procedure for the regulation and approval of human medicines. This procedure results in a single marketing authorization that is valid in all E.U. countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or our collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of operations.

***We may not be successful in our efforts to identify, develop or commercialize additional product candidates.***

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all;

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing;
- our potential product candidates may fail to show sufficient biosimilarity to originator molecules; and
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

### **Risks Related to Our Compliance with Applicable Laws**

#### ***Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.***

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (together the "ACA"), was passed, which substantially changed the way health care is financed by both governmental and private insurers and has impacted and continues to impact the U.S. pharmaceutical industry. The ACA, among other things, addressed 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, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and promoted a new Medicare Part D coverage gap discount program.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. By way of example, at the end of 2017, the Tax Cuts and Jobs Act (the "Tax Act") was enacted, which, among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the ACA. At this time, the full effect that the ACA and any subsequent changes would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. Recently there has also been heightened government scrutiny over the manner in which manufacturers set prices for their approved products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures, such as a single reimbursement code for biosimilar products.

In the E.U., similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the E.U. or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the E.U., including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than E.U., law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most E.U. member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing E.U. and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the U.S. and E.U., reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

***We may be subject, directly or indirectly, to federal and state healthcare laws, including fraud and abuse, false claims and physician payment transparency laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.***

Our operations are directly or indirectly through our customers subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws impact, among other things, sales, marketing and education programs. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or in return for the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;
- federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or

entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal physician “sunshine” requirements under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians, as defined in the statute, including their immediate family members, certain other healthcare professionals as of 2022, and teaching hospitals and ownership and investment interests held by such physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws.

Efforts to ensure that our operations and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***If we participate in and then fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

With the approval of UDENYCA®, we now participate in the Medicaid Drug Rebate Program, Medicare Coverage Gap Discount Program and a number of other federal and state government pricing programs in the United States in order to obtain coverage for the product by certain government healthcare programs. These programs generally require us to pay rebates or provide discounts to certain private purchasers or government payers in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would affect our obligations to pay rebates or

offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

### **Risks Related to Ownership of Our Common Stock**

***The market price of our common stock may be highly volatile, and purchasers of our common stock could incur substantial losses.***

The market price of our common stock has been highly volatile since our Initial Public Offering (“IPO”) and the intraday sales price per share has ranged from \$8.05 to \$38.10 per share during the period from November 6, 2014 through April 30, 2021 and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in the “Risk Factors” section of this Quarterly Report on Form 10-Q and others such as:

- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, original BLA, 351(k) BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency’s review of that IND, NDA, original BLA, 351(k) BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;

- the outcomes of any citizen petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- reductions in the prices of originator products that could reduce the overall market opportunity for our product candidates intended as biosimilars to such originator products; and
- changes in biosimilar regulatory requirements that could make it more difficult for us to develop our product candidates.

In addition, biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of March 31, 2021, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 62.1% of our voting stock (assuming no exercise of outstanding options or conversion of our outstanding convertible notes). These stockholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market the market price of our common stock could decline. As of March 31, 2021, there were approximately 73.1 million shares of common stock outstanding.

In addition, as of March 31, 2021, approximately 27.3 million shares of common stock that are either subject to outstanding options and restricted stock units or reserved for future issuance under our equity incentive plans were eligible or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.



***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans and convertible notes, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We have needed and anticipate we will need additional capital in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. Similar to prior financing transactions, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. Any future debt financing may involve covenants that restrict our operations, including, among other restrictions, limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Pursuant to our 2014 Equity Incentive Award Plan (the "2014 Plan"), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2014 Plan, the number of shares of our common stock initially reserved for issuance is 2,300,000 plus the number of shares remaining available for future awards under the 2010 Plan. The number of shares available for future grant under the 2014 Plan will be increased by (i) the number of shares pursuant to outstanding awards under the 2010 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under the 2010 Plan and (ii) an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 4% of the shares of stock outstanding as of the last day of the preceding fiscal year, or such smaller number of shares as determined by our board of directors. Pursuant to our 2014 Employee Stock Purchase Plan ("2014 ESPP"), eligible employees are able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 320,000 shares are initially available for issuance under the 2014 ESPP. The number of shares available for issuance under the 2014 ESPP will automatically increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year or such smaller number of shares as determined by our board of directors. If our board of directors elects to increase the number of shares available for future grant under the 2014 Plan or the 2014 ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall. Pursuant to our 2016 Employment Commencement Incentive Plan (the "2016 Plan"), our management is authorized to grant stock options and other equity-based awards to our new employees. The 2016 Plan is designed to comply with the inducement exemption contained in Nasdaq's Rule 5635(c)(4), which provides for the grant of non-qualified stock options, restricted stock units, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with us. As of March 31, 2021, we reserved for future issuance under the 2016 Plan a total of 1.6 million shares of common stock for new employees. The 2016 Plan does not provide for any annual increases in the number of shares available.

In February 2016, we issued and sold \$100.0 million aggregate principal amount of our 8.2% senior convertible notes due March 2022 (the "2022 Convertible Notes"). The holders may convert their 2022 Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding March 31, 2022. Upon conversion of the 2022 Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. The initial conversion rate is 44.7387 shares of common stock per \$1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately \$22.35 per share, and is subject to adjustment in certain events.

In April 2020, we issued and sold \$230.0 million aggregate principal amount of our 1.5% senior convertible notes due April 2026 (the "2026 Convertible Notes"). The holders may convert their 2026 Convertible Notes at their option at

any time prior to the close of business on the second scheduled trading day immediately before April 15, 2026. Upon conversion of the 2026 Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. The initial conversion rate is 51.9224 shares of common stock per \$1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately \$19.26 per share, and is subject to adjustment in certain events.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

***Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.***

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our corporate secretary pursuant to a resolution adopted by a majority of our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors other than nominations made by or at the direction of the board of directors or a committee of the board of directors;
- provide that our directors may be removed only for cause or without cause by the holders of 66 2/3% of the voting power of all then outstanding shares of voting stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require holders of 66 2/3% of the voting power of all then outstanding shares of voting stock to amend specified provisions of our amended and restated certificate of incorporation except for the provision making it possible for our board of directors to issue “blank check” preferred stock, and amended and restated bylaws.

These provisions, alone or together, could delay, deter or prevent hostile takeovers and changes in control or changes in our management.



In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

### **General Risk Factors**

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaboration partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

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

Our corporate headquarters and laboratory are located in the San Francisco Bay Area and in Southern California (Camarillo), respectively. These locations have in the past experienced severe earthquakes and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party contract manufacturers) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

***So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.***

The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from an application that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may issue to our competitors covering our biosimilar product candidates or our pipeline candidates and thereby cause significant market entry delay, defeat our ability to market our products or cause us to abandon development and/or commercialization of a molecule.

Examples of submarine patents include Brockhaus, et al., U.S. patents 8,063,182 and 8,163,522 (controlled by Amgen), which are directed to the fusion protein in Enbrel. On July 1, 2020, the U.S. Court of Appeals for the Federal Circuit issued a decision that affirmed the lower court's decision upholding the validity of these patents. As a result, we discontinued the development of CHS-0214 (our etanercept (Enbrel®) biosimilar candidate).

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a biosimilar candidate into the United States market.

***We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.***

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline molecules. We may incorrectly determine that our products are not covered by a third party patent.

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of an originator product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products.

***Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.***

If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in our successful development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us.

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output

before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications.

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Our patents and patent applications, even if they are unchallenged, may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business.

In addition, changes to U.S. patent laws provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before we do, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the U.S. resulting from the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

We have issued patents and have filed patent applications, which are currently pending, covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any

patents, which may issue to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

While our business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents and on avoiding infringing valid and enforceable rights of third parties, we have filed a number of patent applications seeking patents that cover various proprietary elements of our product candidates when we have believed securing such patents may afford a competitive advantage. Our patent portfolio includes pending patent applications and issued patents, in the United States and globally, covering our biosimilar product candidates and methods of making them. We cannot guarantee that our proprietary technologies will avoid infringement of third party patents. Moreover, because competitors may be able to develop their own proprietary technologies, it is uncertain whether any of our issued patents or pending patent applications directed to etanercept and adalimumab would cover the etanercept and adalimumab products of any competitors. The product and patent landscape is highly uncertain and we cannot predict whether our patent filings will afford us a competitive advantage against third parties or if our etanercept and adalimumab products will avoid infringement of third party patents.

We do not consider it necessary for us or our competitors to obtain or maintain a proprietary patent position in order to engage in the business of biosimilar development and commercialization. Hence, while our ability to secure patent coverage on our own proprietary developments may improve our competitive position with respect to the product candidates we intend to commercialize, we do not view our own patent filings as a necessary or essential requirement for conducting our business nor do we rely on our own patent filings or the potential for any commercial advantage they may provide us as a basis for our success.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or importing products made using our inventions into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor

the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***If we are unable to maintain effective (non-patent) proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.***

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, for example, our employees, consultants, scientific advisors, board members, contractors, potential collaborators and investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States and the EU, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

***We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.***

Although we are not currently aware of any claims challenging the inventorship of our patent applications or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from

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

***We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.***

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel must devote a substantial amount of time to ensure that we maintain compliance with all of these requirements. Moreover, the reporting requirements, rules and regulations have increased our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we have made, and may make in the future to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, may also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 ("Section 404"), and the related rules of the Securities and Exchange Commission ("SEC"), which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.

Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.



***Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, computer viruses, “phishing” attacks, malware, ransomware, denial of service and other cyber-attacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/ or proprietary data, including health-related information or other personal information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. If we or any of our third-party collaborators were to experience any material failure or security breach, it could result in a material disruption of our development programs, reputation, and business operations. For example, the loss of clinical study data from completed or ongoing clinical studies could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal information, including health-related information, we may have to notify individuals, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party CROs and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business. The COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal information, including health-related information, we could incur liability and suffer reputational harm, and the development and commercialization of our products could be delayed. Our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation.

***We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.***

Privacy and data security have become significant issues in the United States, E.U. and in many other jurisdictions where we may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we may be subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and the CCPA (defined below), and, in the E.U. and the EEA, Regulation 2016/679, known as the General Data Protection Regulation (“GDPR”). Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In the United States, we and our partners may be subject to numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain



health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission (“FTC”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act (the “CCPA”) on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the CPRA recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and the CPRA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the GDPR took effect. The GDPR is applicable in each EEA member state and applies to companies established in the EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EEA, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union (“CJEU”) invalidated the EU-US Privacy Shield Framework (“Privacy Shield”) under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. Penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher.

Additionally, as of January 1, 2021, we have to comply with the GDPR and the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the E.U. with respect to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the E.U. and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from E.U. member states to the United Kingdom for a four-year period, subject to subsequent extensions.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and have a material adverse effect on our business, financial condition and results of operations.

***The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S.***

We currently have limited international operations of our own and have and may have in the future a number of international collaborations. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems by our collaboration partners;
- limits in our or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;

- certain expenses including, among others, expenses for travel, translation and insurance;
- expose us to sanctions, such as the sanctions levied by U.S., E.U. and Russian regulatory bodies in connection with Russia's military intervention in the Ukraine in March 2014; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

**ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds**

Not applicable

**ITEM 3. Defaults Upon Senior Securities**

Not applicable

**ITEM 4. Mine Safety Disclosures**

Not applicable

**ITEM 5. Other Information**

Not applicable

**ITEM 6. Exhibits**

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

## INDEX TO EXHIBITS

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	3.1	11/13/2014	
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	3.2	11/13/2014	
4.1	Reference is made to exhibits 3.1 and 3.2				
4.2	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	4.2	10/24/2014	
4.3	<a href="#">Description of Coherus' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.</a>	10-K	4.3	2/27/2020	
4.4	<a href="#">Indenture, dated as of April 17, 2020, between Coherus Biosciences, Inc. and U.S. Bank National Association, as Trustee.</a>	8-K	4.1	4/17/2020	
4.5	<a href="#">Form of certificate representing the 1.5% Convertible Senior Subordinated Notes due 2026.</a>	8-K	4.2	4/17/2020	
10.1	<a href="#">Exclusive License and Commercialization Agreement, dated February 1, 2021, by and between the Coherus Biosciences, Inc. and Shanghai Junshi Biosciences, Co. Ltd.</a>				X
10.2	<a href="#">Stock Purchase Agreement, dated February 1, 2021, by and between the Coherus Biosciences, Inc. and Shanghai Junshi Biosciences, Co. Ltd.</a>				X
31.1	<a href="#">Certification of Principal Executive Officer Required under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).</a>				X
31.2	<a href="#">Certification of Principal Financial Officer under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).</a>				X
32.1	<a href="#">Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 and Securities Exchange Act Rule 13a-14(b).</a>				X

<u>Exhibit Number</u>	<u>Description</u>	<u>Incorporated by Reference</u>			<u>Filed Herewith</u>
		<u>Form</u>	<u>Exhibit</u>	<u>Date Filed</u>	
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 formatted in inline eXtensible Business Reporting Language (iXBRL) includes: (i) Condensed Consolidated Balance Sheets at March 31, 2021 (unaudited) and December 31, 2020, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2021 and 2020, (iii) Condensed Consolidated Statements of Comprehensive Income (unaudited) for the three months ended March 31, 2021 and 2020, (iv) Condensed Consolidated Statements of Stockholders' Equity (Deficit) (unaudited) for the three months ended March 31, 2021 and 2020, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2021 and 2020, and (vi) Notes to the Condensed Consolidated Financial Statements.				X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 has been formatted in Inline XBRL.				X

**SIGNATURES**

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

**COHERUS BIOSCIENCES, INC.**

Date: May 6, 2021

/s/ Dennis M. Lanfear  
Dennis M. Lanfear  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 6, 2021

/s/ McDavid Stilwell  
McDavid Stilwell  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**EXCLUSIVE LICENSE AND COMMERCIALIZATION AGREEMENT**

**BY AND BETWEEN**

**COHERUS BIOSCIENCES, INC.**

**AND**

**SHANGHAI JUNSHI BIOSCIENCES CO., LTD.**

**DATED AS OF FEBRUARY 1, 2021**

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## EXCLUSIVE LICENSE AND COMMERCIALIZATION AGREEMENT

**THIS EXCLUSIVE LICENSE AND COMMERCIALIZATION AGREEMENT** (this “**Agreement**”) is entered into as of 1 February 2021 (the “**Execution Date**”) by and among Shanghai Junshi Biosciences Co., Ltd., a corporation organized and existing under the laws of the People’s Republic of China, with a registered address at Level 13, Building 2, Nos. 36 and 58, Hai Qu Road, China (Shanghai) Pilot Free Trade Zone, China 201203 (“**Junshi**”), and **Coherus BioSciences, Inc.**, a Delaware corporation having its principal place of business at 333 Twin Dolphin Drive, Suite 600 Redwood City, CA 94065 (“**Coherus**”). Junshi and Coherus are referred to herein individually as a “**Party**” and collectively as the “**Parties.**”

### BACKGROUND

**WHEREAS**, Junshi and its Affiliates Control certain Patent Rights and Know-How relating to the Licensed Antibody and are conducting research and development with respect to additional products.

**WHEREAS**, Junshi desires to grant, and Coherus desires to receive, an exclusive license under such Patent Rights and Know-How related to the Licensed Antibody to permit Coherus to Develop, Manufacture, Commercialize, and otherwise Exploit the Licensed Antibody and Licensed Products within the Coherus Territory.

**WHEREAS**, Junshi desires to grant, and Coherus desires to receive, an exclusive option to receive an exclusive license to Exploit products that are the subject of two other programs Controlled by Junshi.

**WHEREAS**, Junshi desires to grant, and Coherus desires to receive, a right of first negotiation with respect to the grant of rights to Exploit products that are the subject of two additional programs Controlled by Junshi.

**NOW THEREFORE**, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

- 1.1 “**Additional Cure Period**” has the meaning set forth in Section 13.3(c) (Disputes Regarding Material Breach).
  - 1.2 “**Additional Third Party IP**” has the meaning set forth in Section 2.5 (Third Party In-Licenses).
  - 1.3 “**Additional Third Party License**” has the meaning set forth in Section 2.5 (Third Party In- Licenses).
  - 1.4 “**Affiliate**” means, with respect to a Party, a person, corporation, partnership, or other entity that controls, is controlled by, controlling or is under common control with such Party, but only for so long as such control will continue. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by”, “controlling” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
  - 1.5 “**Agreement**” has the meaning set forth in the Preamble.
  - 1.6 “**Alliance Manager**” has the meaning set forth in Section 3.1 (Alliance Manager).
  - 1.7 “**Antibody**” means an antibody, or an antigen binding fragment thereof.
  - 1.8 “**Antitrust Clearance Date**” means the earliest date on which all applicable waiting periods and approvals required under Antitrust Laws in the Clearance Countries with respect to the transactions
-

contemplated under this Agreement have expired or have been terminated (in the case of waiting periods) or been received (in the case of approvals), in each case, without the imposition of any conditions.

- 1.9 “**Antitrust Filing**” means filings by Junshi and Coherus with the United States Federal Trade Commission and the United States Department of Justice and any applicable governmental authority in the Clearance Countries, as required under any Antitrust Laws with respect to the transactions contemplated under this Agreement, together with all required documentary attachments thereto.
- 1.10 “**Antitrust Laws**” means any and all applicable law designed to prohibit, restrict, or regulate actions for the purpose or effect of monopolization or restraint of trade.
- 1.11 “**Arising Know-How**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).
- 1.12 “**Arising Patent Rights**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).
- 1.13 “**Arising Technology**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).
- 1.14 “**BLA**” means a Biologics License Application submitted to the FDA pursuant to 21 U.S.C. §601.2, for purposes of obtaining Regulatory Approval to introduce a biologic product into interstate commerce in the United States, or any equivalent filing in a country or regulatory jurisdiction other than the United States.
- 1.15 “**Business Day**” means a day other than a Saturday, Sunday, or a day on which banking institutions in Redwood City, CA or Shanghai, China are required by applicable law to remain closed.
- 1.16 “**Calendar Quarter**” means a period of three consecutive months ending on the last day of March, June, September, or December, respectively.
- 1.17 “**Calendar Year**” means a period of 12 consecutive months beginning on January 1 and ending on December 31.
- 1.18 “**CD112r**” means receptor for cluster of differentiation 112.
- 1.19 “**cGMP**” means applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 600, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the ICH’s Q7 guidelines, and (d) the applicable laws the Coherus Territory corresponding to (a) through (c) above, each as may be amended and applicable from time to time.
- 1.20 “**Chairperson**” has the meaning set forth in Section 3.2 (Joint Development Committee).
- 1.21 “**Change of Control**” means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction, owning more than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party’s consolidated assets taken as a whole, through one or more related transactions.
- 1.22 “**Claim**” has the meaning set forth in Section 11.3 (Indemnification Procedures).

- 1.23 “**Clearance Countries**” means the countries and jurisdictions where antitrust clearance is required under any Antitrust Laws with respect to the transactions contemplated under this Agreement.
- 1.24 “**Clinical Trial**” means a study in humans to obtain information regarding a product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of such product, including a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and a Pivotal Trial.
- 1.25 “**Closing Disclosure Letter**” has the meaning set forth in Section 10.3(a) (Closing Disclosure Letter).
- 1.26 “**CMO**” means a contract manufacturing organization.
- 1.27 “**Coherus**” has the meaning set forth in the Preamble.
- 1.28 “**Coherus Arising Patent Rights**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).
- 1.29 “**Coherus CMO**” has the meaning set forth in Section 2.6(a) (Initial Technology Transfer).
- 1.30 “**Coherus Indemnitees**” has the meaning set forth in Section 11.1 (Indemnification by Junshi).
- 1.31 “**Coherus Territory**” means the United States and Canada.
- 1.32 “**Combination Product**” means a Licensed Product that is (a) sold in the form of a combination that contains or comprises a Licensed Antibody together with one or more other therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold for a single price), (b) sold for a single invoice price together with any (i) delivery device or component therefor, (ii) companion diagnostic related to a Licensed Antibody, or (iii) product, process, service, or therapy (including possibly another Licensed Antibody, such additional therapeutically active pharmaceutical agent and each of (i) – (iii), an “**Other Component**”); or (c) defined as a “combination product” by the FDA pursuant to 21 C.F.R. §3.2(e) or its foreign equivalent.
- 1.33 “**Combination Regimen**” means any product or treatment regimen that comprises, or is a combination of (a) a Licensed Product, and (b) any Other Component (whether or not the intellectual property rights for such Other Component are Controlled by a Party), where (a) and (b) are labeled for use together or Regulatory Approval is being sought for use together either simultaneously or in a separate or sequential administration, whether or not sold for a single price.
- 1.34 “**Commercialization**,” “**Commercializing**,” or “**Commercialize**” means any and all activities directed to the marketing, promotion, distribution, offering for sale, sale, having sold, importing, having imported, exporting, having exported or other commercialization of a pharmaceutical or biologic product, but excluding activities directed to Manufacturing, Development, or Medical Affairs. “**Commercialize**,” “**Commercializing**,” and “**Commercialized**” will be construed accordingly.
- 1.35 “**Commercially Reasonable Efforts**” means, with respect to the efforts to be expended by a Party or its Affiliate with respect to any Development or Commercialization objective, activity, or goal related to a Licensed Product or Option Product (as applicable) under this Agreement, those efforts that a Party would normally use to accomplish such objective, activity, or goal, and specifically means the carrying out of Development and Commercialization activities using efforts that a Party would normally devote to a product at a similar stage in its development or product life and of similar market potential, strategic importance, and profit potential (taking into account payments under this Agreement), based on conditions then prevailing and taking into account efficacy, safety, product labeling, profitability, the competitiveness of alternative products sold by Third Parties in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, and all other relevant factors.

Commercially Reasonable Efforts will be determined on a country-by-country and indication-by- indication basis for the applicable Licensed Product and it is anticipated that the level of effort will change over time, reflecting changes in the status of such Licensed Product (as applicable) and the market or country involved.

- 1.36 **“Competitive Product”** means, (a) with respect to the Licensed Antibody and Licensed Products as of the Effective Date, any pharmaceutical or biologic product, other than a Licensed Product, that is an anti-PD-1 monospecific Antibody or anti-PD-L1 monospecific Antibody, excluding, in each case, any other modality molecule including such Antibody (such as a bi-specific or multi- specific Antibody or fused cytokine), (b) with respect to the Licensed Antibody and Licensed Products that are the subject of the Option Program for the Junshi IL-2 Molecule any pharmaceutical or biologic product, other than such Licensed Products that are the subject of the Option Program for the Junshi IL-2 Molecule, that is a molecule derived from IL-2, excluding, in each case, any IL-2 derived molecule fused with an Antibody or any IL-2 derived molecule described in clause (i) and (ii) of the definition of Junshi IL-2 Molecule, and (c) with respect to the Licensed Antibody and Licensed Products that are the subject of the Option Program for the Junshi TIGIT Antibody, any pharmaceutical or biologic product, other than such Licensed Products that are the subject of the Option Program for the Junshi TIGIT Antibody, that is an anti-TIGIT monospecific Antibody, excluding, in each case, any other modality molecule including such Antibody (such as a bi-specific or multi-specific Antibody or fused cytokine). For clarity, any product described in clauses (b) or (c) will not be a “Competitive Product” unless and until Coherus exercises the option with respect to the applicable Option Program.
- 1.37 **“Confidential Information”** has the meaning set forth in Section 12.1 (Confidentiality; Exceptions).
- 1.38 **“Continuing Technology Transfer”** has the meaning set forth in Section 2.6(c) (Continuing Technology Transfer).
- 1.39 **“Control”** or **“Controlled”** means (a) the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (i) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (ii) with respect to Patent Right, Regulatory Approvals, Regulatory Materials, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Right, Regulatory Approvals, Regulatory Materials, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((i) and (ii)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such possession, access, right to use, licenses, or sublicense; and (b) with respect to any product, the possession by a Party of the ability (whether by sole or joint ownership, license or otherwise, other than pursuant to this Agreement) to grant a license or sublicense of Patent Rights that claim such product or proprietary Know-How that is used in connection with the Exploitation of such product. Notwithstanding the foregoing, (A) a Party and its Affiliates will not be deemed to “Control” any Patent Rights, Know-How, or product that, prior to the consummation of a Change of Control of such Party, are owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such Change of Control, unless after the consummation of the Change of Control, such acquired Party uses any such Patent Rights, Know- How, or product in connection with the Exploitation of a Combination Regimen (if Junshi is the acquired Party); and (B) any Additional Third Party IP that is licensed to a Party will not be deemed to be “Controlled” by such Party unless and until the Parties enter into a written agreement with

terms under which a Party or its Affiliate will grant to the other Party a sublicense thereunder in accordance with Section 2.5 (Third Party In-Licenses).

- 1.40 “**Cover,**” “**Covering,**” or “**Covered**” means, when used to refer to the relationship between a particular Patent Right and particular subject matter, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in, or is otherwise claimed by, such Patent Right.
- 1.41 “**CPA Firm**” has the meaning set forth in Section 8.6 (Books and Records; Audit Rights).
- 1.42 “**CTLA-4**” means cytotoxic T-lymphocyte antigen 4.
- 1.43 “**Date of First Regulatory Approval**” has the meaning set forth in Section 7.3 (Commercialization Report).
- 1.44 “**Defaulting Party**” has the meaning set forth in Section 13.3(c) (Disputes Regarding Material Breach).
- 1.45 “**Develop**” or “**Development**” means all internal and external research, development, and regulatory activities related to pharmaceutical or biologic products, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, but excluding activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include development and regulatory activities for additional forms, formulations, or indications for a pharmaceutical or biologic product after receipt of Regulatory Approval of such product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or indication (such as post-marketing studies, observational studies, implementation and management of registries and analysis thereof, in each case, if required by any Regulatory Authority in any region to support or maintain Regulatory Approval for a pharmaceutical or biologic product in such region). “**Develop,**” “**Developing,**” and “**Developed**” will be construed accordingly.
- 1.46 “**Developing Party**” has the meaning set forth in Section 4.5 (Independent Development in the Coherus Territory).
- 1.47 “**Development Proposal**” has the meaning set forth in Section 4.3(a) (Proposals and JDC Review).
- 1.48 “**Effective Date**” has the meaning set forth in Section 14.1 (Effective Date).
- 1.49 “**Execution Date**” has the meaning set forth in the Preamble.
- 1.50 “**Executive Officer**” means (a) in the case of Coherus, the chief executive officer of Coherus, and (b) in the case of Junshi, the chief executive officer of Junshi, neither of who will be a member of the JDC.
- 1.51 “**Existing Nondisclosure Agreement**” means the Confidentiality Agreement entered into by Coherus and Junshi, effective as of April 1, 2020.
- 1.52 “**Exploit**” and “**Exploitation**” means Develop, use, perform Medical Affairs, offer for sale, sell, export, import, Manufacture, have Manufactured, Commercialize, or otherwise exploit. “**Exploitation**” and “**Exploiting**” will be construed accordingly.

- 1.53 “**FDA**” means the U.S. Food and Drug Administration or any successor agency thereto.
- 1.54 “**Field**” means treatment or prevention of diseases and disorders in humans.
- 1.55 “**First Commercial Sale**” means, with respect to a Licensed Product in a country or region in the Coherus Territory, the first sale to a Third Party of such Licensed Product in such country or region after receipt of Regulatory Approval and, where applicable for the Commercialization of such Licensed Product in such country or region, Pricing and Reimbursement Approval. First Commercial Sale excludes any sale or other distribution of a Licensed Product for promotional or advertising purposes, Clinical Trials, preclinical trials, or other Development purposes, free samples, named patient use, compassionate use, patient assistance, expanded access, or charitable use.
- 1.56 “**For the Coherus Territory**” means, with respect to any Clinical Trial or other Development of a Licensed Product, that such Development is conducted for purposes of obtaining, maintaining, or supporting Regulatory Approval of such Licensed Antibodies and Licensed Products in the Field in the Coherus Territory, including when Clinical Trials are conducted under an IND in the US or its Canadian counterpart.
- 1.57 “**FTE**” means the equivalent of the work of one duly qualified employee of either Party full time for one year (consisting of a total of 1,800 hours per year) carrying out Development or Manufacturing activities, or other scientific or technical work under this Agreement. Overtime and work on weekends, holidays, and the like, in each case, will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. The portion of an FTE billable for one individual during a given accounting period will be determined by dividing the number of hours worked directly by such individual on the work to be conducted under this Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on 1,800 working hours per Calendar Year.
- 1.58 “**FTE Rate**” means with respect to an employee or contractor of either Party, the amount for an FTE per Calendar Year, which for the Calendar Year ending on December 31, 2021 will be \$306,000 per FTE pro-rated for the period beginning on the Effective Date and ending on December 31, 2021, and thereafter will be adjusted annually based on the change in the Chinese Consumer Price Index as published by the National Bureau of Statistics of China (中华人民共和国国家统计局) available at <http://data.stats.gov.cn/english/>.
- 1.59 “**Fully Burdened Manufacturing Costs**” means, with respect to any Licensed Antibody or Licensed Product, supplied by or on behalf of the applicable Party to the other Party or its Affiliates hereunder:
- (a) if and to the extent the Licensed Antibody or Licensed Product is Manufactured by a CMO, the actual Third Party costs of such Manufacturing incurred by the supplying Party, including the costs of raw materials, intermediates and components, reference materials, or standards required for release testing, materials necessary to support stability studies, drug substance and drug product Manufacturing, quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, insurance, storage and freight, shipping, tariffs, sales and excise taxes imposed thereon, customs and duty and charges levied by governmental authorities and all costs of packaging and labeling; or
  - (b) if and to the extent the Licensed Antibody or Licensed Product is Manufactured by a Party or its Affiliate, the actual, fully burdened costs that are directly attributable to such Manufacturing, including the cost of raw materials and any costs incurred by such supplying Party for time spent by such Party’s personnel necessary for the other Party to obtain such raw materials, at the applicable FTE Rate, direct labor and benefits, a



proportionate share of indirect Manufacturing costs to the extent the foregoing are allocable to the Manufacture of such Licensed Antibody or Licensed Product (based on actual utilization for such product in a particular Calendar Year as compared to the actual working days during such Calendar Year), and all other reasonable and customary Manufacturing- related costs for such Licensed Antibody or Licensed Product, including management and process improvement costs (collectively, not to exceed 15% of the total of the Fully Burdened Manufacturing Costs for such Licensed Antibody or Licensed Product), factory, plant, or equipment start-up or start-up amortization costs, scale-up expenses, quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, insurance, storage and freight, shipping, tariffs, customs and duty and charges levied by governmental authorities (including export fees), and all costs of packaging and labeling. Such fully burdened costs will be calculated in accordance with GAAP (when calculated by a Party or its Affiliate in the USA) or IFRS (when calculated by a Party or its Affiliate outside of the USA), in each case, as consistently applied. Notwithstanding the foregoing, Fully Burdened Manufacturing Cost will be computed on a theoretical basis of no less than 70% capacity, and no overhead, equipment, or facilities costs will be included for unutilized, vacant, or dormant facilities or equipment (and Manufacturing overhead costs related to an underutilized facility or underutilized equipment will be allocated proportionately over the entire Manufacturing production (based on a theoretical full-capacity production schedule) of the facility and applicable equipment, whether or not the entire Manufacturing facility is being utilized).

- 1.60 “**GCP**” means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice E6(R2) and any other guidelines for good clinical practice for trials on medicinal products in the Coherus Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), 312 (Investigational New Drug Application) and any other regulations related to good clinical practice for trials on medicinal products in the Coherus Territory, as may be amended from time to time, and (d) the equivalent applicable laws in the region in the Coherus Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.
- 1.61 “**Global Brand Elements**” has the meaning set forth in Section 9.6 (Trademarks).
- 1.62 “**GLP**” means all applicable Good Laboratory Practice standards, including, as set forth in the then- current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent applicable laws in the Coherus Territory, each as may be amended and applicable from time to time.
- 1.63 “**HKSE**” has the meaning set forth in Section 12.2(c) (Disclosure on HKSE and SSE).
- 1.64 “**ICH**” means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
- 1.65 “**ICH Guidelines**” means guidelines established by ICH regarding quality, safety, efficacy and multidisciplinary topics.
- 1.66 “**IL-2**” means the interleukin-2 cytokine.

- 1.67 “**IL-2 Program**” means the program of Development of the Junshi IL-2 Molecules.
- 1.68 “**IND**” means (a) an Investigational New Drug Application as defined in the United States Federal Food, Drug and Cosmetic Act, as amended (the “**FD&C Act**”) and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical or biological product in humans in such jurisdiction.
- 1.69 “**Indemnified Party**” has the meaning set forth in Section 11.3 (Indemnification Procedures).
- 1.70 “**Indemnifying Party**” has the meaning set forth in Section 11.3 (Indemnification Procedures).
- 1.71 “**Independent Development Budget**” has the meaning set forth in Section 4.5 (Independent Development).
- 1.72 “**Independent Development Plan**” has the meaning set forth in Section 4.5 (Independent Development).
- 1.73 “**Independent Trial**” has the meaning set forth in Section 4.5 (Independent Development).
- 1.74 “**Initial Technology Transfer**” has the meaning set forth in Section 2.6(c) (Initial Technology Transfer).
- 1.75 “**JAMS**” has the meaning set forth in Section 15.1(b) (Dispute Resolution).
- 1.76 “**JAMS Rules**” has the meaning set forth in Section 15.1(c) (Dispute Resolution).
- 1.77 “**Joint Arising Know-How**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).
- 1.78 “**Joint Arising Patent Rights**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).
- 1.79 “**Joint Arising Technology**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).
- 1.80 “**Joint Development Committee**” and “**JDC**” have the meaning set forth in Section 3.2(a) (Formation; Composition).
- 1.81 “**Joint Development Budget**” has the meaning set forth in Section 4.4 (Joint Development).
- 1.82 “**Joint Development Plan**” has the meaning set forth in Section 4.4 (Joint Development).
- 1.83 “**Joint Development Proposal**” has the meaning set forth in Section 4.3(a) (Proposals and JDC Review).
- 1.84 “**JS001**” has the meaning set forth in Section 1.99 (Licensed Antibody).
- 1.85 “**JS001 Upstream License**” means that certain Multi-Product Licence Agreement by and between Junshi and Lonza Sales AG effective as of 4 May 2020, as amended.
- 1.86 “**JS001 Upstream License Costs**” has the meaning set forth in Section 8.5(a) (JS001 Upstream License).
- 1.87 “**JS018-1 Upstream License**” means that certain Technology License Contract in respect of Intramolecular Disulfide Bond IL-2 Drug (Contract No. LT20200828), signed on Aug 28, 2020 in Shanghai City.
- 1.88 “**JS018-1 Upstream License Costs**” has the meaning set forth in Section 8.5(b) (JS018-1 Upstream License).
- 1.89 “**Junshi**” has the meaning set forth in the Preamble.
- 1.90 “**Junshi Arising Patent Rights**” has the meaning set forth in Section 9.1(b)(i) (Arising Technology).

- 1.91 “**Junshi Arising Technology**” has the meaning set forth in Section 9.1(b) (Arising Technology).
- 1.92 “**Junshi Clinical Trials**” means (a) the Ongoing JS001 Clinical Trials, (b) those Independent Trials for which Junshi is the Developing Party, and (c) the Optioned Licensed Product Trials.
- 1.93 “**Junshi IL-2 Molecule**” means (a) the recombinant cytokine that is known as of the Execution Date as JS018-1, which has the sequence set forth on Schedule 1.93 (JS018-1 Sequence) and (b) any successor molecule that is Controlled by Junshi or any of its Affiliates, is derived from human IL-2, and is specifically engineered to reduce its CD25 binding affinity (compared to wild-type human IL-2), *excluding* (i) any molecules derived from IL-2 that are specifically engineered to alter the binding or effects of IL-2 on any IL-2 binding partners or effectors other than CD25 or (ii) any such IL-2 derived molecule when it is fused to other cytokines, antibodies, or other functional moiety.
- 1.94 “**Junshi Indemnitees**” has the meaning set forth in Section 11.2 (Indemnification by Coherus).
- 1.95 “**Junshi Territory**” means all countries in the world other than the Coherus Territory.
- 1.96 “**Junshi TIGIT Antibody**” means (a) the monoclonal Antibody that is known as of the Execution Date as JS006, which has the sequence set forth on Schedule 1.96 (JS006 Sequence) and (b) any successor monospecific Antibody that is Controlled by Junshi or any of its Affiliates and is directed to TIGIT, *excluding* any other modality molecule (such as bi-specific or multi-specific Antibody or fused cytokine) that contains the same CDR region as JS006.
- 1.97 “**Know-How**” means any data, results, and information of any type whatsoever, in any tangible or intangible form, including trade secrets, practices, techniques, methods, processes, inventions, discoveries, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, clinical and non-clinical study reports, clinical and non-clinical data, regulatory filings and regulatory submission documents and summaries, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, stability data, studies and procedures and any other know-how, and any physical embodiments of any of the foregoing.
- 1.98 “**License Option**” has the meaning set forth in Section 2.8(a) (Grant of Options).
- 1.99 “**Licensed Antibody**” means (a) (i) the monoclonal Antibody known as JS001 and with the International Nonproprietary Name of TORIPALIMAB, which has the sequence set forth on Schedule 1.99 (JS001 Sequence) (“**JS001**”) and (ii) any successor anti-PD-1 monospecific Antibody that is Controlled by Junshi or its Affiliates, but *excluding* any other modality molecule (such as bi-specific or multi-specific Antibody or fused cytokine) that contains the same CDR region as JS001 and (b) upon the exercise of a License Option with respect to an Option Program, all Option Molecules that are the subject of such Option Program.
- 1.100 “**Licensed Know-How**” means any and all Know-How, other than any Joint Arising Know-How, that is owned or Controlled by Junshi or any of its Affiliates as of the Execution Date or during the Term and that is necessary or reasonably useful to Exploit any Licensed Antibody or Licensed Product in the Field.
- 1.101 “**Licensed Manufacturing Technology**” has the meaning set forth in Section 2.6(b) (Manufacturing Technology Transfer).
- 1.102 “**Licensed Patent Rights**” means any and all Patent Rights, other than any Joint Arising Patent Rights, that are owned or Controlled by Junshi or any of its Affiliates as of the Execution Date or during the Term and that are necessary or reasonably useful to Exploit any Licensed Antibody or

Licensed Product in the Field. All Licensed Patent Rights existing as of the Execution Date are listed on Schedule 10.2(d) (Existing Patent Rights).

- 1.103 “**Licensed Product**” means any product that contains a Licensed Antibody, alone or in combination with one or more therapeutically active pharmaceutical ingredients, in all forms, presentations, compositions, dosages, and formulations.
- 1.104 “**Licensed Technology**” means Licensed Know-How, Licensed Patent Rights, and Junshi’s and its Affiliates’ interest in the Joint Arising Technology.
- 1.105 “**Manufacture**” or “**Manufacturing**” means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding activities directed to Development, Commercialization, or Medical Affairs. “**Manufacturing**” will be construed accordingly.
- 1.106 “**Manufacturing Technology Transfer**” has the meaning set forth in Section 2.6(b) (Manufacturing Technology Transfer).
- 1.107 “**Medical Affairs**” means, with respect to a Licensed Product, any and all activities performed by or on behalf of a Party’s or its Affiliates’ medical affairs departments interacting with physicians or other healthcare professionals who utilize or conduct research related to a drug or biological product, including: supporting continuing medical education and other medical programs and communications; development, publication, and dissemination of publications; development and fulfillment of medical information responses; development and execution of disease awareness education including symposia and digital education initiatives; sponsorship and booth exhibition at key congresses; conducting health economic, burden of illness/disease, natural history and real world evidence studies; supporting educational fellowships and research grants, supporting external research efforts such as scientific research agreements and investigator initiated trials (following Regulatory Approval); medical resourcing, training and allocation; medical and scientific platform, content development, publications, and communications; conducting appropriate activities involving opinion leaders, including communications and engagement; conducting medical science liaison activities; advisory boards (to the extent related to medical affairs or clinical guidance) and conducting advisory board meetings or other consultant programs; establishing patient registries and expanded access programs; post-approval investigator initiated trials or scientific research agreements; life cycle management activities and clinical research.
- 1.108 “**Net Sales**” means, with respect to a Licensed Product, the aggregate gross sales invoiced of such Licensed Product sold by Coherus or any of its Affiliates or Sublicensees (other than Junshi or any distributors, resellers, wholesalers, hospitals, or end users) (each, a “**Selling Party**”) to a Third Party (including distributors, resellers, wholesalers, hospitals, and end users) (each, a “**Buying Party**”) in the Coherus Territory, less the following deductions:
- (a) trade, cash, and quantity discounts, allowances, and credits allowed or paid, in the form of deductions actually allowed with respect to sales of such Licensed Product;
  - (b) retroactive price reductions, allowances, or credits granted upon rejections or returns of Licensed Product, including for recalls or damaged good and billing errors;
  - (c) discounts, chargeback payments, rebates, and reimbursements related to sales of Licensed Products granted to wholesalers and other distributors, pharmacies and other retailers,

managed care organizations, group purchasing organizations, patients (through-co-pay assistance programs), or other buying groups, pharmacy benefit management companies, health maintenance organizations, federal, state, provincial, local, or other governments, and any other providers of health insurance coverage, health care organizations, or other health care institutions (including hospitals), health care administrators, or patient assistance or other similar programs to the extent actually given;

- (d) compulsory payments and cash rebates related to the sales of such Licensed Product paid to a governmental authority (or agent thereof) pursuant to applicable law by reason of any national or local health insurance program or similar program, including required chargebacks and retroactive price reductions, to the extent allowed and taken, including government levied fees as a result of healthcare reform policies (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48));
- (e) customary freight, shipping insurance and other transportation expenses to the extent separately itemized and included in the gross amount invoiced and charged to the Buying Party;
- (f) tariffs, duties, import, export, excise, sales, use, turnover, value-added, and other similar taxes (other than taxes based on income); customs duties; or other government charges, in each case, imposed on the sale of Licensed Product to the extent included in the price and separately itemized on the invoice, including VAT;
- (g) other similar and customary deductions that are in accordance with GAAP or other accounting standard applicable to such entity as consistently applied and actually given.

For the avoidance of doubt, if a single item falls into more than one of the categories set forth in clauses (a) to (h) above, then such item may not be deducted more than once. All amounts set forth in clauses (a) to (h) above will only be deducted to the extent permitted under GAAP or other accounting standard applicable to such entity as consistently applied.

Sales and other transfer of a Licensed Product between any Selling Party to another Selling Party will not give rise to Net Sales, but rather Net Sales will be deemed to have arisen upon the subsequent sale of a Licensed Product to a Third Party.

Any Licensed Products used for promotional or advertising purposes, used for Clinical Trials, preclinical trials or other research purposes, free samples, named patient use, compassionate use, patient assistance, expanded access, charitable use or distributed at no charge to patients unable to purchase the same will not be included in Net Sales. Donations, dispositions, or transfers for charitable reasons that are at or below fully-burdened manufacturing costs therefor will also not be included in Net Sales.

Calculations of Net Sales will be consistently applied across all products of a Selling Party. Such amounts will be determined from the books and records of the Selling Party, and will be calculated in accordance with GAAP or other accounting standard applicable to such entity as consistently applied.

In the case of any Combination Product sold in a given country and reporting period, Net Sales for the purpose of determining Royalties and sales milestone events of the Combination Product in such country will be calculated by multiplying actual Net Sales of such Combination Product by the fraction  $A/(A+B)$ , where A is the invoice price of the Licensed Antibody if sold

separately in the same indication in such country, and B is the total invoice price of the Other Components in the Combination Product, if sold separately in the same indication in such country.

If, on a country-by-country basis in a particular reporting period, the Licensed Antibody is sold separately in the same indication in a country, but the Other Components in the Combination Product are not sold separately in the same indication in such country, then Net Sales for the purpose of determining Royalties and sales milestone events of the Combination Product for such country will be calculated by multiplying actual Net Sales of the Combination Product by the fraction  $A/C$ , where A is the invoice price of the Licensed Antibody if sold separately in the same indication in such country, and C is the invoice price of the Combination Product in such country.

If, on a country-by-country basis in a particular reporting period, the Licensed Antibody in the Combination Product is not sold separately in the same indication in such country, but the Other Components included in the Combination Product are sold separately in the same indication in such country, then Net Sales for the purpose of determining Royalties and sales milestone events of the Combination Product for such country will be calculated by multiplying actual Net Sales of the Combination Product by the fraction  $(C-B)/C$ , where B is the invoice price of the Other Components included in such Combination Product if sold separately in the same indication in such country, and C is the invoice price of the Combination Product in such country.

Notwithstanding the foregoing, in the case as set forth in the preceding paragraphs of any Combination Product that is sold in a given country and reporting period, the Net Sales for each Licensed Antibody for the purpose of determining Royalties and sales milestone events of a Combination Product in such country will never be less than 25% of the total Net Sales for the Combination Product (even if as a result of the applicable calculations using A, B, or C above would lead to an allocation of less than 25% for a Licensed Antibody).

If neither the Licensed Antibody nor the Other Components are sold separately in the same indication in a given country during a particular reporting period, then Net Sales will be calculated based on the fair market value of the Licensed Product as A and the fair market value of each of the Other Components included in such Combination Product as B when A and B would be sold in such indication in such country. In such a case as described in this paragraph, the Net Sales for each Licensed Antibody for the purpose of determining Royalties and sales milestone events of a Combination Product in such country will never be less than  $1/(X+Y)$  of the total Net Sales for the Combination Product, wherein X is the number of active ingredients that are or contain Licensed Antibody(ies) and Y is the number of active ingredients that are Other Component(s) (other than Licensed Antibody(ies)).

- 1.109 “**Non-Defaulting Party**” has the meaning set forth in Section 13.3(c) (Disputes Regarding Material Breach).
- 1.110 “**Non-Developing Party**” has the meaning set forth in Section 4.5 (Independent Development in the Coherus Territory).
- 1.111 “**Ongoing JS001 Trial Cap**” has the meaning set forth in Section 4.2(b) (Costs to be Reimbursed).
- 1.112 “**Ongoing JS001 Trial Costs**” has the meaning set forth in Section 4.2(b) (Costs to be Reimbursed).
- 1.113 “**Ongoing JS001 Trials**” means the Clinical Trials identified on Schedule 1.113 (Ongoing JS001 Trials).

- 1.114 “**Ongoing JS001 Development Budget**” has the meaning set forth in Section 4.2 (Ongoing JS001 Trials).
- 1.115 “**Ongoing JS001 Development Plan**” has the meaning set forth in Section 4.2 (Ongoing JS001 Trials).
- 1.116 “**Option Data Package**” means, with respect to each Option Program, the information and materials set forth on Schedule 1.116 (Option Data Package).
- 1.117 “**Option Data Package Delivery Date**” has the meaning set forth in Section 10.2 (Representations and Warranties by Junshi).
- 1.118 “**Option Disclosure Letter**” has the meaning set forth in Section 10.2 (Representations and Warranties by Junshi).
- 1.119 “**Option Exercise**” has the meaning set forth in Section 2.8(g) (Exercise of a License Option).
- 1.120 “**Option Exercise Date**” has the meaning set forth in Section 2.8(g) (Exercise of a License Option).
- 1.121 “**Option Exercise Notice**” has the meaning set forth in Section 2.8(g) (Exercise of a License Option).
- 1.122 “**Optioned Licensed Products**” has the meaning set forth in Section 4.6 (Development of Optioned Licensed Products).
- 1.123 “**Optioned Licensed Product Trial**” has the meaning set forth in Section 4.6(a) (Trials Ongoing as of Option Exercise).
- 1.124 “**Optioned Licensed Product Development Budget**” means, for each of the IL-2 Program and the TIGIT Program, the budget of the costs and expenses to be incurred in the performance of activities under the Optioned Licensed Product Development Plan for such program.
- 1.125 “**Optioned Licensed Product Development Costs**” has the meaning set forth in Section 2.8(h) (Coherus Share of Option Program Development Costs).
- 1.126 “**Optioned Licensed Product Development Plan**” means, for each of the IL-2 Program and the TIGIT Program, the plan of the Development activities to be conducted with respect to Optioned Licensed Product Trials for the Option Molecules and Optioned Licensed Products that are the subject of such program. Such Optioned Licensed Product Development Plan may include a plan of the Development activities to be conducted both inside and outside the Coherus Territory.
- 1.127 “**Option Molecule**” means any (a) Junshi TIGIT Antibody or (b) Junshi IL-2 Molecule.
- 1.128 “**Option Notice**” has the meaning set forth in Section 2.8(b)(i) (Delivery).
- 1.129 “**Option Patent Rights**” has the meaning set forth in Section 10.2(f).
- 1.130 “**Option Product**” means any product that contains an Option Molecule, alone or in combination with one or more therapeutically active pharmaceutical ingredients, in all forms, presentations, compositions, dosages, and formulations.
- 1.131 “**Option Program**” means each of the IL-2 Program and the TIGIT Program.
- 1.132 “**Option Term**” has the meaning set forth in Section 2.8(g) (Exercise of a License Option).



- 1.133 “**Other Component**” has the meaning set forth in Section 1.32 (Combination Product).
- 1.134 “**Panel**” has the meaning set forth in Section 4.3(b) (Restrictions on Additional Development).
- 1.135 “**Party**” and “**Parties**” have the meaning set forth in the Preamble.
- 1.136 “**Patent Proceeding**” means any proceeding before a patent office related to the post-grant review of any Patent Right, including any post-grant proceeding brought pursuant to the America Invents Act (such as any *inter partes* review, post-grant review, opposition, interference, re-examination), or any foreign equivalent thereof. Any appeal, action, or proceeding related to a Patent Right that is brought before any court of competent jurisdiction will be deemed a “Patent Proceeding”; *provided* that prosecution activities including any *ex parte* examination and *ex parte* re-issue examination, appeal of *ex parte* patent prosecution decisions to a court or a board of a patent office, or supplemental examination before the U.S. Patent Office will not be considered a “Patent Proceeding.”
- 1.137 “**Patent Right**” means (a) any national, regional, or international patent or patent application, including any provisional patent application, (b) any patent application filed either from such a patent, patent application, or provisional application or from an application claiming priority from any of these, including any divisional, continuation, continuation-in-part, provisional, converted provisional, and continued prosecution application, (c) any patent that has issued or in the future issues from any of the foregoing patent applications ((a) and (b)), including any utility model, petty patent, design patent, and certificate of invention, (d) any extension or restoration by existing or future extension or restoration mechanisms, including any revalidation, reissue, re-examination, and extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications ((a), (b), and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent, or registration patent or patent of additions to any such foregoing patent application or patent.
- 1.138 “**Payee**” has the meaning set forth in Section 8.7(b) (Tax Withholding).
- 1.139 “**Payor**” has the meaning set forth in Section 8.7(b) (Tax Withholding).
- 1.140 “**PD-1**” means programmed death-1, and refers to an inhibitory checkpoint receptor expressed on T cells, which binds with PD-L1 and PD-L2 to inhibit T cell and cytokine activation.
- 1.141 “**PD-1 Program**” means the program of Development of JS001 and any other Licensed Antibody described in clause (a) of the definition of Licensed Antibody.
- 1.142 “**Person**” means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Regulatory Authority, or any other entity not specifically listed in this definition.
- 1.143 “**Pharmacovigilance Agreement**” has the meaning set forth in Section 5.5 (Adverse Event Reporting).
- 1.144 “**Phase I Clinical Trial**” means a clinical trial in humans that generally provides for the first introduction into humans of a pharmaceutical or biologic product with the primary purpose of determining safety, metabolism, and pharmacokinetic properties and clinical pharmacology of such product, in a manner that meets the requirements of 21 C.F.R. § 312.21(a), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

- 1.145 “**Phase II Clinical Trial**” means a clinical trial in humans that is intended to explore the feasibility, safety, dose ranging, or efficacy of a pharmaceutical or biologic product that is prospectively designed to generate sufficient data (if successful) to commence a Phase III Clinical Trial for such product, in a manner that meets the requirements of 21 C.F.R. § 312.21(b), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.
- 1.146 “**Phase III Clinical Trial**” means a clinical trial in humans of a pharmaceutical or biologic product that the FDA permits to be conducted under an open IND and that is performed to gain evidence with statistical significance of the efficacy of such product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of a BLA by a Regulatory Authority and to provide an adequate basis for physician labeling, in a manner that meets the requirements of 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region. Notwithstanding anything to the contrary set forth in this Agreement, treatment of patients as part of an expanded access program, compassionate sales or use program (including named patient program or single patient program), or an indigent program, in each case, will not be included in determining whether or not a clinical trial is a Phase III Clinical Trial or whether a patient has been dosed thereunder.
- 1.147 “**Pivotal Trial**” means any Clinical Trial of the active substance of a pharmaceutical or biologic product, the results of which, together with prior data and information concerning such product, are intended to be sufficient, without any additional Clinical Trial, to meet the evidentiary standard for demonstrating the safety, purity, and potency of such active substance of such product established by a Regulatory Authority in any particular jurisdiction and is intended to support the acceptance and approval of a BLA by a Regulatory Authority in such jurisdiction.
- 1.148 “**Pricing and Reimbursement Approval**” means the later of (a) the approval, agreement, determination, or governmental decision establishing a price for a pharmaceutical or biologic product that can be legally charged to consumers, if required in a given jurisdiction or country for the Commercialization of such pharmaceutical or biologic product in such jurisdiction or country; and (b) the approval, agreement, determination, or governmental decision establishing the level of reimbursement for a pharmaceutical or biologic product that will be reimbursed by governmental authorities, if either required or otherwise commercially beneficial in a given jurisdiction or country for the Commercialization of such pharmaceutical or biologic product in such jurisdiction or country.
- 1.149 “**Product Marks**” has the meaning set forth in Section 9.6 (Trademarks).
- 1.150 “**Proprietary Combination Regimen**” has the meaning set forth in Section 4.5(a) (Right to Opt- In).
- 1.151 “**Quality Agreement**” has the meaning set forth in Section 6.1 (Manufacturing by Junshi).
- 1.152 “**Regulatory Approval**” means all approvals by a governmental authority necessary for the Manufacture, marketing, importation, and sale of a product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements. Regulatory Approvals include approvals by Regulatory Authorities of INDs and BLAs, and all Pricing and Reimbursement Approvals.

- 1.153 “**Regulatory Authority**” means, in a particular country or regulatory jurisdiction, any applicable governmental authority involved in granting Regulatory Approval or, to the extent required in such country or regulatory jurisdiction, Pricing and Reimbursement Approval of a product in such country or regulatory jurisdiction.
- 1.154 “**Regulatory Exclusivity**” means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product other than Patent Rights, including rights conferred in the U.S. under the FDA Modernization Act of 1997 (including pediatric exclusivity), orphan drug exclusivity, or rights similar thereto outside the U.S.
- 1.155 “**Regulatory Materials**” means regulatory applications, submissions, notifications, registrations, or other filings or documents maintained or made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Develop, Manufacture, market, sell, or otherwise Commercialize a Licensed Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs and BLAs (as applications, but not the approvals with respect thereto).
- 1.156 “**Required Filings**” has the meaning set forth in Section 14.2 (Filings).
- 1.157 “**ROFN Exercise Notice**” has the meaning set forth in Section 2.9 (Right of First Negotiation ).
- 1.158 “**ROFN Jurisdiction**” has the meaning set forth in Section 2.9 (Right of First Negotiation).
- 1.159 “**ROFN Product**” has the meaning set forth in Section 2.9 (Right of First Negotiation).
- 1.160 “**ROFN Product Activity**” has the meaning set forth in Section 2.9 (Right of First Negotiation).
- 1.161 “**Royalty**” has the meaning set forth in Section 8.4 (Royalties).
- 1.162 “**Royalty Report**” has the meaning set forth in Section 8.4(b) (Reports; Payment).
- 1.163 “**Royalty Term**” means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period commencing upon the First Commercial Sale of a Licensed Product in a country, and ending upon the later to occur of (a) the expiration in such country of the last to expire of any Licensed Patent Right Covering the composition of matter, formulation, or approved method of treatment or use of such Licensed Product that would be infringed by the manufacture, use, sale, offer for sale, or import of such Licensed Product in such country; (b) the expiration of all Regulatory Exclusivities for such Licensed Product in such country; or (c) 10 years after the First Commercial Sale in such country of such Licensed Product.
- 1.164 “**SEC**” has the meaning set forth in Section 12.2(b) (Disclosure to SEC).
- 1.165 “**SSE**” has the meaning set forth in Section 12.2(c) (Disclosure on HKSE and SSE).
- 1.166 “**Sublicensee**” means any Third Party granted a sublicense by Coherus under the rights licensed to Coherus pursuant to Article 2 (Licenses and Exclusivity) hereof.
- 1.167 “**Supply Agreement**” has the meaning set forth in Section 6.1 (Manufacturing by Junshi).
- 1.168 “**Supply Price**” has the meaning set forth in Section 6.1 (Manufacturing by Junshi).
- 1.169 “**Technology Transfer**” has the meaning set forth in Section 2.6(c) (Continuing Technology Transfer).

- 1.170 “**Term**” has the meaning set forth in Section 13.1 (Term).
- 1.171 “**Third Party**” means any entity other than Junshi or Coherus or their respective Affiliates.
- 1.172 “**Third Party Agreements**” has the meaning set forth in Section 10.2(g) (Third Party Agreements).
- 1.173 “**TIGIT**” means the T-cell immunoreceptor with immunoglobulin and ITIM domains.
- 1.174 “**TIGIT Program**” means the program of Development of the Junshi TIGIT Antibodies.
- 1.175 “**Transition Plan**” has the meaning set forth in Section 5.1 (Regulatory Responsibilities).
- 1.176 “**United States**” means the United States of America and all of its territories and possessions.
- 1.177 “**Upfront Payment**” has the meaning set forth in Section 8.1 (Upfront Payment).
- 1.178 “**Valid Claim**” means a claim of (a) an issued, unexpired, and in-force patent, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination, *inter partes* review, post grant review or disclaimer, opposition procedure, nullity suit, or otherwise, or (b) a pending patent application that has not been finally abandoned, finally rejected from which no appeal can be or has been taken, or expired; *provided, however*, that if a claim of a pending patent application will not have issued within seven years after the earliest filing date from which such claim takes priority, then such claim will not constitute a Valid Claim for the purposes of this Agreement unless and until a patent issues with such claim.
- 1.179 “**VAT**” has the meaning set forth in Section 8.7(c) (VAT in Coherus Territory).

**ARTICLE 2**  
**LICENSES AND EXCLUSIVITY**

- 2.1 **Licenses to Coherus.** Subject to the terms and conditions of this Agreement, Junshi, on behalf of itself and its Affiliates, hereby grants to Coherus (a) an exclusive (even as to Junshi and each of its Affiliates), non-transferable (except as permitted in accordance with Section 16.6 (Assignment)) license, with the right to sublicense (solely as permitted in accordance with Section 2.2 (Sublicensing)), under the Licensed Technology, to Exploit the Licensed Antibodies and Licensed Products in the Field in the Coherus Territory; and (b) a non-exclusive, non-transferable (except as permitted in accordance with Section 16.6 (Assignment)) license, with the right to sublicense (solely as permitted in accordance with Section 2.2 (Sublicensing)), under the Licensed Technology, to conduct Clinical Trials using the Licensed Antibodies and Licensed Products in the Field outside of the Coherus Territory solely for purposes of obtaining, maintaining, or supporting Regulatory Approval of such Licensed Antibodies and Licensed Products in the Field in the Coherus Territory.
- 2.2 **Sublicensing.**
- (a) **Consent; Responsibility.** Coherus may grant sublicenses of the rights granted to it under Section 2.1 (Licenses to Coherus) to (i) its Affiliates during only such time as such Person remains an Affiliate of Coherus and (ii) contractors of Coherus and its sublicensed Affiliates for the sole purpose of performing Coherus’ obligations or exercising Coherus’ rights with respect to the Exploitation of Licensed Products in accordance with the terms of this Agreement, in each case, (i) and (ii), without the consent of Junshi so long as such sublicense also satisfies the requirements of Section 2.2(b) (Certain Requirements).

Coherus may grant sublicenses under such rights otherwise only with the advance, written consent of Junshi, such consent not to be unreasonably withheld. Coherus will remain primarily liable to Junshi for the performance of all of Coherus' obligations under this Agreement and will be liable for any act or failure to act by any such sublicensed Affiliate or Third Party Sublicensee that if committed (or not committed) by such Person would be a breach of any of Coherus' obligations under this Agreement as though the same were a breach by Coherus.

- (b) **Certain Requirements.** Without limiting the foregoing, each sublicense to a Third Party must be granted in writing and all sublicenses (to Affiliates and Third Parties) (i) must be consistent with, and are and will be subject to, the terms and conditions of this Agreement, (ii) terminate automatically upon termination of the corresponding licensed rights granted under Section 2.1 (Licenses to Coherus). In addition, in each sublicense, Coherus will include terms that enable Coherus to grant a license or sublicense to Junshi under the Coherus Arising Technology consistent with the terms of Section 2.3 (Licenses to Junshi) under all Coherus Arising Technology.
- (c) **Notice; Copy.** Coherus will, within 30 days after granting any sublicense to a Third Party Sublicensee that is not an agent or a consultant, contract manufacturing organization, contract research organization, or other similar type contractor acting for or on behalf of Coherus, notify Junshi of the grant of such sublicense and provide Junshi with a copy of such sublicense; *provided* that Coherus may redact any portion of such sublicense agreement to the extent not necessary for Junshi to determine compliance with this Agreement.

2.3 **Licenses to Junshi.** Subject to the terms and conditions of this Agreement, Coherus hereby grants to Junshi (a) an irrevocable, non-exclusive, royalty-free license, with the right to sublicense, under the Coherus Arising Technology to Exploit the Licensed Antibodies and Licensed Products in the Field in the Junshi Territory, and (b) an irrevocable, non-exclusive, royalty-free license, with the right to sublicense, under the Coherus Arising Technology to Exploit the Licensed Antibodies and Licensed Products in the Field in the Coherus Territory for the purposes for which Junshi retains rights to Exploit the Licensed Technology under Section 2.4 (No Implied Licenses; Retained Rights). Without limiting the foregoing, each sublicense by Junshi of the foregoing rights to a Third Party must be granted in writing, and all sublicenses must be consistent with, and will be subject to, the terms and conditions of this Agreement, and will terminate automatically upon termination of the corresponding licensed rights granted under this Section 2.3 (Licenses to Junshi). Junshi will, within 30 days after granting any sublicense to a Third Party Sublicensee that is not an agent or a consultant, contract manufacturing organization, contract research organization, or other similar type contractor acting for or on behalf Junshi, notify Coherus of the grant of such sublicense.

2.4 **No Implied Licenses; Retained Rights.** Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license or other rights, express or implied, under any intellectual property rights (whether by implication, estoppel, or otherwise). Notwithstanding the exclusive license granted to Coherus in Section 2.1 (Licenses to Coherus), Junshi retains rights under the Licensed Technology (including its joint interest in any Joint Arising Technology) solely to (and to grant its Affiliates and Third Parties the right to), within the Coherus Territory: (a) conduct the Junshi Clinical Trials, (b) conduct Clinical Trials in the Coherus Territory solely for purposes of Junshi, its Affiliates or its and their respective licensees/sublicensees obtaining, maintaining, or supporting Regulatory Approval of Licensed Antibodies and Licensed Products outside of the Coherus Territory, (c) supply or import Licensed Antibodies and Licensed Products into the Coherus Territory (i) to Coherus or its Affiliates or Sublicensees and (ii) to perform the Junshi Clinical Trials, and (d) Manufacture Licensed Products in the Coherus Territory for use in the Junshi Clinical Trials and for export to, and use and sale outside of, the Coherus Territory. The

Licensed Technology Controlled by Junshi pursuant to any Third Party Agreement is licensed to Coherus under this Agreement subject to sections 4.1, 4.2, 4.3, 4.4, 4.5, 6.1, 8.1 and 10.5 of the JS001 Upstream License, and if Coherus assumes responsibility for making any payments directly to Lonza under Section 8.5(a) (JS001 Upstream License), then also Sections 6.2, 6.4.2 and 6.5 therein, and Sections 5.1(1), 5.1(2), and 5.1(3) of the JS018-1 Upstream License, as such agreements were transmitted to Coherus in emails dated as of January 21, 2021 at 10:05 PM Pacific Time and January 23, 2021 at 7:11 PM Pacific Time, respectively. The Licensed Technology Controlled by Junshi pursuant to any Additional Third Party License is licensed to Coherus under this Agreement subject to the terms agreed by the Parties in accordance with Section 2.5 (Third Party In-Licenses).

2.5 **Third Party In-Licenses.** During the Term, if either Party identifies any Patent Right or Know- How owned or controlled by a Third Party that it reasonably believes may be necessary or reasonably useful to Exploit any Licensed Antibody or Licensed Product in the Field in the Coherus Territory (other than a Third Party License Agreement), or absent a license or agreement with such Third Party to such intellectual property, would be infringed by the Exploitation of any Licensed Antibody or Licensed Product in the Field in the Coherus Territory (“**Additional Third Party IP**”), then it may raise such matter with the JDC. Unless otherwise agreed by the Parties, neither Party will enter into an agreement with a Third Party to obtain a license, covenant not to sue, or other similar rights under any such Patent Right or Know-How (each, an “**Additional Third Party License**”) for a period of three months after first raising the matter to the JDC unless during such three month period the Parties agree in writing on the cost-sharing terms applicable to any such Additional Third Party License between the Parties and the other terms on which the applicable Party might sublicense rights to the other Party under such Additional Third Party IP. Any such agreement between the Parties should be effective prior to or concurrently with the execution of the Additional Third Party License. If the Parties do not enter into such written agreement within such three month period (or such other period as may be agreed) or the Parties otherwise agree, then the Party desiring to enter into the Additional Third Party License may do so, and such Additional Third Party IP will not be deemed Controlled by the Party that is party to such Additional Third Party License for purposes of this Agreement. Unless the Parties otherwise agree, Coherus may deduct any royalties paid by Coherus to Junshi in consideration for any such sublicensed rights under any Additional Third Party IP in accordance with Section 8.4(c)(iii) (Reduction for Additional Third Party IP). If Coherus is the party to an Additional Third Party License, then Coherus may deduct any royalties paid by Coherus to the Third Party in consideration for any such sublicensed rights in accordance with Section 8.4(c)(iii) (Reduction for Additional Third Party IP).

2.6 **Technology Transfer.**

(a) **Initial Technology Transfer.** As soon as reasonably practicable (i) with respect to JS001 and any Antibody thereof that is the subject of the PD-1 Program, after the Effective Date or (ii) with respect to each Option Molecule for which Coherus exercises a License Option, after exercise of such License Option, and in each case ((i) and (ii)), in accordance with a plan to be agreed between the Parties no later than 60 days after the Effective Date or the Option Exercise Date (as applicable), Junshi will transfer to Coherus electronic copies of appropriate documents, data, regulatory correspondence, clinical and pre-clinical data, or other Know-How included within the Licensed Know-How existing as of the Effective Date or the applicable Option Exercise Date, other than Licensed Manufacturing Technology, which will be transferred to Coherus as contemplated in Section 2.6(b) (Manufacturing Technology Transfer) (the “**Initial Technology Transfer**”).

- (b) **Manufacturing Technology Transfer.** In addition to the documents, data, or other Licensed Know-How provided to Coherus pursuant to the Initial Technology Transfer, on a Licensed Antibody-by-Licensed Antibody basis, upon the request of Coherus during the Term (which, for JS001, will be promptly following the Effective Date), Junshi will evaluate jointly with Coherus a CMO designated by Coherus (such CMO designated by Coherus, a “**Coherus CMO**”). For each Licensed Antibody, Junshi will promptly conduct a transfer to such Coherus CMO (a “**Coherus CMO**”), of appropriate documents, data (including an appropriate set of base reference Manufacturing process data), other Licensed Know-How, or activities necessary to Manufacture the Licensed Products that include each such Licensed Antibody in accordance with the terms of this Agreement (“**Licensed Manufacturing Technology**”) and necessary to enable such Coherus CMO to assume the Manufacturing activities of the Licensed Products that include the applicable Licensed Antibody (for each such Licensed Antibody, a “**Manufacturing Technology Transfer**”); *provided* that, solely to the extent required under the JS001 Upstream License with respect to JS001, such Coherus CMO is reasonably acceptable to Lonza. The Manufacturing Technology Transfer for each Licensed Antibody (including all Licensed Products that include such Licensed Antibody) will be conducted pursuant to a transfer plan and timeline, and terms and conditions limiting the Coherus CMO’s use and disclosure of Licensed Technology, which terms are set forth on Schedule 2.6(b) (Manufacturing Technology Transfer Additional Terms), (for each Manufacturing Technology Transfer, a “**Technology Transfer Agreement**”). Thereafter during the Term following completion of the Manufacturing Technology Transfer for a particular Licensed Antibody, Junshi will provide any additional Licensed Manufacturing Technology related to the Manufacture of such Licensed Antibody or Licensed Product that include such Licensed Antibody as part of the Continuing Technology Transfer in accordance with Section 2.6(c) (Continuing Technology Transfer).
- (c) **Continuing Technology Transfer; Coherus Arising Technology.** After the completion of the Initial Technology Transfer for each Licensed Antibody, Junshi will transfer to Coherus (through the JDC) or a Coherus CMO (if applicable to the Manufacture of Licensed Products) any additional documents, data (including all data from the Ongoing JS001 Clinical Trials, and data from Independent Trials for which Junshi is the Developing Party after Coherus opts-in thereto pursuant to Section 4.5 (Independent Development)), or other Licensed Know-How, in each case, that is in Junshi’s Control and has not been previously transferred to Coherus or a Coherus CMO (the “**Continuing Technology Transfer**,” and together with the Initial Technology Transfer and the Manufacturing Technology Transfer, the “**Technology Transfer**”). The Continuing Technology Transfer will not include any of the foregoing arising from an Independent Development for which Junshi is the Developing Party unless and until Coherus opts-in to share the costs of such activities in accordance with Section 4.5 (Independent Development). After completion of the Manufacturing Technology Transfer for a given Licensed Antibody, Junshi will also transfer to the Coherus CMO any Continuing Technology Transfer for Manufacturing Licensed Products that include such Licensed Antibody in accordance with the terms of the applicable Technology Transfer Agreement (as then existing or as may be amended by the Parties and the Coherus CMO to accommodate the Continuing Technology Transfer related to Manufacture of such Licensed Products). Junshi shall perform such applicable Continuing Technology Transfer reasonably in advance of the last JDC meeting of each Calendar Year and additionally in advance of the second JDC meeting of the Calendar Year for Continuing Technology Transfer not related to Licensed Manufacturing Technology. Coherus will transfer to the JDC all Coherus Arising Technology and data from Independent Trials for which Coherus is the Developing Party after Junshi opts-in thereto



pursuant to Section 4.5 (Independent Development) with the same frequency and about the same time as Junshi is required to undertake the Continuing Technology Transfer pursuant to this Section 2.6(c) (Continuing Technology Transfer; Coherus Arising Technology).

- (d) **Costs of Technology Transfer.** Junshi will reasonably cooperate with Coherus to facilitate the Technology Transfer to Coherus or a Coherus CMO (as applicable). In the course of any Technology Transfer, Junshi will provide Coherus or the applicable Coherus CMO with reasonable access by teleconference or in-person at Junshi's or any of its Affiliates' facilities to Junshi or any of its Affiliates' personnel involved in the Development or Manufacture of the Licensed Antibodies and designated by Junshi to provide Coherus or the Coherus CMO with a reasonable level of technical assistance and consultation in connection with all Technology Transfers. Junshi will be responsible for its internal costs for up to a total of 100 hours in connection with all Technology Transfers. Coherus will reimburse Junshi for (i) internal costs (at the FTE Rate) reasonably incurred by or on behalf of Junshi or its Affiliates in connection with Technology Transfer in excess of 100 hours of consultation and assistance related thereto, and (ii) all verifiable external or out-of-pocket costs actually incurred by or on behalf of Junshi or its Affiliates in connection with any Technology Transfer, in each case ((i) and (ii)), within 45 days after receiving Junshi's invoice therefor.

## 2.7 Exclusivity.

- (a) **Exclusivity Covenant.** Subject to Section 2.7(b) (Acquisition by Third Parties) and Section 2.7(c) (Acquisition of Third Parties), during the Term, neither Party will, and will ensure that its Affiliates do not, independently or for or with any Third Party, directly or indirectly, clinically Develop or Commercialize any Competitive Product in the Coherus Territory (or license or otherwise authorize any Third Party to do any of the foregoing) (the "**Competitive Activities**") unless agreed in writing by the Parties.
- (b) **Acquisition by Third Parties.** If either Party undergoes a Change of Control with a Third Party that is (either directly or through an Affiliate, or in collaboration with another Third Party) performing Competitive Activities with respect to one or more Competitive Products in the Coherus Territory at the closing of the Change of Control transaction, then it will not be in breach of the restrictions set forth in Section 2.7(a) (Exclusivity Covenant) due to such Change of Control with such a Third Party, and such Third Party may continue to perform, or commence the performance of, the applicable Competitive Activities with respect to such Competitive Products after such Change of Control transaction as long as: (i) such Party notifies the other Party of the Change of Control and the nature of the Competitive Activities following the closing of such Change of Control, (ii) no Licensed Technology is used by or on behalf of such Party or its Affiliates in more than a *de minimis* fashion in connection with any subsequent clinical Development or Commercialization of such Competitive Products, and (iii) such Party and its Affiliates institute commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (ii) are met, including by creating "firewalls" between the personnel working on such Competitive Products and the personnel working on the Licensed Antibody and Licensed Products or having access to data from activities performed under this Agreement or Confidential Information of the other Party. If (A) Coherus is the Party that undergoes such a Change of Control, (B) the Third Party acquirer or any of its Affiliates is performing Competitive Activities with respect to one or more Competitive Products in the Coherus Territory at the closing of the Change of Control transaction, and (C) (i) any Clinical Trials involving the applicable Licensed Product being conducted or planned to be conducted by Coherus or any of its Affiliates or Sublicensees are discontinued before their clinical endpoint(s) or (ii) on two separate occasions (which more

or may not be consecutive) the Net Sales of any applicable Licensed Product drop from one Calendar Quarter to the next Calendar Quarter, then in either case ((i) or (ii)), Coherus must promptly notify Junshi of such result. If any such discontinuation of such a Clinical Trial or drop in Net Sales is not (1) by written agreement of the Parties, (2) a result of Coherus' reasonable response to specific guidance from, or action by, a Regulatory Authority in the Coherus Territory with respect to the applicable Licensed Products (such as a clinical hold, or a recall or withdrawal), (3) caused by Junshi's uncured failure to perform its applicable obligations under and in accordance with this Agreement or the Supply Agreement (such that Coherus is prevented or hindered from performing any such activities that would have advanced the Development or Commercialization of the applicable Licensed Product but for such failure by Junshi), (4) prevented by applicable law, or (5) prevented by a Force Majeure, then, Junshi may notify Coherus that Coherus or such Third Party must (and Coherus or such Third Party will), at Coherus' election: (I) divest, or cause its relevant Affiliates to divest, whether by sale, assignment, exclusive license or otherwise, its interest in the applicable Competitive Products within 12 months following such notice by Junshi; (II) terminate any further Competitive Activities with respect to such Competitive Products within 12 months following such notice by Junshi; or (III) provide a notice of termination under Section 13.2 (Termination by Coherus) within 15 days after such notice by Junshi.

- (c) **Acquisition of Third Parties.** If a Party or any of its Affiliates merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation, or similar transaction) (the "**Acquiring Party**") and at such time such Third Party is performing Competitive Activities with respect to one or more Competitive Products or is engaged in activities that would otherwise constitute a breach of Section 2.7(a) (Exclusivity Covenant), then, unless the Parties agree otherwise in writing, such Acquiring Party will not be in breach of Section 2.7(a) (Exclusivity Covenant) if such Party notifies the other Party of the Change of Control and the nature of the Competitive Activities promptly after the closing thereof and thereafter does one of following: (i) divests, or cause its relevant Affiliates to divest, whether by sale, assignment, exclusive license or otherwise, its interest in such Competitive Products within 12 months following such acquisition; (ii) terminates any further Competitive Activities with respect to such Competitive Products within 12 months following such acquisition; (iii) if the Acquiring Party is Coherus, provide within 15 days after such acquisition a notice of termination under Section 13.2 (Termination by Coherus). The Acquiring Party will notify the other Party as to whether it intends to select option (i), (ii), or (iii) above within 15 days following the consummation of such acquisition. The Acquiring Party will keep the other Party reasonably informed of its efforts and progress in effecting such divestiture or termination until the Acquiring Party completes the same. If the Acquiring Party selects either option (i) or (ii) above, then until the divestiture or termination is complete, it will ensure that (A) no Licensed Technology is used by or on behalf of the Acquiring Party or its Affiliates in more than a *de minimis* fashion in connection with any subsequent clinical Development or Commercialization of such Competitive Products, and (B) the Acquiring Party and its Affiliates institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (A) are met, including by creating "firewalls" between the personnel working on such Competitive Products and the personnel working on the Licensed Antibody and Licensed Products or having access to data from activities performed under this Agreement or Confidential Information of the other Party.

## 2.8 Coherus License Options.

- (a) **Grant of Options.** Junshi hereby grants Coherus, on an Option Program-by-Option Program basis, the exclusive option during the Option Term for each Option Program to obtain an exclusive license to Exploit the Option Molecule and Option Products that are the subject of each Option Program in the Field in the Coherus Territory (for each Option Program, a “**License Option**”) upon the same terms in this Agreement as applicable to the Licensed Antibody and Licensed Products existing as of the Effective Date, except as otherwise specified. If Coherus does not exercise the License Option with respect to an Option Program prior to expiration of the applicable Option Term for such Option Program, then Coherus will no longer have any right to exercise the License Option for such Option Program.
- (b) **Option Data Package.**
- (i) **Delivery.** On an Option Program-by-Option Program basis with respect to a given Option Program, after Junshi has conducted sufficient number of Phase I Clinical Trials to generate safety data and a recommended dosage for conducting Phase II Clinical Trials for a Junshi IL-2 Molecule or Junshi TIGIT Antibody, as applicable, Junshi will deliver to Coherus (collectively, for each Option Program, an “**Option Notice**”):
  - (ii) the Option Data Package for such Option Program;
  - (iii) a description in reasonable detail of the Development (within and outside of the Coherus Territory) in an Optioned Licensed Product Development Plan, including the Optioned Licensed Product Development Budget for all costs and expenses for such Development to be incurred after the date of the Option Notice;
  - (iv) an Option Disclosure Letter for such Option Program; and
  - (v) a certification of an officer of Junshi as to the accuracy and completeness of the provided information, and a statement that, subject to the disclosures contained in the Option Disclosure Letter for such Option Program, the representations and warranties of Junshi set forth in Section 10.2 (Representations and Warranties of Junshi) being remade as of the Option Data Package Delivery Date are true and correct in all respects with respect to such Option Program as of the Option Data Package Delivery Date.
- (c) **Incomplete Option Data Package.** Following receipt of an Option Data Package for an Option Program, Coherus will have the right (subject to the remainder of this Section 2.8(c) (Incomplete Option Data Package)) to promptly notify Junshi if Coherus believes that any such Option Data Package is missing any required information. Junshi will provide Coherus with the missing information identified in such notice within 10 Business Days after the date of Coherus’ request. If, following any such request from Coherus, Junshi does provide any such missing information that is available to Junshi, then the Option Term with respect to such Option Program will be extended only one time to end 20 days after delivery of such missing information.
- (d) **Due Diligence.** During the Option Term for a given Option Program, to assist Coherus in conducting thorough due diligence to decide whether to exercise the License Option for such Option Program, at least once every Calendar Quarter Junshi will provide a report of all data and results from all non-clinical and pre-clinical studies and Clinical Trials for Option Products that are the subject of each Option Program, and Junshi will afford to Coherus and its representatives an opportunity to discuss such activities with Junshi

personnel during normal business hours. In addition, during the Option Term following delivery to Coherus of the Option Data Package for an Option Program, as the case may be, upon Coherus' request, (i) Junshi will use reasonable efforts to afford to Coherus and its representatives reasonable access during normal business hours to Junshi's and its Affiliates' personnel, records and data, offices, and laboratories, in each case, as Coherus may reasonably request related to such Option Program to conduct customary and reasonable due diligence of such Option Program and (ii) subject to customary and reasonable due diligence procedures to preserve the confidential nature of any such information, Junshi will promptly provide to Coherus through an electronic data room copies of (A) any documents reasonably requested by Coherus, (B) any patent or regulatory information, and (C) any results of preclinical, clinical and CMC activities relating to such Option Program, in each case ((A) – (C)), then Controlled by Junshi or its Affiliates, to the extent that such information has not been previously provided by or on behalf of Junshi to Coherus and pertains to such Option Program.

- (e) **Junshi Restrictions.** During the Option Term for a given Option Program, other than with the prior written consent of Coherus, Junshi will not grant to any Third Party any right to Exploit any Option Molecule or Option Products that are the subject of such Option Program in a manner that would conflict with the License Option granted to Coherus hereunder with respect to such Option Program or the rights granted to Coherus if Coherus were to exercise such License Option.
- (f) **Termination of Option.** If Coherus does not provide an Option Exercise Notice in respect of a given Option Program prior to the expiration of the Option Term for such Option Program, then Coherus' right to exercise the License Option for such Option Program will terminate and Junshi will have no further obligations to Coherus with respect to such Option Program and this Agreement will terminate with respect to such Option Program.
- (g) **Exercise of a License Option.** Coherus may exercise the License Option for a given Option Program at any time during the period commencing on the Effective Date and ending 60 days following receipt of an Option Notice with respect to such Option Program (the "**Option Term**" and each such exercise, an "**Option Exercise**"), by providing Junshi with written notice of its intent with respect thereto (each, an "**Option Exercise Notice**") and payment of the amounts due under Section 8.2 (Option Exercise Payment) so long as at such time neither Coherus nor any of its Affiliates is undertaking any activities that would, if the subject Option Molecules or Option Products were Licensed Antibodies or Licensed Product, constitute Competitive Activities at the time of the Option Exercise with respect to the subject Option Molecules and Option Products. If Coherus or any of its Affiliates is undertaking any Competitive Activities at such time, then, in addition to the foregoing conditions, Coherus may only exercise the License Option with the written consent of Junshi. The date on which Coherus exercises a License Option and pays all such amounts for an Option Program is the "**Option Exercise Date.**" From and after the Option Exercise Date for an Option Program, all Option Molecules and Option Products that are the subject of such Option Program will thereafter become Licensed Antibodies and Licensed Products, as applicable, for purposes of this Agreement upon the same terms in this Agreement as applicable to the other Licensed Antibodies and Licensed Products that existed as of the Effective Date, except as otherwise specified herein, and accordingly Coherus will also have the right to make Development Proposals for such Option Molecules and Optioned Licensed Products in accordance with the provisions of Section 4.3 (Additional Development), conduct joint Development with Junshi under Joint Development Plans approved by the JDC, and conduct Independent Development in connection with such Option Molecules and Optioned Licensed Products.

- (h) **Coherus Share of Option Program Development Costs.** Coherus will pay its share of costs incurred by Junshi or its Affiliates after the Option Notice according to the applicable Optioned Licensed Product Development Plan and Optioned Licensed Product Development Budget presented to Coherus in the Option Notice and each update to such plan and budget as approved by the JDC (“**Optioned Licensed Product Development Costs**”) equal to (i) 100% of such costs and expenses attributable to Development activities in the Coherus Territory *plus* (ii) 25% of such costs and expenses attributable to Development activities outside of the Coherus Territory; *provided, however,* that Coherus will not be obligated to reimburse Junshi for more than \$25,000,000 per Calendar Year (prorated on a daily basis for the partial Calendar Year during which the Option Exercise Date occurs) (the “**Option Program Annual Ongoing Development Cost Cap**”) for the Optioned Licensed Product Development Costs associated with an Option Program.
- (i) **Invoices and Payments.** No later than 30 days after the end of each Calendar Quarter after the Option Exercise Date, Junshi will provide an invoice to Coherus setting forth in reasonable detail Coherus’ share of the Optioned Licensed Product Development Costs incurred by Junshi or its Affiliates during such Calendar Quarter (to the extent less than or equal to the Option Program Annual Ongoing Development Cost Cap for the applicable Calendar Year). Such quarterly invoices will be accompanied by available supporting documentation, receipts, or related information to the extent necessary to verify such share of Optioned Licensed Product Development Costs for a particular Calendar Quarter. Coherus will pay the undisputed share of Optioned Licensed Product Development Costs for each Calendar Quarter (to the extent less than or equal to the Option Program Annual Ongoing Development Cost Cap for the applicable Calendar Year) no later than 45 days after the receipt of such invoice.
- (j) **Plan and Budget Updates.** Once every six months following the Option Exercise, Junshi will provide to the JDC to review, discuss, and determine whether to approve, an updated Optioned Licensed Product Development Plan and Optioned Licensed Product Development Budget.
- 2.9 **Right of First Negotiation.** Junshi hereby grants to Coherus the exclusive right of first negotiation in the event that Junshi or its Affiliates determines to transfer, license, sublicense, assign, grant, or otherwise dispose of rights to any Third Party, other than express or implied licenses/sublicenses granted to an agent or a consultant, contract manufacturing organization, contract research organization, or other similar type contractor acting for or on behalf of Junshi or its Affiliates, to Develop or Commercialize one or more Antibodies Controlled by Junshi or any of its Affiliates directed to CD112r or CTLA-4 (a “**ROFN Product**”) in one or more countries in the Coherus Territory (a “**ROFN Product Activity**” and such countries, the “**ROFN Jurisdictions**”). Promptly upon determining to engage in a ROFN Product Activity, Junshi will notify Coherus in writing of such determination and identify the applicable ROFN Product and ROFN Jurisdictions with respect to which such Development or Commercialization rights would be granted. Coherus will have an exclusive right, exercisable no later than 30 days after receipt of any such written notice from Junshi, to notify Junshi in writing as to whether Coherus desires to negotiate exclusively for the right to Develop or Commercialize such ROFN Product in such ROFN Jurisdiction (for each of CD112r and CTLA-4, each, a “**ROFN Exercise Notice**”). If Coherus provides a ROFN Exercise Notice to Junshi within such 30 day period indicating its desire to negotiate for such rights to the applicable ROFN Product in the applicable ROFN Jurisdiction, then (a) upon Coherus’ request, Junshi will (i) within 20 Business Days of Coherus’ request, provide Coherus with other information and documentation reasonably requested by Coherus relating to such ROFN Product and ROFN Jurisdiction; and (ii) afford Coherus and its representatives reasonable access during normal business hours to Junshi’s personnel; and (b) Coherus will have the exclusive right for 100

days from the date of Junshi's receipt of the ROFN Exercise Notice to enter into an agreement or amendment to this Agreement, as applicable, with respect to the Exploitation by Coherus of such ROFN Product in such ROFN Jurisdiction. If, with respect to a ROFN Product in a ROFN Jurisdiction, either (A) Coherus does not provide the ROFN Exercise Notice to Junshi within such 30 day period, or (B) Coherus and Junshi do not agree on terms under which Coherus would be granted the right to Exploit such ROFN Product in such ROFN Jurisdiction within the 100 day negotiation period after having conducted such negotiations in good faith, then, in each case ((A) and (B)), Junshi will be free to enter into negotiations and an agreement with one or more Third Parties relating to a grant of rights to Develop or Commercialize such ROFN Product (or to Develop or Commercialize any such ROFN Product itself) in such ROFN Jurisdiction.

### ARTICLE 3 GOVERNANCE

- 3.1 **Alliance Manager.** Within 30 days of the Effective Date, each Party will appoint an individual (from the Party or from any Affiliate of such Party) who possesses a general understanding of Development and Manufacturing issues regarding pharmaceutical and biologic products to act as the facilitator of the meetings of the JDC and the first point of contact between the Parties with regard to questions relating to this Agreement or the overall business relationship and related matters between the Parties (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time upon written notice to the other Party.
- 3.2 **Joint Development Committee.**
- (a) **Formation; Composition.** No later than after 30 days after the Effective Date, the Parties will establish a joint development committee (the "**Joint Development Committee**" or "**JDC**") comprised of three representatives from each Party (or appointed representatives of any Affiliate of such Party) with sufficient seniority within the applicable Party to make decisions arising within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual consent of its members, *provided* that the JDC will consist at all times of an equal number of representatives of each of Junshi and Coherus. Each Party may replace its JDC representatives at any time upon written notice to the other Party. The JDC may invite non-members to participate in the discussions and meetings of the JDC, *provided* that such participants will have no voting authority at the JDC. The JDC will be chaired by one of the representatives ("**Chairperson**") and will rotate between the Parties every 12 months during the Term. The role of the Chairperson will be to convene and preside at meetings of the JDC. The Chairperson will have no additional powers or rights beyond those held by the other JDC representatives. The Alliance Managers will work with the Chairperson to prepare and circulate agendas and to ensure the preparation of minutes.
  - (b) **Specific Responsibilities.** The JDC will:
    - (i) facilitate the flow of information between the Parties with respect to the Development and Commercialization of the Licensed Antibodies and Licensed Products;
    - (ii) review, discuss, and determine whether to approve updates to any Ongoing JS001 Development Plan or Ongoing JS001 Development Budget pursuant to Section 4.2(a) (Plans and Budgets);
    - (iii) review and discuss Development Proposals presented by either Party pursuant to Section 4.3(a) (Proposals and JDC Review), and, subject to Section 3.2(b)(iv), Independent Trials, Independent Development Plans, and Independent

Development Budgets presented by either Party pursuant to Section 4.5 (Independent Development);

- (iv) review, discuss, and determine whether to approve each Joint Development Plan and Joint Development Budget, and each update thereto, pursuant to Section 4.4 (Joint Development), which will include any Independent Development Plan or Independent Development Budget that becomes a Joint Development Plan or Joint Development Budget following a Party's opt-in pursuant to Section 4.5 (Independent Development), and any updates thereto;
  - (v) after the Option Exercise with respect to an Option Program, review, discuss, and determine whether to approve all updates or amendments to any applicable Optioned Licensed Product Trials, Optioned Licensed Product Development Plan, and Optioned Licensed Product Development Budget pursuant to Section 4.6 (Development of Optioned Licensed Products) or Section 2.8 (Coherus License Options);
  - (vi) review and discuss any Development reports provided by either Party pursuant to Section 4.10 (Development Reports);
  - (vii) review, discuss, and determine whether to approve the Transition Plan pursuant to Section 5.1 (Regulatory Responsibilities);
  - (viii) review, discuss, and approve (A) the date by which the Parties will complete all transition activities to enable Coherus to assume regulatory responsibilities for the Licensed Antibodies and Licensed Products in the Coherus Territory (other than those related to the Junshi Clinical Trials), and (B) whether Coherus will assume responsibility for further regulatory activities for the Licensed Antibodies and Licensed Products throughout the Coherus Territory for the Ongoing JS001 Trial following transfer of the applicable Regulatory Approvals and Regulatory Materials for the Ongoing JS001 Trial to Coherus, in each case ((A) – (B)) pursuant to Section 5.2 (Assignment of Regulatory Materials);
  - (ix) review and discuss any Commercialization updates provided by Coherus pursuant to Section 7.3 (Commercialization Report);
  - (x) to the extent not specified in a Joint Development Plan approved by the JDC, review, discuss, and determine which Party will have control and decision-making authority with respect to preparing and submitting regulatory filings and conducting communications with Regulatory Authorities, in each case related to the Licensed Antibodies and Licensed Products that is the subject of the Joint Development Plan approved by the JDC, as applicable; and
  - (xi) perform such other functions as appropriate, to further the purposes of this Agreement, in each case as agreed in writing by the Parties.
- (c) **Meetings.** During the Term, the JDC will meet on a quarterly basis, unless otherwise agreed to by the JDC. No later than 10 Business Days prior to any meeting of the JDC, the Alliance Managers will jointly prepare and circulate an agenda for such meeting; *provided, however*, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. Either Party may also call a special meeting of the JDC (by videoconference, teleconference or in person) by providing at least 10 Business Days' prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, in



which event such Party will work with the Chairperson of the JDC to provide the members of the JDC no later than three Business Days prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JDC may meet in person, by videoconference or by teleconference. In-person JDC meetings will be held at locations agreed upon by Junshi and by Coherus. Each Party will bear the expense of its respective JDC members' participation in JDC meetings. Meetings of the JDC will be effective only if at least two JDC members from each Party (which members do not include such Party's Alliance Manager) are present or participating (including by videoconference or teleconference) in such meeting. The Alliance Managers will be responsible for preparing reasonably detailed written minutes of all JDC meetings that reflect material decisions made and action items identified at such meetings. The Alliance Managers will send draft meeting minutes to each member of the JDC for review and approval within 20 Business Days after each JDC meeting. Such minutes will be deemed approved unless one or more members of the JDC objects to the accuracy of such minutes within five Business Days of receipt. Minutes will be officially endorsed by the JDC at the next JDC meeting, and will be signed by the Chairperson.

- (d) **Decision-Making.** The representatives from each Party on the JDC will have, collectively, one vote on behalf of that Party, and all decision making will be by consensus. Disputes at the JDC will be handled in accordance with Section 3.3 (Resolution of JDC Disputes).

### 3.3 Resolution of JDC Disputes.

- (a) **Within the JDC.** All decisions within the JDC will be made by consensus. If the JDC is unable to reach consensus on any issue for which it is responsible within thirty 30 days after a Party affirmatively states that a decision needs to be made, then either Party may elect, by written notice to the other Party, to submit such issue the Parties' Executive Officers, in accordance with Section 3.3(b) (Referral to Executive Officers).
- (b) **Referral to Executive Officers.** If a Party makes an election under Section 3.3(a) (Resolution of JDC Disputes; Within the JDC) to refer a matter to the Executive Officers, then the Executive Officers will use good faith efforts to resolve promptly such matter, which good faith efforts will include at least one in-person, video or telephonic meeting between such Executive Officers within 15 Business Days after the submission of such matter to them.
- (c) **Final Decision-Making Authority.** If the Executive Officers are unable to reach consensus on any such matter within thirty (30) days after its submission to them, then:
  - (i) **No Changes; Status Quo.** Neither Party will have final decision-making authority over: (A) approval of a Joint Development Plan or any update thereto, (B) changes to the Ongoing JS001 Development Plan or the Ongoing JS001 Development Budget, except with respect to any change to any Ongoing JS001 Development Budget that results in a total budget that is less than 10% higher than the then- current total budget, (C) after an Option Exercise for an Option Program, approval of, or changes to, the corresponding Optioned Licensed Product Development Plan or Optioned Licensed Product Development Budget, except with respect to any change to any Optioned Licensed Product Development Budget that results in a total budget that is less than 10% higher than the then-current total budget, (D) any matter that relates to any Clinical Trial that the Parties are conducting pursuant to a Joint Development Plan, (E) the date by which the Parties will complete all transition activities to enable Coherus to assume regulatory responsibilities for the Licensed Antibodies and Licensed Products in the Coherus Territory (other than

those related to the Junshi Clinical Trials), (F) approval of the Transition Plan or any changes to it after its approval, or (G) whether Coherus will assume responsibility for further regulatory activities for the Licensed Antibodies and Licensed Products throughout the Coherus Territory for the Ongoing JS001 Trial following transfer of the applicable Regulatory Approvals and Regulatory Materials for the Ongoing JS001 Trial to Coherus.

- (ii) **Coherus Decisions.** Coherus will have final decision-making authority with respect to matters (A) that relate exclusively to the Coherus Territory (other than any Independent Development for which Junshi is the Developing Party), or (B) that relate to Independent Development for the Coherus Territory for which Coherus is the Developing Party, except those matters set forth under Section 3.3(c)(i) (No Changes; Status Quo), Section 3.3(c)(iii) (Junshi Decisions), or Section 3.3(c)(iv) (Limitations on Decision-Making) and *provided* that Coherus will not exercise its final decision-making authority in a matter that would reasonably be expected to: (1) result in a material quality, safety, toxicity, or side effect concern with respect to the Licensed Antibody or Licensed Product, as such matter, if applicable, may be determined by the Panel in accordance with Section 4.3(b) (Restrictions on Additional Development); or (2) change Coherus' obligations under this Agreement.
- (iii) **Junshi Decisions.** Junshi will have final decision-making authority with respect to (A) matters that relate exclusively to the Junshi Territory (other than Independent Development for which Coherus is the Developing Party), (B) matters that relate to Independent Development for which Junshi is the Developing Party, (C) the Manufacturing of any Licensed Products that include each Licensed Antibody prior to the completion of the Manufacturing Technology Transfer for the applicable Licensed Antibody (except those matters set forth under Section 3.3(c)(i) (No Changes; Status Quo) or Section 3.3(c)(iv) (Limitations on Decision-Making), or (D) modifications of any then-current Ongoing JS001 Development Budget, Joint Development Budget, or Optioned Licensed Product Development Budget to the extent such modifications result in a total budget that is less than 10% higher than the then-current total budget; in each case, (A) through (D), *provided* that, Junshi will not exercise its final decision-making authority in a matter that would reasonably be expected to: (1) result in a material quality, safety, toxicity, or side effect concern with respect to the Licensed Antibody or Licensed Product, as such matter, if applicable, may be determined by the Panel in accordance with Section 4.3(b) (Restrictions on Additional Development); or (2) change Junshi's obligations under this Agreement.
- (iv) **Limitations on Decision-Making.** Without the other Party's prior written consent, neither Party may unilaterally make a decision (in exercise of its final decision-making authority on any such matters) that (A) expands either Party's contractual rights or reduces either Party's contractual obligations under this Agreement, (B) results in a material increase in the other Party's obligations, costs, or expenses or a material limitation to the other Party's rights under this Agreement, (C) conflicts with this Agreement, or would be reasonably likely to result in a violation of applicable law, the requirement of any Regulatory Authorities or any agreement with any Third Party (including any Additional Third Party License), or result in the infringement or misappropriation of intellectual property rights of any Third Party, or (D) is stated to require the agreement or

consent of the Parties under Section 3.3(c)(i) (No Changes; Status Quo) or that is subject to the determination of the other Party pursuant to Section 3.3(c)(ii) (Coherus Decisions) or Section 3.3(c)(iii) (Junshi Decisions) (as applicable). In addition, no exercise by either Party of such Party's decision-making authority can amend or waive compliance with any terms of this Agreement.

- 3.4 **Discontinuation of JDC.** The JDC will continue to exist until the Parties agree to disband the JDC. Once the JDC is disbanded, the JDC will have no further obligations under this Agreement and, thereafter, the Alliance Managers will be the points of contact for the exchange of information between the Parties under this Agreement and any references in this Agreement to decisions of the JDC will automatically become references to decisions by and between the Parties in writing, subject to the other terms of this Agreement and consistent with the terms of Section 3.3(c) (Final Decision-Making Authority).

#### **ARTICLE 4 DEVELOPMENT**

4.1 **Development Diligence Obligations.**

- (a) **Junshi.** Junshi will use Commercially Reasonable Efforts to conduct (i) the Ongoing JS001 Clinical Trials, (ii) a sufficient number of Phase I Clinical Trials to generate safety data and a recommended dosage for conducting Phase II Clinical Trials for a Junshi IL-2 Molecule and for a Junshi TIGIT Antibody, as applicable, and (iii) after the Option Exercise for an Option Program, the corresponding Optioned Licensed Product Trials.
- (b) **Coherus.** Subject to Junshi's satisfaction of its obligations set forth in Section 4.1(a) (Junshi) as applicable, Coherus will use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval (and, where applicable, Pricing and Reimbursement Approval) for (i) a Licensed Product that includes a Licensed Antibody defined in clause (a) of the definition of "Licensed Antibody" in the Field in the United States and Canada and (ii) after the Option Exercise for an Option Program, at least one Licensed Product in the Field in the United States and Canada involving a Junshi IL-2 Molecule or Junshi TIGIT Antibody, as applicable.
- (c) **Joint Development Plans.** If a Joint Development Plan is approved by all members of the JDC, then each Party will use Commercially Reasonable Efforts to conduct those Development activities allocated to such Party under and in accordance with the Joint Development Plan and the applicable Joint Development Budget.

4.2 **Ongoing JS001 Trials.**

- (a) **Plans and Budgets.** Junshi will be responsible for the completion of, will continue to lead clinical operation of, and will use Commercially Reasonable Efforts to complete the Ongoing JS001 Trials in accordance with the Ongoing JS001 Development Plan (as may be revised from time to time). The development plan for the Ongoing JS001 Trials as of the Execution Date is attached to this Agreement as Schedule 4.2 (Ongoing JS001 Development Plan) (the "**Ongoing JS001 Development Plan**"), which includes the budget of the costs and expenses for the completion of the Ongoing JS001 Trials (the "**Ongoing JS001 Development Budget**"). Junshi will provide to Coherus any proposed updates to the Ongoing JS001 Development Plan (including to the Ongoing JS001 Development Budget set forth therein) for Coherus' review and comment and no changes to the Ongoing JS001 Development Plan will be effective unless and until the JDC determines to approve such changes.

- (b) **Costs to be Reimbursed.** Coherus will reimburse Junshi, at Junshi's election, for either: (i) 100% of the documented internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate for Junshi) in the Coherus Territory or (ii) 25% of the documented internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate) globally (including within the Coherus Territory and outside the Coherus Territory), in each case ((i) and (ii)), incurred by Junshi or its Affiliates in the performance of the Ongoing JS001 Trials after the Execution Date to the extent in accordance with the then-current Ongoing JS001 Development Plan and Ongoing JS001 Development Budget (the "**Ongoing JS001 Trial Costs**") up to a maximum of \$25,000,000 per Calendar Year (the "**Ongoing JS001 Trial Cap**").
- (c) **Invoices and Payments.** No later than 30 days after the end of each Calendar Quarter during which an Ongoing JS001 Trial is conducted, Junshi will provide an invoice to Coherus setting forth in reasonable detail Coherus' share of the Ongoing JS001 Trial Costs incurred by Junshi or its Affiliates during such Calendar Quarter (to the extent less than or equal to the Ongoing JS001 Trial Cap for the applicable Calendar Year). Such quarterly invoices will be accompanied by available supporting documentation, receipts, or related information to the extent necessary to verify such share of Ongoing JS001 Trial Costs for a particular Calendar Quarter at the rate selected by Junshi under Section 4.2(b) (Costs to be Reimbursed). Coherus will pay the undisputed share of Ongoing JS001 Trial Costs for each Calendar Quarter (to the extent less than or equal to the Ongoing JS001 Trial Cap for the applicable Calendar Year) no later than 45 days after the receipt of such invoice. At the end of each Calendar Year during which an Ongoing JS001 Trial is conducted, Junshi will provide a final invoice for the preceding Calendar Year so that Coherus is invoiced at the greater of the rates under Section 4.2(b) (Costs to be Reimbursed) for such Calendar Year; *provided, however, that* if such invoice would cause Coherus to exceed the Ongoing JS001 Trial Cap for such Calendar Year, then Junshi will provide to Coherus an invoice for an amount so that Junshi only invoices Coherus a total amount for the subject Calendar Year equal to the Ongoing JS001 Trial Cap for such Calendar Year.
- (d) **Plan and Budget Updates.** No less than once per year, or more frequently as may be required, Junshi will provide to the JDC to review, discuss, and determine whether to approve, an updated Ongoing JS001 Development Plan and Ongoing JS001 Development Budget.

#### 4.3 **Additional Development.**

- (a) **Proposals and JDC Review.** During the Term, either Party may propose to (i) conduct Clinical Trials using a Licensed Antibody as a monotherapy or (ii) Develop a Combination Regimen that includes a Licensed Antibody, in any such case (i) or (ii), either independently or collaboratively with the other Party and involving Clinical Trials the data from which will be used to obtain, maintain, or support Regulatory Approval for the applicable monotherapy or Combination Regimen solely or partly For the Coherus Territory (but that is not at such time already the subject of the Ongoing JS001 Trials, an Optioned Licensed Product Development Plan, a Joint Development Plan approved by the JDC, or an Independent Development Plan). If a Party desires to undertake such new Development, then such Party will submit a proposal to the JDC setting forth the proposed Development activities and its related timeline (a "**Development Proposal**"). Any such proposal that proposes costs sharing between the Parties or other collaboration with respect to such Development activities (a "**Joint Development Proposal**") should also contain the proposed budget and cost sharing arrangements for the corresponding Development activities. Within 30 days after submission to the JDC, the JDC will review, discuss, and determine whether to approve such Development Proposal.

(b) **Restrictions on Additional Development.** Neither Party will conduct any Clinical Trials involving a Licensed Antibody in or For the Coherus Territory (including an Optioned Licensed Product following the Option Exercise for such product) (i) other than as set forth in this Section 4.3 (Additional Development), Section 4.4 (Joint Development), and Section 4.5 (Independent Development) or (ii) if the other Party objects to the conduct of Clinical Trials in or For the Coherus Territory on the basis they are likely to result in a material quality, safety, toxicity, or side effect with respect to the Licensed Antibody or Licensed Product and provides its rationale for such objection in writing to the JDC; *provided* that, if the Parties disagree as to whether such Clinical Trial is likely to result in a material quality, safety, toxicity, or side effect with respect to such Licensed Antibody or Licensed Product, then either Party may escalate such dispute for resolution to the Executive Officers in accordance with the terms of Section 15.1(a) (Dispute Resolution). If the Executive Officers cannot agree on a resolution within the applicable time period, then neither Party may proceed under Section 15.1(b) (Dispute Resolution), but instead either Party may, within 10 days after expiration of such time period, refer such disagreement to expert arbitration pursuant to the following procedures:

- (A) The expert arbitration will be overseen by and conducted as a “baseball” form of binding arbitration conducted by a panel of three (3) arbitrators (“**Panel**”). The Panel will be selected in accordance with the following procedure: Coherus will appoint one (1) arbitrator for the Panel, Junshi will appoint one (1) arbitrator for the Panel, each within fourteen (14) days of the initiation of arbitration, and the two Party-appointed arbitrators will appoint the third arbitrator for the Panel, who will act as the chair, within fourteen (14) days of confirmation of the two Party-appointed arbitrators. The Parties may confer with their respective Party-appointed arbitrators regarding the appointment of the chair. Each arbitrator comprising the Panel will have at least twenty (20) years of experience in the negotiation of biotechnology and pharmaceutical license and collaboration agreements. At the election of any member of the Panel, the Panel may engage one or more independent experts with experience in the subject matter of the dispute to advise the Panel, but final decision-making authority will remain in the Panel.
- (B) Within twenty-one (21) days after the constitution of the Panel, each Party will submit to both the Panel and the other Party a detailed written proposal of no more than thirty (30) pages setting forth its proposed resolution of the dispute, which proposal should indicate one of the following: (1) that the proposed Clinical Trials can proceed as most recently proposed by the Developing Party to the JDC, (2) that the proposed Clinical Trials cannot proceed, or (3) that the proposed Clinical Trials can proceed but with the modifications as described by such Party in the proposal to the Panel. The Parties will also provide to the Panel a copy of this Agreement, as may be amended at such time.
- (C) There will be no discovery and there will be no hearing, although the arbitration proceeding will be deemed to have its seat in New York, New York, U.S.A.
- (D) Within thirty (30) days after the submission of the Parties’ legal briefs, the Panel will select one of the two detailed written proposals (without modification) provided by the Parties that the Panel believes is most

consistent with the intention underlying and agreed principles set forth in this Agreement. The decision of the Panel will be final and unappealable. The detailed written proposal selected by the Panel will automatically be binding on the Parties.

- (E) The Panel must select one of the two detailed written proposals and may not combine elements of both detailed written proposals or take any other action.
- (F) Each Party will bear its own attorneys' fees, costs and disbursements arising out of the arbitration, and will pay an equal share of the fees and costs of the Panel.

4.4 **Joint Development.** If within 30 days after submission of a Joint Development Proposal the JDC determines to further consider such proposal (either as originally proposed or with revisions), then (a) the Parties will develop for approval by the JDC a written plan to govern such Development, including the activities to be conducted by each Party with respect to the Development activities and associated budget and cost sharing arrangement, and (b) the Parties may enter into an amendment of this Agreement or a separate written agreement governing the Parties' rights and obligations with respect to such Development, if appropriate, to be effective concurrently with the approval of such plan by the JDC. Any such plan approved by all members of the JDC is a "**Joint Development Plan**" and its associated budget a "**Joint Development Budget**." Any Joint Development Proposal not approved by the JDC within 60 days (unless such time is extended by written agreement of the Parties) after it is first presented by a Party to the JDC as a Joint Development Proposal will be deemed not approved by the JDC.

4.5 **Independent Development.** If either (a) the JDC does not approve a Joint Development Proposal within the applicable time or (b) the Development Proposal was not presented to the JDC as a Joint Development Proposal, then the proposing Party (the "**Developing Party**") will have the right, but not the obligation, to proceed with the Development activities as most recently proposed by such proposing Party to the JDC ("**Independent Development**") at its sole cost and expense subject to the following conditions.

- (a) **Right to Opt-In.** If a Developing Party desires to proceed with any Independent Development, then it must provide the other Party (the "**Non-Developing Party**") with the option to share in the costs of the Clinical Trials associated with such Independent Development on the terms described in this Section 4.5 (Independent Development) below (and be granted rights to the data and results from such Clinical Trials), unless the Independent Development is for a Combination Regimen in which any of the Other Component(s) is/are Controlled by the Developing Party. If the Developing Party desires to proceed with any Independent Development for a Combination Regimen in which any of the Other Component(s) is/are Controlled by the Developing Party (including when any such Other Component(s) is/are still in Development or the subject of one or more Regulatory Approval(s), a "**Proprietary Combination Regimen**"), then the Developing Party may, but is not required to, provide the Non-Developing Party with such option.
- (b) **Non-Developing Party Opt-In.** If a Developing Party undertakes any Independent Development in which the Non-Developing Party has the option to share in the data, results and costs of the Clinical Trials associated with such Independent Development (each such Clinical Trial, an "**Independent Trial**") then within 30 days following the JDC's decision not to approve a Joint Development Proposal or the Developing Party's presentation to the JDC of such option (if not presented as a possible Joint Development Proposal), the Developing Party will provide to the Non-Developing Party a plan of the Development activities to be conducted with respect to such Independent Development (the

“**Independent Development Plan**”) and a budget of the costs and expenses to be incurred in the performance of activities under such plan (the “**Independent Development Budget**”).

- (c) **Early Opt-In Cost Sharing.** If the Non-Developing Party notifies the Developing Party in writing that it is electing to be granted such rights within 30 days after receipt of the Independent Development Plan and Independent Development Budget, then the applicable Independent Development Plan will become a Joint Development Plan and the applicable Independent Development Budget will become a Joint Development Budget, and:
- (i) If the Non-Developing Party is Coherus, Coherus will reimburse Junshi each Calendar Quarter for: (A) 100% of the documented internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate) in the Coherus Territory plus (B) 25% of the documented internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate) outside of the Coherus Territory, in each case ((A) and (B)), incurred by Junshi or its Affiliates in the performance of the Independent Development Plan to the extent in accordance with the applicable and then-current Independent Development Budget, which reimbursements will be conducted in accordance with the terms of Section 2.8(i) (Invoices and Payments) *mutatis mutandis*; *provided, however*, that Coherus will not be obligated to reimburse Junshi for more than \$25,000,000 per Calendar Year for the PD-1 Program or \$25,000,000 per Calendar Year for an Option Program; or
  - (ii) If the Non-Developing Party is Junshi, Junshi will reimburse Coherus each Calendar Quarter for 35% of the documented internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate) in the Coherus Territory incurred by Coherus in the performance of the Independent Development Plan to the extent in accordance with the applicable and then current Independent Development Budget; *provided, however*, that Junshi will not be obligated to reimburse Coherus for more than \$25,000,000 per Calendar Year for the PD-1 Program or \$25,000,000 per Calendar Year for an Option Program.
  - (iii) No less than once per year, or more frequently as may be required (including to add new Independent Trials), the Developing Party will provide to the JDC to review, discuss, and determine whether to approve, any updates to an existing Independent Development Plan and corresponding Independent Development Budget.
- (d) **Later Opt-In Cost-Sharing Premium.** If the Non-Developing Party does not elect to reimburse the Developing Party in accordance with Section 4.5(c) (Early Opt-In Cost Sharing), then the Non-Developing Party will not have any rights with respect to any data or results generated from the Independent Trials or other Development activities of the Independent Development or any related Regulatory Materials, unless and until the Non- Developing Party notifies the Developing Party of its election to be granted such rights and reimburses the Developing Party for 50% more than the Non-Developing Party would be required to pay if the Non-Developing Party had elected to share in the costs and expenses as provided under Section 4.5(c) (Early Opt-In Cost Sharing) for all such costs and expenses incurred by the Developing Party through the date of such election and thereafter. After the Non-Developing Party makes such election and reimburses the Developing Party for its share of such costs and expenses incurred through such time, the Non-Developing Party will be responsible for its applicable costs and expenses incurred after the date of election and the data and results generated from such Independent Trials or other



Independent Development activities will be subject to the Non-Developing Party's right of use and right of reference under Section 4.8 (Data Exchange and Use) and Section 5.5 (Right of Reference).

- 4.6 **Development of Optioned Licensed Products.** This Section 4.6 (Development of Optioned Licensed Products) only applies to Licensed Products that are the subject of the TIGIT Program or the IL-2 Program following the Option Exercise with respect to the applicable Option Program ("**Optioned Licensed Products**"). Upon and after the Option Exercise with respect to an Option Program:
- (a) **Trials Ongoing as of Option Exercise.** Coherus will have the right to participate in any Clinical Trials conducted by Junshi or its Affiliates with respect to the Optioned Licensed Products that are the subject of the TIGIT Program or the IL-2 Program (as applicable) in the Coherus Territory, according to the applicable Optioned Licensed Product Development Plan and Optioned Licensed Product Development Budget presented to Coherus in the Option Notice and each update to such plan and budget as proposed to JDC pursuant to the terms of this Agreement, whether such Clinical Trials are ongoing as of the Option Exercise Date for such program or thereafter (each, an "**Optioned Licensed Product Trial**").
  - (b) **Cost Sharing.** In addition to the amounts that Coherus must pay to Junshi as part of the Option Exercise as provided in Section 2.8(h) (Coherus Share of Option Program Development Costs), upon and after the Option Exercise, Coherus must co-fund its share of Optioned Licensed Product Development Costs in accordance with Section 2.8(i) (Invoices and Payments), subject to the Option Program Annual Ongoing Development Cost Cap.
  - (c) **Rights to Data.** Coherus will obtain rights to use and reference the data and results generated from the Development activities conducted in connection with the Optioned Licensed Product Development Plan in accordance with Section 4.8 (Data Exchange and Use) and Section 5.5 (Right of Reference).
- 4.7 **Responsibility for Development.** Other than with respect to Development related to the Junshi Clinical Trials in accordance with this Article 4 (Development) and Article 3 (Governance), or as otherwise set forth under a Joint Development Plan approved by the JDC, each Party will be solely responsible for Development activities with respect to the Licensed Antibodies and Licensed Products for its respective territory.
- 4.8 **Data Exchange and Use.** In addition to its adverse event and safety data reporting obligations set forth in Section 5.6 (Adverse Event Reporting), each Party will promptly provide the other Party with copies of all data and results and all supporting documentation (*e.g.*, protocols, Investigator's Brochures, case report forms, analysis plans) Controlled by such Party that are generated by or on behalf of such Party or its Affiliates, Sublicensees, or subcontractors, if applicable, in the Development of any Licensed Product For the Coherus Territory (whether as part of any Clinical Trials inside or outside of the Coherus Territory, involving any monotherapy or Combination Regimens conducted independently or jointly); *provided, however, that* in the case of Proprietary Combination Regimens, a Party is only required to disclose such data and results about the Licensed Product portion of the Proprietary Combination Regimen. Subject to payment of any amounts agreed in writing by the Parties or specified to be due under Section 4.2 (Ongoing JS001 Trials) through and including Section 4.6 (Development of Optioned Licensed Products), as applicable, each Party will have the right to use and reference such data and results provided by the other Party for the purpose of obtaining, supporting, and maintaining Regulatory Approvals, as applicable, of the Licensed Products (but not any other part of a Proprietary Combination Regimen, if applicable)

in the recipient's respective territory, without additional consideration. If either Party obtains the right to use or a right of reference to data Controlled by a Third Party with respect to a Combination Regimen, then such Party will attempt to obtain sufficient rights from such Third Party to grant a further right to use or right of reference with respect to such data to the other Party consistent with the foregoing rights to data and results Controlled by a Party.

- 4.9 **Development Records.** Each Party will, and will cause its Affiliates, Sublicensees, and subcontractors to, maintain reasonably complete, current, and accurate records of all Development activities conducted by or on behalf of it and its Affiliates, Sublicensees, and subcontractors, respectively, for any Licensed Product (including any Combination Regimen) For the Coherus Territory and all data and other information resulting from such activities consistent with its usual practices, in validated computer systems that are compliant with 21 C.F.R. §11 and in accordance with applicable law in the Coherus Territory. Each Party will maintain all such records relating to the Development of Licensed Products for a period of five years, or a longer period as may be required by applicable law or regulation, after the end of the Term. Each Party will document all non-clinical and preclinical studies and Clinical Trials in formal written study reports in accordance with GLP, cGMP, and GCP in compliance with ICH Guidelines, as applicable, and in compliance with applicable law. Upon either Party's reasonable request, not more frequently than once each Calendar Year during which the other Party or its Affiliates, Sublicensees, or subcontractors are performing or having performed Development activities for any Licensed Product (including any Combination Regimen) For the Coherus Territory, the other Party will, and will cause its Affiliates, Sublicensees, and subcontractors to, provide copies of such records (including access to relevant databases) to the requesting Party.
- 4.10 **Development Reports.** At each JDC meeting for a Calendar Quarter during which either Party is performing, or having performed, Development activities for any Licensed Product (including any Combination Regimen) For the Coherus Territory, such Party will provide a report to the other Party summarizing the Development activities for the Licensed Products performed during the period since the preceding JDC meeting, the Development activities for the Licensed Products in process, and the future Development activities for the Licensed Products that such Party or its Sublicensees or subcontractors expect to initiate, including a summary of the data, timelines, and results of such Development activities. Such reports and any additional information provided by a Party regarding Development activities for the Licensed Products, in each case, will be the Confidential Information of the providing Party and subject to the terms of Article 12 (Confidentiality).

## **ARTICLE 5 REGULATORY**

- 5.1 **Regulatory Responsibilities.** Subject to the terms and conditions of this Agreement, Junshi and Coherus will be jointly responsible for all regulatory activities with respect to the Ongoing JS001 Clinical Trials in the Coherus Territory, until the transfer and assignment to Coherus, on a Licensed Antibody-by-Licensed Antibody basis, of the applicable Regulatory Approvals and Regulatory Materials in the Coherus Territory related to the Licensed Products that include a given Licensed Antibody pursuant to Section 5.2 (Assignment of Regulatory Materials). After such transfer and assignment, other than with respect to any Junshi Clinical Trials, Coherus will have sole responsibility for, and sole decision-making authority over, all further regulatory activities and associated costs and expenses for the applicable Licensed Antibody and all Licensed Products that include such Licensed Antibody in the Field in the Coherus Territory. Junshi will reasonably cooperate with Coherus in maintaining all Regulatory Approvals for the Licensed Products in the Coherus Territory and all regulatory activities related to the Exploitation of the Licensed Products in the Coherus Territory. Within 60 days after the Effective Date, the Parties will submit to the JDC to review, discuss, and determine whether to approve a plan for transitioning the regulatory

activities with respect to the Ongoing JS001 Clinical Trials from Junshi to Coherus (“**Transition Plan**”).

5.2 **Assignment of Regulatory Materials.** To the extent permissible under applicable law and as specified within the Transition Plan, (a) Junshi will transfer and assign, or will cause the transfer or assignment, to Coherus or its regulatory agent, Junshi’s, or any of Junshi’s Affiliates’, entire rights, title, and interests in and to all Regulatory Approvals and Regulatory Materials in the Coherus Territory with respect to the Licensed Antibodies and Licensed Products (other than those related to any Junshi Clinical Trial) that are owned, Controlled, or possessed by Junshi or any of its Affiliates, and (b) the Parties will complete all other transition activities to enable Coherus to assume the regulatory responsibilities for the Licensed Antibodies and Licensed Products in the Coherus Territory (other than those related to the Junshi Clinical Trials) by such time as agreed by the JDC (i) after the Effective Date with respect to JS001 and (ii) after each Option Exercise Date with respect to all Option Molecules and Option Products that are the subject of the Option Program for which Coherus exercises the License Option. In any event, Junshi will use reasonable efforts to provide any relevant documents to Coherus as soon as practical following the Effective Date or the Option Exercise Date, as applicable. Except as otherwise specified in the Transition Plan, Junshi will continue to hold in its name, throughout the world, all Regulatory Approvals and Regulatory Materials related to the Ongoing JS001 Clinical Trials until the completion thereof, and Junshi will continue to be responsible for all regulatory responsibilities related to the Ongoing JS001 Clinical Trials in the Coherus Territory until completion thereof and receipt of Regulatory Approval in the Coherus Territory for the Licensed Antibody and Licensed Product that is the subject of a trial. Promptly following receipt of any such Regulatory Approval, Junshi will transfer and assign, or will cause the transfer or assignment, to Coherus or its regulatory agent, Junshi’s, or any of Junshi’s Affiliates’, entire rights, title, and interests in and to all such Regulatory Approvals and Regulatory Materials with respect to such Ongoing JS001 Trial in the Coherus Territory that are Controlled by Junshi or any of its Affiliates, and following the completion of such transfer and assignment, unless otherwise agreed by the JDC, Coherus will assume responsibility for all further regulatory activities for the Licensed Antibodies and Licensed Products throughout the Coherus Territory related to such Ongoing JS001 Trial.

5.3 **Regulatory Filings; Control and Ownership.**

(a) **By Coherus.** As between the Parties, other than with respect to the Junshi Clinical Trials or as specified in the Transition Plan or a Joint Development Plan approved by the JDC, Coherus will lead and have sole control over and decision-making authority with respect to preparing and submitting to Regulatory Authorities in the Coherus Territory all regulatory filings related to the Licensed Antibodies and Licensed Products For the Coherus Territory, including all applications for Regulatory Approval for the Licensed Products in the Coherus Territory. As between the Parties, Coherus will own any and all such Regulatory Approvals and Regulatory Materials in the Coherus Territory related to the Licensed Antibodies and Licensed Products (including all Regulatory Approvals and Regulatory Materials in relation to any Ongoing JS001 Trial after such Regulatory Approvals and Regulatory Materials are assigned to Coherus pursuant to Section 5.2 (Assignment of Regulatory Materials)), which after such assignment will be held in the name of Coherus or its regulatory agent. Coherus will use reasonable efforts to: (i) keep Junshi informed of receipt of any Regulatory Approvals in the Coherus Territory with respect to any Licensed Products within one week after approval and (ii) provide copies of any applications for Regulatory Approvals (in its original language) in the Coherus Territory to Junshi within one week after filing for Junshi’s records, in each case to the extent not in violation of any law or contract. If Junshi obtains a BLA for a Combination Regimen in the Coherus Territory, then Coherus will update the label for the corresponding

Licensed Product in the Coherus Territory as reasonably necessary for Coherus to be able to Commercialize the applicable Licensed Product as part of the Combination Regimen in the Coherus Territory, and Junshi will provide all assistance reasonably requested by Coherus related to any such label update. Except as may be required under applicable law, Coherus will not communicate with any Regulatory Authority outside of the Coherus Territory regarding any Regulatory Approval of a Licensed Product outside of the Coherus Territory.

- (b) **Junshi Clinical Trials.** Subject to Sections 5.1 (Regulatory Responsibilities) and Section 5.2 (Assignment of Regulatory Materials) with respect to the Ongoing JS001 Clinical Trials, as between the Parties, Junshi will lead and have sole control over and decision- making authority with respect to preparing and submitting (i) all regulatory filings related to Junshi Clinical Trials (including Independent Trials for which Junshi is the Developing Party) within or For the Coherus Territory, including all such applications for Regulatory Approval in the Coherus Territory, as well as (ii) all regulatory filings for or within the Junshi Territory. As between the Parties, Junshi will own any and all such Regulatory Approvals in the Coherus Territory and Regulatory Materials submitted to such Regulatory Authorities in the Coherus Territory unless and until they are assigned to Coherus pursuant to Section 5.2 (Assignment of Regulatory Materials)). As between the Parties, Junshi will also own any and all Regulatory Approvals for or within the Junshi Territory and all associated Regulatory Materials. Junshi will use reasonable efforts to: (A) keep Coherus informed of receipt of any such Regulatory Approvals in the Coherus Territory with respect to any Licensed Products within one week after approval and (B) provide copies of any such applications for Regulatory Approvals (in its original language) in the Coherus Territory to Coherus within one week after filing for Coherus' records, in each case to the extent not in violation of any law or contract.
- (c) **Joint Development Plans.** Each Party will have the rights and responsibilities for Regulatory Approvals and Regulatory Materials involving a Joint Development Plan approved by the JDC as specified in such plan or otherwise determined by the JDC.

- 5.4 **Interactions with Regulatory Authorities.** Until assignment to Coherus of the Regulatory Materials that are the subject of Section 5.2 (Assignment of Regulatory Materials), Junshi will have the joint right with Coherus to conduct communications with Regulatory Authorities in the Coherus Territory related to the Licensed Products that are the subject of those Regulatory Materials, including all meetings, conferences, and discussions (including advisory committee meetings). Unless otherwise agreed by the Parties in writing or determined by the JDC, the Party designated as having control over and decision-making authority with respect to preparing and submitting all regulatory filings related to the Licensed Antibodies and Licensed Products under Section 5.3 (Regulatory Filings Control and Ownership) within or For the Coherus Territory or Junshi Territory (as applicable) also has the sole right to conduct all communications with Regulatory Authorities related to the applicable Licensed Antibody(ies) or Licensed Product(s) for such territory, including all meetings, conferences, and discussions (including advisory committee meetings). The Party who controls such communications will disclose to the JDC within four (4) Business Days of such determination (a) any communications with a Regulatory Authority in the Coherus Territory that such Party reasonably determines would be likely to have a material impact on obtaining Regulatory Approval for a Licensed Product in the Coherus Territory, and (b) any communications with a Regulatory Authority in the Coherus Territory that such Party reasonably determines indicates the Regulatory Authority will require any specific pre-approval or post-approval commitments or requirements for Regulatory Approval or Commercialization in the Coherus Territory.

- 5.5 **Right of Reference.** Each Party will grant, and hereby does grant, to the other Party a right of reference to all Regulatory Approvals and Regulatory Materials pertaining to the Licensed Products in the Field Controlled and submitted by or on behalf of such Party or its Affiliates, subject to payment of any amounts agreed in writing by the Parties or specified to be due under Section 4.2 (Ongoing JS001 Clinical Trials) through and including Section 4.6 (Development of Optioned Licensed Products), as applicable, to obtain such right or reference. Coherus may use such right of reference to such Regulatory Approvals and Regulatory Materials Controlled by Junshi or its Affiliates, if any, solely for the purpose of seeking, obtaining, supporting, and maintaining Regulatory Approval and any Pricing and Reimbursement Approvals of the Licensed Products in the Coherus Territory. Junshi may use such right of reference to such Regulatory Approvals and Regulatory Materials Controlled by Coherus or any of its Affiliates solely for the purpose of seeking, obtaining, supporting, and maintaining Regulatory Approval and any Pricing and Reimbursement Approvals of (a) the Licensed Products in the Junshi Territory and (b) any product Controlled by Junshi that is included in any Combination Regimen in the Coherus Territory. The Party using such right of reference will bear (i) its own costs and expenses and (ii) the reasonable and verifiable costs and expenses incurred by the other Party associated with providing assistance to enable such use of the right of reference pursuant to this Section 5.5 (Right of Reference), including (A) internal costs (calculated at the FTE Rate) reasonably incurred by or on behalf of the other Party or its Affiliates in connection with such activities, and (B) all verifiable external or out-of-pocket costs reasonably incurred by or on behalf of the other Party or its Affiliates in connection with such activities under this Section 5.5, in each case ((A) and (B)), within 45 days after receiving the invoice therefor. Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 5.5 (Right of Reference) and to give the other Party the benefit of the granting Party's Regulatory Approvals and Regulatory Materials in the other Party's territory as provided herein, including by executing any letters of authorization or similar correspondence for submitting to an applicable Regulatory Authority to further evidence or give effect to the rights contemplated hereby.
- 5.6 **Adverse Event Reporting.** No later than 90 days after the Effective Date, and in any event before the conduct of any Clinical Trial by Coherus in the Coherus Territory, Junshi and Coherus will develop and agree in a written agreement on worldwide safety and pharmacovigilance procedures for the Parties with respect to all Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement will contain terms no less stringent than those required by ICH or other applicable guidelines in order to allow the Parties to meet the applicable law and other applicable regulatory requirements regarding the management of safety data in the Coherus Territory. The Pharmacovigilance Agreement will provide for (a) reimbursement by Coherus of Junshi's internal and out-of-pocket costs and expenses associated with reporting adverse events or assisting Coherus with reporting adverse events, in each case, within the Coherus Territory and (b) reimbursement by Junshi of Coherus' internal and out-of-pocket costs and expenses associated with reporting adverse events or assisting Junshi with reporting adverse events, in each case, outside of the Coherus Territory (in each case (a) and (b), to the extent not already reimbursed as part of any arrangement between the Parties involving Clinical Trials of Licensed Products).
- 5.7 **Cost Reimbursement.** With respect to the cooperation and assistance of Junshi provided pursuant to this Article 5 (Regulatory) (which will be separate from the cooperation and assistance provided in connection with the Technology Transfers), Coherus will reimburse Junshi for (a) internal costs (at the FTE Rate) reasonably incurred by or on behalf of Junshi or its Affiliates in connection with in relation to such activities in excess of 100 hours, and (b) all verifiable external or out-of-pocket costs actually incurred by or on behalf of Junshi or its Affiliates in connection with such activities,

in each case ((a) and (b)), within 45 days after receiving Junshi's invoice therefor and to the extent not otherwise reimbursed as part of any arrangement between the Parties involving Clinical Trials of Licensed Products, pursuant to Section 5.5 (Right of Reference), or the terms of the Pharmacovigilance Agreement.

## ARTICLE 6 MANUFACTURING

- 6.1 **Manufacturing by Junshi.** Prior to the completion of the Manufacturing Technology Transfer for a Licensed Antibody (and all Licensed Products that include such Licensed Antibody) pursuant to Section 2.6(b) (Manufacturing Technology Transfer), Junshi will, either by itself or through a CMO, Manufacture and supply the Licensed Products to facilitate continuous supply, sale, and registry of Licensed Products to Coherus and its Affiliates and Sublicensees in the Coherus Territory until such time as the applicable Coherus CMO is adequately Manufacturing such Licensed Products for use in the Coherus Territory. During such time, Coherus will purchase its requirements of such Licensed Products from Junshi for use by Coherus and its Affiliates and Sublicensees in the Coherus Territory pursuant to a supply agreement (the “**Supply Agreement**”) and a quality agreement (the “**Quality Agreement**”), each to be entered into between the Parties promptly after the Execution Date. The Supply Agreement will specify that Junshi will deliver the Licensed Products to Coherus EXW (Incoterms 2020). Neither Junshi nor its CMO may initiate any changes with respect to the Manufacture of any Licensed Product that could reasonably be expected to affect the quality, performance, or requirements of the FDA in any BLA, in each case, of such Licensed Product as Manufactured by Junshi or its CMO without the prior written consent of Coherus. The terms of the Supply Agreement and Quality Agreement will be consistent with the terms of this Agreement. Junshi will supply the Licensed Products in drug substance or drug product form, as requested by Coherus, in each case, pursuant to this Section 6.1 (Manufacturing by Junshi) at a transfer price equal to the Fully Burdened Manufacturing Costs plus 15% (the “**Supply Price**”) of Junshi. All Manufacturing activities by or on behalf of Junshi and its Affiliates will at all times be in compliance with cGMP and ICH Guidelines and in compliance with applicable law.
- 6.2 **Manufacturing by Coherus.** Following the completion of the Manufacturing Technology Transfer for a Licensed Antibody (and all Licensed Products that include such Licensed Antibody), Coherus will have sole control over and decision-making authority with respect to, through the applicable Coherus CMO, the Manufacture of such Licensed Products in the Coherus Territory for clinical and commercial uses in the Coherus Territory. If the Parties have completed a Manufacturing Technology Transfer for the Licensed Antibody then, upon request by Junshi, Coherus will Manufacture and supply to Junshi the applicable Licensed Antibody or Licensed Product at the Supply Price of Coherus.

## ARTICLE 7 COMMERCIALIZATION

- 7.1 **Commercialization Responsibilities.** Coherus will have sole control over and decision-making authority with respect to the Commercialization of all Licensed Products in the Coherus Territory, including the right to determine the price of the Licensed Products sold in the Coherus Territory.
- 7.2 **Commercialization Diligence Obligations.** Coherus will use Commercially Reasonable Efforts to Commercialize the Licensed Products in each country in the Coherus Territory in which it has obtained Regulatory Approval (and, where applicable, Pricing and Reimbursement Approval) for such Licensed Products, at its sole cost and expense.



- 7.3 **Commercialization Report.** Following the date upon which the first Regulatory Approval for a Licensed Product in the Coherus Territory is granted (the “**Date of First Regulatory Approval**”), at each meeting of the JDC, Coherus will provide a report summarizing on a Licensed Product-by- Licensed Product and a country-by-country basis the Commercialization activities performed by or on behalf of Coherus and its Affiliates and Sublicensees in the Coherus Territory for the Licensed Products since the prior such report provided by Coherus or, in the case of the first such report, since the Date of First Regulatory Approval. Such reports will be Confidential Information of Coherus and subject to the terms of Article 12 (Confidentiality). Coherus will provide updates to any such report at each meeting of the JDC.
- 7.4 **Diversion.** Each Party agrees that it will not, and will ensure that its Affiliates and Sublicensees and subcontractors will not, either directly or indirectly, promote, market, distribute, import, sell, or have sold any Licensed Products to any Third Party or to any address or Internet Protocol address or the like in the other Party’s territory, including via the Internet or mail order. Neither Party will engage, nor permit its Affiliates or Sublicensees to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or other buyers or users of the Licensed Products located in any country or jurisdiction in the other Party’s territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party’s territory. If a Party or its Affiliates or Sublicensees receive any order for any Licensed Products from a prospective purchaser located in a country or jurisdiction in the other Party’s territory, then such Party will immediately refer that order to such other Party and will not accept any such orders. Neither Party will, nor permit its Affiliates or Sublicensees to, deliver or tender (or cause to be delivered or tendered) any Licensed Products to Third Parties for use in the other Party’s territory except in accordance with a Joint Development Plan, to fulfill an obligation under this Agreement or the Supply Agreement to the other Party, or to perform a Junshi Clinical Trial in accordance with this Agreement, or except in connection with a Manufacturing Technology Transfer pursuant to Section 2.6(b) (Manufacturing Technology Transfer). Notwithstanding any provision to the contrary set forth in this Agreement, each Party will have the right to attend conferences and meetings of congresses in the other Party’s territory and to promote and market the Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 7.4 (Diversion). Each Party will have the right to engage key opinion leaders from outside its territory and to participate in education, advisory, and other activities relating to Licensed Products in the other Party’s territory.

## **ARTICLE 8 FINANCIALS**

- 8.1 **Upfront Payment.** No later than 20 days after the Effective Date, Coherus will pay a one-time, non-refundable payment in the amount of \$150,000,000 (the “**Upfront Payment**”).
- 8.2 **Option Exercise Payment.** No later than 10 days after Coherus’ delivery of the Option Exercise Notice for a given License Option for an Option Program, Coherus will pay to Junshi a one-time, non-refundable payment in the amount of \$35,000,000.
- 8.3 **Regulatory and Sales Milestone Payments.**
- (a) **For the PD1 Program.** Coherus will make the one-time milestone payments set forth in Table 8.3(a) upon the first achievement by Coherus or its Affiliates or Sublicensees of the corresponding milestone event by the first Licensed Product that contains a Licensed Antibody described in clause (a) of the definition of Licensed Antibody:



**Table 8.3(a) – Regulatory and Sales Milestones for the PD1 Program**

<b>No.</b>	<b>Milestone Event</b>	<b>Milestone Payment</b>
1	Receipt of the first Regulatory Approval from the FDA for a Licensed Product that contains a Licensed Antibody described in clause (a) of the definition of Licensed Antibody in either Urothelial Carcinoma or Esophagus Carcinoma	\$25,000,000
2	Receipt of the first Regulatory Approval from the FDA for a Licensed Product that contains a Licensed Antibody described in clause (a) of the definition of Licensed Antibody in Nasopharyngeal Cancer	\$25,000,000
3	Receipt of the first Regulatory Approval from the FDA for a Licensed Product that contains a Licensed Antibody described in clause (a) of the definition of Licensed Antibody in Non Small Cell Lung Cancer	\$40,000,000
4	Annual Net Sales for Licensed Products that contain a Licensed Antibody described in clause (a) of the definition of Licensed Antibody meet or exceed \$250,000,000	\$30,000,000
5	Annual Net Sales of Licensed Products that contain a Licensed Antibody described in clause (a) of the definition of Licensed Antibody meet or exceed \$500,000,000	\$50,000,000
6	Annual Net Sales of Licensed Products that contain a Licensed Antibody described in clause (a) of the definition of Licensed Antibody meet or exceed \$1,000,000,000	\$90,000,000
7	Annual Net Sales for Licensed Products that contain a Licensed Antibody described in clause (a) of the definition of Licensed Antibody meet or exceed \$1,500,000,000	\$120,000,000

- (b) **For each Option Program.** Separately, for each of (i) the Junshi IL-2 Molecules and (ii) the Junshi TIGIT Antibodies for which Coherus exercises the License Option, Coherus will make the one-time milestone payments set forth in Table 8.3(b) upon the first achievement by Coherus or its Affiliates or Sublicensees of the corresponding milestone event by the first Licensed Product that contains the subject Option Molecule:

**Table 8.3(b) – Regulatory and Sales Milestones for each Option Program**

<b>No.</b>	<b>Milestone Event</b>	<b>Milestone Payment</b>
1	Initiation of the first Pivotal Trial for a Licensed Product that contains an Option Molecule	\$20,000,000
2	Receipt of the first Regulatory Approval from the FDA for an Optioned Licensed Product that contains an Option Molecule, which Regulatory Approval is not for Non Small Cell Lung Cancer	\$25,000,000
3	Receipt of the first Regulatory Approval from the FDA for an Optioned Licensed Product that contains an Option Molecule in Non Small Cell Lung Cancer	\$40,000,000
4	Annual Net Sales of Optioned Licensed Products meet or exceed \$250,000,000	\$30,000,000
5	Annual Net Sales of Optioned Licensed Products meet or exceed \$500,000,000	\$50,000,000
6	Annual Net Sales of Optioned Licensed Products meet or exceed \$1,000,000,000	\$90,000,000

- (c) Each milestone payment under this Section 8.3 (Regulatory and Sales Milestone Payments) is payable only once for the PD-1 Program, once for the TIGIT Program, and once for the IL-2 Program, upon the first achievement by Coherus or its Affiliate or Sublicensee for a Licensed Product in the Coherus Territory that is the subject of each such program, notwithstanding whether a Licensed Product achieves the milestone event more than once for a given program or whether more than one Licensed Product that is the subject of a given program achieves a milestone event.

Coherus will provide Junshi with written notice of the achievement of the milestone event in this Section 8.3 (Regulatory and Sales Milestone Payments) no later than 15 Business Days after the achievement of the applicable milestone event by Coherus or any of its Affiliates or Sublicensees. Junshi will invoice Coherus following receipt of such written notice as soon as reasonably practicable and Coherus will pay the associated milestone payment no later than 45 days after the receipt of such invoice. Such payment will be made by wire transfer of immediately available funds into an account designated by Junshi.

#### 8.4 **Royalties.**

- (a) **Royalty Rates.** During the Royalty Term for a given Licensed Product in a country in the Coherus Territory, on a Licensed Product-by-Licensed Product and country-by-country basis, Coherus will pay Junshi royalties on Net Sales of a given Licensed Product in the Coherus Territory at a royalty rate of (i) 20% with respect to any Licensed Product that is the subject of the PD-1 Program and (ii) 18% with respect to any Licensed Product that is the subject of an Option Program (“**Royalties**”).
- (b) **Reports; Payment.** Coherus will deliver to Junshi a calculation of the Royalties due in a given Calendar Quarter no later than 30 days after the end of each Calendar Quarter, provided that the Royalty calculation for the third month of such Calendar Quarter will be a non-binding good faith estimate (each, a “**Royalty Report**”). All royalty payments will be payable no later than 45 days after the end of each Calendar Quarter. All payments under this Agreement will be payable, in full, in U.S. dollars, regardless of the country(ies) in which such sales are made. If any Licensed Product is sold in a currency other than United States dollars, the report should list the Net Sales for such Licensed Product in both the original currency and in United States dollars. For purposes of computing the Royalty, the original such currency will be converted into United States dollars at the median of the buying rate and the selling rate of exchange reported by the Wall Street Journal on the last day for the month in which such sales were recorded.
- (c) **Reductions.**
  - (i) **Royalty Reduction upon Expiration of Valid Claims.** If, on a Licensed Product- by-Licensed Product and country-by-country basis, any Royalties are payable pursuant to Section 8.4(a) (Royalty Rates) on Net Sales of a Licensed Product attributable to a country in the Coherus Territory in which there is no Valid Claim within the Licensed Patent Rights Covering the composition of matter,

formulation, or approved method of treatment or use of such Licensed Product that would be infringed by the manufacture, use, sale, offer for sale, or import of such Licensed Product in such country, then the applicable royalty rate applicable to those Net Sales of such Licensed Product for such country will be reduced by 25%.

- (ii) **Reduction for Loss of Regulatory Exclusivity.** If, on a Licensed Product-by- Licensed Product and country-by-country basis, any Royalties are payable pursuant to Section 8.4(a) (Royalty Rates) on Net Sales of a Licensed Product attributable to a country in the Coherus Territory in which there is both (A) no Valid Claim within the Licensed Patent Rights Covering the composition of matter, formulation, or approved method of treatment or use of such Licensed Product that would be infringed by the manufacture, use, sale, offer for sale, or import of such Licensed Product in such country, and (B) no Regulatory Exclusivity for such Licensed Product in such country, then the applicable royalty rate applicable to those Net Sales of such Licensed Product for such country will be reduced by 50%.
- (iii) **Reduction for Additional Third Party IP.** With respect to any Additional Third Party License pursuant to which Coherus is granted rights under any Additional Third Party IP that is necessary to Exploit a Licensed Product in a country or jurisdiction in the Coherus Territory, Coherus will be entitled to deduct from any Royalties payable hereunder with respect to that country or other jurisdiction 50% of royalties paid to such Third Party under such Additional Third Party License to the extent allocable or specific to the Licensed Products; *provided* that in no event will the Royalties due to Junshi under this Agreement in a Calendar Quarter be reduced by more than 30% of the Royalties that would otherwise be due in such Calendar Quarter for the Licensed Products as a result of the foregoing reductions. However, if Coherus is unable to fully offset against Royalties paid to any Third Party pursuant to an Additional Third Party License in consideration for rights with respect to Additional Third Party IP as permitted under this Section 8.4(c)(iii) (Reduction for Additional Third Party IP) on account of the foregoing 30% floor, then any such permitted deductions may be carried forward to reduce subsequent Calendar Quarter in which Royalties are due (subject to the same floor in such future periods).

#### 8.5 Existing License Agreements.

- (a) **JS001 Upstream License.** Junshi will be solely responsible for all upfront payments, milestone payments, royalties, or other payments due to the licensor(s) under the JS001 Upstream License (collectively, “**JS001 Upstream License Costs**”), *provided* that, to the extent that Coherus does not use Lonza as the Coherus CMO to Manufacture Licensed Antibodies and Licensed Products for Coherus, Coherus will be responsible for all amounts owed by Junshi to Lonza for such Licensed Antibodies and Licensed Products. Coherus will pay to Junshi any amounts due thereunder for a Calendar Quarter within 45 days after the end of the Calendar Quarter in which such payments accrue. Without limiting the foregoing, if (i) Junshi fails to pay any JS001 Upstream License Costs or otherwise fails to maintain the JS001 Upstream License as required by Section 10.3(e) (Control of Upstream Licenses), (ii) Coherus has paid to Junshi all amounts due from Coherus for JS001 Upstream License Costs as a result of Coherus’ selection of the Coherus CMO other than Lonza, and (iii) Coherus pays such JS001 Upstream License Costs on Junshi’s behalf or otherwise incurs any costs in connection with maintaining the JS001 Upstream License, including costs associated with securing and maintaining a replacement agreement if Junshi allows the JS001 Upstream License to terminate or expire in violation of Section 10.3(e)

(Control of Upstream Licenses), then Coherus will be entitled to offset any such costs from any payments due to Junshi hereunder.

- (b) **JS018-1 Upstream License.** Junshi will be solely responsible for all upfront payments, milestone payments, royalties, or other payments due to the licensor(s) under the JS018-1 Upstream License (collectively, “**JS018-1 Upstream License Costs**”). Without limiting the foregoing, if (i) Junshi fails to pay any JS018-1 Upstream License Costs or otherwise fails to maintain the JS018-1 Upstream License as required by Section 10.3(e) (Control of Licensed Technology), and (ii) Coherus pays such JS018-1 Upstream License Costs on Junshi’s behalf or otherwise incurs any costs in connection with maintaining the JS018-1 Upstream License, including costs associated with securing and maintaining a replacement agreement if Junshi allows the JS018-1 Upstream License to terminate or expire in violation of Section 10.3(e) (Control of Licensed Technology), then Coherus will be entitled to offset any such costs from any payments due to Junshi hereunder.

#### 8.6 **Books and Records; Audit Rights.**

- (a) Junshi will have the right to engage, at its own cost and expense, subject to this Section 8.6 (Books and Records; Audit Rights), an independent nationally recognized public accounting firm in the United States chosen by Junshi and reasonably acceptable to Coherus (which accounting firm will not be the external auditor of Junshi, will not have been hired or paid on a contingency basis, and will have experience auditing pharmaceutical companies) (a “**CPA Firm**”) to conduct an audit of Coherus for the purposes of confirming Coherus’ compliance with the payment provisions of this Agreement.
- (b) The CPA Firm will be given access to and will be permitted to examine such books and records of Coherus as it will reasonably request, upon 30 days’ prior written notice having been given by Junshi, during regular business hours, for the sole purpose of determining compliance with the payment provisions of this Agreement. Prior to any such examination taking place, the CPA Firm will enter into a confidentiality agreement reasonably acceptable to Coherus with respect to the Know-How to which they are given access and will not contain in its report or otherwise disclose to Junshi or any Third Party any information labeled by Coherus as being confidential customer information regarding pricing or other competitively sensitive proprietary information.
- (c) Junshi and Coherus will be entitled to receive a full written report of the CPA Firm with respect to its findings and Junshi will provide, without condition or qualification, Coherus with a copy of the report, or other summary of findings, prepared by such CPA Firm promptly following Junshi’s receipt of same. In the event of any dispute between Junshi and Coherus regarding the findings of any such inspection or audit, the Parties will initially attempt in good faith to resolve the dispute amicably between themselves, and if the Parties are unable to resolve such dispute within 30 days after delivery to both Parties of the CPA Firm’s report, each Party will select an internationally recognized independent certified public accounting firm (other than the CPA Firm), and the two firms chosen by the Parties will choose a third internationally recognized independent certified public accounting firm which will resolve the dispute, and such accounting firm’s determination will be binding on both Parties, absent manifest error by such accounting firm.
- (d) Within 45 days after completion of the CPA Firm’s audit, Coherus will pay to Junshi any deficiency in the payment amount determined by the CPA Firm *plus* interest pursuant to Section 8.8 (Late Payments). If the report of the CPA Firm shows that Coherus underpaid Junshi by more than 7.5% of the amount due for any Calendar Quarter and such amount

was more than \$50,000, then Coherus must pay for the amount charged by the CPA Firm to conduct such audit together with the amount of such deficiency and interest. If the report of the CPA Firm shows that Coherus overpaid, then Coherus will be entitled to off-set such overpayment against any Royalty then owed to Junshi. If no royalty is then owed to Junshi, then Junshi will remit such overpayment to Coherus.

- (e) Junshi's exercise of its audit rights under this Section 8.6 (Books and Records; Audit Rights) may not (i) be conducted for any Calendar Quarter more than three years after the end of such Calendar Quarter to which such books and records pertain, (ii) be conducted more than once in any 12 month period (unless a previous audit during such 12 month period revealed a material underpayment with respect to such period), or (iii) be repeated for any Calendar Quarter previously audited.
- (f) Coherus will ensure that it has the right to engage a CPA Firm to conduct an audit of Sublicensees for the purposes of confirming Coherus' ability to pay amounts due to Coherus under this Agreement based upon activities of the Sublicensees and Sublicensee's compliance with the terms of this Agreement. Coherus will provide, without condition or qualification, to Junshi with a copy of the report, or other summary of findings (redacted for any materials unrelated to the confirming Coherus' compliance with the payment provisions of this Agreement), prepared by any such CPA Firm in connection with an audit of a Sublicensee promptly following Coherus' receipt of same.

#### 8.7 Taxes.

- (a) **Taxes on Income.** Except as set forth in this Section 8.7 (Taxes), each Party will be solely responsible for and bear all taxes imposed on it under applicable laws in connection with the implementation of this Agreement.
- (b) **Tax Withholding.** If applicable laws require a paying Party ("**Payor**") to withhold any tax from any payment due to the other Party ("**Payee**") under this Agreement (taking into account any legally available reduction or elimination of such tax pursuant to an applicable tax treaty or otherwise), then the Payor will subtract the amount thereof from the payments to the Payee, and pay such amount to the proper taxing authority. The Payor will promptly (as available) submit to the Payee appropriate proof of payment of the withheld taxes as well as the official receipts within a reasonable period of time. The Payor will provide the Payee reasonable assistance in order to allow the Payee to obtain the benefit of any present or future treaty against double taxation or refund or reduction in taxes that may apply to the payments under this Agreement. Without limiting the generality of the foregoing, if the Payee is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding taxes, it may deliver to the Payor or the appropriate governmental authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Payor of its obligation to withhold taxes. In such case, the Payor will apply the reduced rate of withholding, or not withhold, as the case may be, *provided* that the Payor is in receipt of evidence, in a form reasonably satisfactory to the Payor (*e.g.*, the Payee's delivery of all applicable documentation) prior to the time that the applicable payments are due.
- (c) **VAT in Coherus Territory.** Notwithstanding Section 8.7(a) (Taxes on Income) and Section 8.7(b) (Tax Withholding), and subject to the following sentence, all sums payable from Coherus to Junshi under this Agreement will be exclusive of sales, use, turnover, value added taxes or similar taxes, including any applicable surcharges on value added

taxes or similar taxes (“VAT”). As between the Parties, Junshi will pay for and bear any VAT applicable to any payment by Coherus to Junshi under this Agreement imposed by any Chinese (central, provincial, or municipal) tax authority. Coherus will pay for and bear any VAT applicable to any payment by Coherus to Junshi under this Agreement imposed by any non-Chinese tax authority.

- (d) **Tax Cooperation.** Each Party will provide the other with reasonable assistance to enable the recovery of or exemption from, as permitted by applicable law, withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery or exemption to be for the benefit of the Party bearing such withholding tax or VAT.

8.8 **Late Payments.** Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: (a) two percentage points above the prime rate as published by *The Wall Street Journal* or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue; or (b) the maximum rate permitted by applicable law; in each case, calculated on the number of days such payment is delinquent, compounded monthly.

8.9 **No Other Compensation.** Other than as explicitly set forth (and as applicable) in this Agreement, neither Coherus nor any of its Affiliates will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to or on behalf of Junshi or any of its Affiliates under this Agreement.

8.10 **Other Amounts Payable.** With respect to any amounts owed under this Agreement by a Party to the other Party for which no other invoicing and payment procedure is specified in this Agreement, the payee Party will provide an invoice, together with reasonable supporting documentation, to the paying Party for such amounts owed. The paying Party will pay any undisputed amounts no later than 60 days after receipt of the invoice, and will pay any disputed amounts owed by the paying Party no later than 60 days after resolution of the dispute.

## ARTICLE 9 INTELLECTUAL PROPERTY

### 9.1 **Ownership.**

- (a) **Background Technology.** As between the Parties, and except with respect to any Arising Technology, which is addressed in Section 9.1(b) (Arising Technology), (i) Junshi will retain all rights, title, and interest in and to any Patent Rights, Know-How, and other intellectual property rights owned or Controlled by Junshi or any of its Affiliates as of the Effective Date or generated or obtained by or on behalf of Junshi or any of its Affiliates during the Term outside of the scope of performance of activities under this Agreement, and (ii) Coherus will retain all rights, title, and interest in and to any Patent Rights, Know-How, and other intellectual property rights owned or Controlled by Coherus or any of its Affiliates as of the Effective Date or generated or obtained by or on behalf of Coherus or any of its Affiliates during the Term outside of the scope of performance of activities under this Agreement.

- (b) **Arising Technology.**

- (i) As between the Parties, ownership will follow inventorship for (A) any and all Know-How developed, created, conceived, or reduced to practice during the Term solely by or on behalf of a Party or any of its Affiliates in a Party’s performance

of activities under this Agreement or Sublicensee's performance of activities under a sublicense ("**Arising Know-How**") and (B) any Patent Right claiming any such Know-How described in clause (A) (the "**Arising Patent Rights**" and the Arising Know-How and Arising Patent Rights, the "**Arising Technology**"), with inventorship being determined in accordance with United States patent laws (regardless of where the applicable activities occurred). Arising Know-How invented solely by or on behalf of Junshi or any of its Affiliates, and all Arising Patent Rights claiming any such Arising Know-How (the "**Junshi Arising Patent Rights**") will be solely owned by Junshi or any of its Affiliates ("**Junshi Arising Technology**"). As between the Parties, Arising Technology invented solely by or on behalf of Coherus or any of its Affiliates or Sublicensees, and all Arising Patent Rights claiming any such Arising Know-How (the "**Coherus Arising Patent Rights**") will be solely owned by Coherus or any of its Affiliates ("**Coherus Arising Technology**"). As between the Parties, Arising Technology invented jointly by Junshi or any of its Affiliates and Coherus or any of its Affiliates or Sublicensees, and all Arising Patent Rights claiming any such Arising Know-How (the "**Joint Arising Patent Rights**") will be jointly owned by both Parties ("**Joint Arising Technology**").

- (ii) Junshi will promptly disclose to Coherus any Junshi Arising Technology or Joint Arising Technology, as applicable, developed, created, conceived, or reduced to practice by or on behalf of Junshi or any of its Affiliates during the Term. Coherus will promptly disclose to Junshi any Coherus Arising Technology or Joint Arising Technology, as applicable, developed, created, conceived, or reduced to practice by or on behalf of Coherus or any of its Affiliates during the Term.
  - (iii) Each Party will have an undivided one-half (1/2) interest in and to the Joint Arising Technology. Each Party will exercise its ownership rights in and to such Joint Arising Technology, including the right to license and sublicense or otherwise to exploit, transfer, or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to the licenses hereunder and the other relevant terms and conditions of this Agreement. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Arising Technology. Each Party, for itself and on behalf of any of its Affiliates, licensees, and Sublicensees, and employees, subcontractors, consultants, and agents of any of the foregoing, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to the other Party a joint and undivided interest in and to all Joint Arising Technology.
- (c) Notwithstanding any provision to the contrary set forth in this Agreement, neither Party may invoke this Agreement as a "joint research agreement" pursuant to the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) without the prior written consent of the other Party.

## 9.2 Prosecution and Maintenance.

- (a) **Coherus Arising Patent Rights.** Coherus will have the sole right and discretion to file, prosecute, and maintain all Coherus Arising Patent Rights at its sole cost and expense.
- (b) **Junshi Arising Patent Rights.** Subject to Section 9.2(d) (Licensed Patent Rights), Junshi will have the sole right and discretion to file, prosecute, and maintain all Junshi Arising Patent Rights that are not Licensed Patent Rights at its sole cost and expense.



- (c) **Joint Arising Patent Rights.** Subject to Section 9.3(c) (Patent Proceedings for Joint Arising Patent Rights), Coherus will have the first right, responsibility, and discretion to file, prosecute, and maintain all Joint Arising Patent Rights in the Coherus Territory at its sole cost and expense. Junshi will have the first right, responsibility, and discretion to file, prosecute, and maintain all Joint Arising Patent Rights in the Junshi Territory at its sole cost and expense. The Parties will use good faith efforts to agree on a mutually acceptable strategy and will coordinate with each other for the prosecution and maintenance of all Joint Arising Patent Rights. If the prosecuting Party decides it is no longer interested in the prosecution or maintenance of a particular Patent Right pertaining to the Joint Arising Technology in its territory, then it will promptly provide written notice to the other Party of such decision. The other Party may, upon written notice to the prosecuting Party, assume the prosecution and maintenance of such Patent Right in the applicable territory.
- (d) **Licensed Patent Rights.**
- (i) **Junshi Right to Control Prosecution and Maintenance.** Subject to Section 9.3(d) (Patent Proceedings for Licensed Patent Rights), from and after the Effective Date, Junshi will have the first right, responsibility, and discretion to file, prosecute, and maintain all Licensed Patent Rights (other than Joint Arising Patent Rights), including all Junshi Arising Patent Rights in (and outside) the Coherus Territory, at Junshi's cost and expense, as well as, subject to Section 9.7(a) (Patent Right Term Extension), filing for any patent term extensions or similar protections in (and outside) the Coherus Territory.
- (ii) **Abandonment.** Junshi will not abandon any issued Licensed Patent Rights in the Coherus Territory without first offering to Coherus the right to perform the activities described in clause (i) above at the discretion and sole cost and expense of Coherus. In the event Coherus assumes control of the prosecution and maintenance in the Coherus Territory of any Licensed Patent Right, then Junshi will (A) provide Coherus with copies of any relevant communications, filings, drafts, and documents, as well as written notice of any pending deadlines or communications applicable thereto, and (B) execute and deliver any legal papers reasonably requested by Coherus to effectuate transfer of control of the filing, prosecution, and maintenance of such Licensed Patent Rights (including papers that transfer any right, title or interest in or to the Licensed Patent Rights to Coherus).
- (iii) **Cooperation.** Each Party will reasonably cooperate with the other Party in the filing, prosecution, and maintenance of the Licensed Patent Rights in the Coherus Territory, including with respect to any appeal of any *ex parte* patent prosecution decision to a court or board of a patent office. Such cooperation includes each Party providing to the other Party copies of substantive correspondence received from any patent office in the Coherus Territory, each Party providing to the other Party with drafts of proposed substantive filings with any such patent office reasonably in advance of the date due, each Party providing prompt feedback to any such proposed filings, and each Party giving reasonable and good faith consideration to any requests of the other Party with respect to such filings provided in a timely manner, *provided* that Junshi will incorporate any reasonable feedback provided to it by Coherus with respect to such filings.

### 9.3 Patent Proceedings.

- (a) **Patent Proceedings for Coherus Arising Patent Rights.** Coherus will have the first right and discretion to institute, defend, and conduct all Patent Proceedings for the Coherus

Arising Patent Rights at its sole cost and expense. If Coherus decides it is no longer interested in controlling a Patent Proceeding pertaining to the Coherus Arising Patent Rights, then it will promptly provide written notice to Junshi of such decision. Junshi may, upon written notice to Coherus, assume control of such Patent Proceeding.

- (b) **Patent Proceedings for Junshi Arising Patent Rights.** Junshi will have the sole right and discretion to control, at its sole cost and expense, the institution, defense, and conduct of all Patent Proceedings for the Junshi Arising Patent Rights that are not Licensed Patent Rights.
- (c) **Patent Proceedings for Joint Arising Patent Rights.** Coherus will have the first right and discretion to control, at its sole cost and expense, the institution, defense, and conduct of all Patent Proceedings for all Joint Arising Patent Rights in the Coherus Territory at its sole cost and expense. Junshi will have the first right and discretion to control, at its sole cost and expense, the institution, defense, and conduct of all Patent Proceedings for all Joint Arising Patent Rights in the Junshi Territory at its sole cost and expense. The Parties will use good faith efforts to agree on a mutually acceptable strategy and will coordinate with each other for the conduct of Patent Proceedings for all Joint Arising Patent Rights. If the controlling Party decides it is no longer interested in controlling a Patent Proceeding pertaining to the Joint Arising Technology in its territory, then it will promptly provide written notice to the other Party of such decision. The other Party may, upon written notice to the controlling Party, assume control of such Patent Proceeding in the applicable territory. Neither Party will voluntarily abandon or admit that any claim of any Joint Arising Patent Right involved in a Patent Proceeding is unpatentable, invalid, or unenforceable without the advance, written consent of the other Party (not to be unreasonably withheld).
- (d) **Patent Proceedings for Licensed Patent Rights.** From and after the Effective Date, Coherus will have the first right and discretion to control, at its sole cost and expense, the institution, defense, and conduct of all Patent Proceedings for the Licensed Patent Rights within the Coherus Territory. If Coherus decides it is no longer interested in controlling a Patent Proceeding pertaining to Licensed Patent Rights, then it will promptly provide written notice to Junshi of such decision. Junshi may, upon written notice to Coherus, assume control of such Patent Proceeding. Junshi will have the sole right, responsibility and discretion to control, at its sole cost and expense, the institution, defense, and conduct of all Patent Proceedings for the Licensed Patent Rights within the Junshi Territory. Coherus will not voluntarily abandon or admit that any claim of any Licensed Patent Rights involved in a Patent Proceeding is unpatentable, invalid or unenforceable without the advance, written consent of Junshi (not to be unreasonably withheld).
- (e) **Cooperation.** Each Party will reasonably cooperate with the other Party in the institution, defense, and conduct of any Patent Proceeding within the Coherus Territory. Such cooperation includes each Party providing to the other Party copies of substantive correspondence related to such Patent Proceeding, each Party providing to the other Party with drafts of proposed substantive filings for such Patent Proceeding reasonably in advance of the date due, each Party providing prompt feedback to any such proposed filings, and each Party giving reasonable and good faith consideration to any requests of the other Party with respect to such filings provided in a timely manner.

- 9.4 **Defense and Settlement of Third Party Claims.** From and after the Effective Date, if a Third Party asserts that a Patent Right or other right owned by it is infringed by the Exploitation of any Licensed Antibody or Licensed Product in the Field in the Coherus Territory, then Coherus will have the sole right to defend against any such assertions at Coherus' sole cost or elect to settle such

claims (except as set forth below). Junshi or any of its Affiliates will assist Coherus and cooperate in any such litigation at Junshi's request. Junshi may join any defense pursuant to this Section 9.4 (Defense and Settlement of Third Party Claims), with its own counsel, at its sole cost and expense. Coherus or any of its Affiliates may settle or consent to the entry of any judgment in any enforcement action hereunder without Junshi's prior consent; *provided, however*, that any such settlement or consent judgment will not, without the prior written consent of Junshi (such consent not to be unreasonably withheld, conditioned or delayed), impose any liability or obligation on Junshi or any of its Affiliates. Each Party will give the other Party prompt written notice of any allegation by any Third Party that a Patent Right or other right owned by it is infringed by the Exploitation of any Licensed Antibody or Licensed Product in the Coherus Territory.

## 9.5 Enforcement.

- (a) **Enforcement and Cooperation.** If in the Coherus Territory, (i) Junshi or Coherus becomes aware of any actual or suspected infringement of any Licensed Patent Right or Joint Arising Patent Right, or (ii) any such Licensed Patent Right or Joint Arising Patent Right is challenged in any action or proceeding (other than any Patent Proceeding, which is addressed in Section 9.3 (Patent Proceedings)), then such Party will notify the other Party promptly, and following such notification, the Parties will confer. Coherus will have the first right, but will not be obligated, to defend any such action or proceeding in the Coherus Territory or bring an infringement action with respect to such infringement in the Coherus Territory at its own expense, in its own name, and entirely under its own direction and control, or settle any such action or proceeding by sublicense (including, at Coherus' sole discretion, granting a sublicense, covenant not to sue or other right with respect to an Antibody or product in the Field in the Coherus Territory in accordance with Section 2.2 (Sublicensing)). If Coherus fails to defend such action, abate such infringement, or file an action to abate such infringement in the Coherus Territory within 180 days after a written request from the Junshi to do so, or if Coherus discontinues the prosecution of any such action after filing without abating such infringement, then Junshi will have the second right, but will not be obligated, to defend any such action or proceeding in the Coherus Territory or bring an infringement action with respect to such infringement in the Coherus Territory at its own expense, in its own name and under its own direction and control. Regardless of which Party exercises its right under this Section 9.5(a) (Enforcement and Cooperation), the other Party and its Affiliates will reasonably assist such enforcing Party in any action or proceeding being defended or prosecuted if so requested, and will agree to be named in or join such action or proceeding if requested by such enforcing Party and necessary for standing under the applicable rules of procedure. If the other Party elects to be represented by legal counsel, then the enforcing Party will bear all of such Party's related and reasonable legal costs and expenses if the other Party is required to be named in or joined in such action or proceeding or is joined in such action or proceeding at the enforcing Party's request.
- (b) **Damages.** In the event that either Party exercises the rights conferred in this Section 9.5 (Enforcement) and recovers any damages, payments, or other sums in such action or proceeding or in settlement thereof, then such damages or other sums recovered will first be applied to all out-of-pocket costs and expenses incurred by such enforcing Party in connection therewith (including attorney's fees). If such recovery is insufficient to cover all such costs and expenses of both Parties, then the enforcing Party's costs will be paid in full first before any of the other Party's costs. If after such reimbursement any funds will remain from such damages or other sums recovered and Coherus is the enforcing Party, then Junshi will be entitled to 40% of such funds and Coherus may retain the remainder. If after such reimbursement any funds will remain from such damages or other sums

recovered and Junshi is the enforcing Party, then Junshi will be entitled to retain 50% of such funds and Coherus may retain the remainder

- 9.6 **Trademarks.** The Parties may develop and adopt certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of the Licensed Products on a global basis (such branding elements, collectively, the “**Global Brand Elements**”). Each Party will have the right to brand the Licensed Products in its respective territory using trademarks, logos, and trade names that it determines appropriate, which may vary by region or within a region, and that are consistent with the Global Brand Elements (the “**Product Marks**”). Each Party will solely own all rights, title, and interest in and to any Product Marks adopted for use with the Licensed Products in its respective territory, and will be responsible for the registration, filing, maintenance, and enforcement thereof at its own cost and expense.
- 9.7 **Patent Right Extensions; Regulatory Exclusivity.**
- (a) **Patent Right Term Extension.** If elections with respect to obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Coherus Territory with respect to any Licensed Product becomes available, upon Regulatory Approval or otherwise, then, following discussions with Coherus and consideration in good faith of Coherus’ comments thereon, Junshi will have the sole right to file for patent term extension or supplemental protection certificates or their equivalents and to determine which issued patent to extend. Coherus and its Affiliates and Sublicensees will reasonably cooperate with Junshi so as to enable Junshi to exercise its rights under this Section 9.7(a) (Patent Right Term Extension). Such cooperation includes promptly executing all documents, requiring inventors to be available to discuss and review any filings, and requiring inventors, subcontractors, employees, consultants, and agents of Coherus or any of its Affiliates or Sublicensees to execute all documents, as reasonable and appropriate so as to enable Junshi to exercise its rights under this Section 9.7(a) (Patent Right Term Extension).
- (b) **Regulatory Exclusivity.** With respect to regulatory exclusivity periods (such as orphan drug exclusivity and any available pediatric extensions), Coherus will have the sole right to seek and maintain all such regulatory exclusivity periods that may be available for the Licensed Products in the Field in the Coherus Territory.

## ARTICLE 10 REPRESENTATIONS, WARRANTIES, AND COVENANTS

- 10.1 **Mutual Representations, Warranties, and Covenants.** Each Party hereby represents and warrants to the other Party as of the Execution Date and the Effective Date, and covenants, as applicable, as a material inducement for such other Party’s entry into this Agreement, as follows:
- (a) **Corporate Existence and Power.** It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.
- (b) **Authority and Binding Agreement.** (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes

a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

- (c) **No Conflict.** It is not a party to and will not enter into any agreement that would prevent it from granting the rights or exclusivity granted or intended to be granted to the other Party under this Agreement or performing its obligations under this Agreement.
- (d) **Consents.** All consents, approvals, and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained, other than, with respect to Junshi, from Lonza Sales AG pursuant to the JS001 Upstream License to grant the licenses to Coherus under Section 2.1 (Licenses to Coherus).
- (e) **Bankruptcy; Insolvency.** It and its Affiliates are not subject to any action or petition, pending or otherwise, for bankruptcy or insolvency in any state, country, or other jurisdiction, and it is not aware of any facts or circumstances that could result in such Party or any of its Affiliates becoming or being declared insolvent, bankrupt, or otherwise incapable of meeting its obligations under this Agreement as they become due in the ordinary course of business.
- (f) **No Debarment.** Neither it nor any of its employees nor to its knowledge, any of the agents performing hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity, or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this Agreement, the following definitions will apply:
  - (i) A “**Debarred Individual**” is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.
  - (ii) A “**Debarred Entity**” is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or Affiliate of a Debarred Entity.
  - (iii) An “**Excluded Individual**” or “**Excluded Entity**” is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).
  - (iv) A “**Convicted Individual**” or “**Convicted Entity**” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

10.2 **Representations and Warranties by Junshi.** Junshi further represents and warrants to Coherus (a) with respect to the content below applicable to the PD-1 Program or the Licensed Antibodies, Licensed Products, Licensed Patent Rights, and Licensed Technology (as each such term is defined on the Execution Date), as of the Execution Date and, if not specified as applicable “as of the Execution Date”, then again on the Effective Date), and (b) with respect to the content below

applicable to an Option Program or its corresponding Option Molecule, Option Product, or Option Patent Rights, on an Option Program-by-Option Program basis, as of the Execution Date and, if not specified as applicable “as of the Execution Date”, then again on the date of delivery to Coherus of the Option Data Package for such Option Program in accordance with Section 2.8(b) (Option Data Package) (the “**Option Data Package Delivery Date**”), except as set forth in the disclosure letter delivered to Coherus on the Option Data Package Delivery Date (the “**Option Disclosure Letter**”), as follows:

- (a) **No Conflicts.** Neither Junshi nor any of its Affiliates has entered into any agreement (other than agreements with subcontractors) granting any right, interest or claim in or to, any Licensed Technology to any Third Party that would conflict with the licenses and other rights granted to Coherus under this Agreement. The Licensed Technology constitutes all intellectual property rights Controlled by Junshi and any of its Affiliates that are necessary or reasonably useful for the Exploitation of the Licensed Antibodies or Licensed Products in the Field in the Coherus Territory. All Licensed Patent Rights are solely owned by Junshi or any of its Affiliates free and clear of any liens, charges, security interests, encumbrances, licenses claims or covenants that would conflict with or limit the scope of any of the rights or licenses granted to Coherus hereunder or would give rise to any Third Party claims for payment against Coherus or any of its Affiliates. The Licensed Patent Rights that have issued are subsisting, and, to the knowledge of Junshi, enforceable and valid.
- (b) **No Notice of Infringement, Misappropriation or Invalidity.** As of the Execution Date and the Option Package Delivery Date, as applicable: (i) neither Junshi nor any of its Affiliates have received or is aware of any written notice from any Third Party asserting or alleging that any Exploitation of any Licensed Technology, any Licensed Antibody, any Licensed Products, any Know-How or Patent Rights Controlled by Junshi or its Affiliates related to (with respect to such Know-How) or Covering (with respect to such Patent Rights) an Option Molecule, or Option Molecule, in each case, has infringed or misappropriated, or would infringe or misappropriate, the intellectual property rights of any Third Party, and (ii) no claim is pending, and Junshi and any of its Affiliates and, to Junshi’s knowledge, any Third Party collaborator, has not received from a Third Party notice of a claim or threatened claim to the effect that any granted Patent Right rights within the Licensed Technology licensed to Coherus under this Agreement or any Patent Rights Controlled by Junshi or its Affiliates that Cover an Option Molecule, in each case, is invalid or unenforceable. Additionally, as of the Execution Date, to Junshi’s knowledge, there is no unauthorized use, infringement or misappropriation by any Third Party of any Licensed Technology or any Know-How or Patent Rights Controlled by Junshi or its Affiliates related to (with respect to such Know-How) or Covering (with respect to such Patent Rights) an Option Molecule. Junshi has provided to Coherus a translated complete copy of all freedom to operate analyses and reports it has conducted as of the Execution Date with respect to the Licensed Technology, Licensed Antibody, Option Molecule, and Option Product. Except as Junshi has disclosed to Coherus pursuant to a letter from Junshi to Coherus dated 30 January 2021, as of the Execution Date, to Junshi’s knowledge, the Exploitation of the Licensed Products does not infringe, misappropriate, or otherwise violate the intellectual property rights of any Third Party.
- (c) **No Misappropriation.** No employee, consultant, agent or independent contractor of Junshi, any of its Affiliates, or Third Party, has, to Junshi’s knowledge as of the Execution Date, (i) misappropriated any Licensed Know-How or (ii) misappropriated any Know-How related to any Option Molecule.

- (d) **Licensed Technology.** All Patent Rights Controlled by Junshi or its Affiliates, and that are necessary or reasonably useful for the Exploitation of the Licensed Antibodies or Licensed Products in the Field are listed on Schedule 10.2(d) (Existing Patent Rights) as of the Execution Date. As of the Execution Date, the Effective Date, and the Option Package Delivery Date, all Patent Rights listed on Schedule 10.2(d) (Existing Patent Rights) (as such schedule is updated on the Effective Date and the Option Data Package Delivery Date) have been and are being prosecuted in the respective patent offices in the Coherus Territory in accordance with applicable law, have been and are being filed and appropriately maintained, and all applicable fees have been paid on or before the due date for payment, and, to Junshi's knowledge, are not invalid or unenforceable, in whole or in part. Junshi does not own or hold rights to any Patent Rights that would otherwise fall within the definition of Licensed Patent Rights but for the fact that it does not Control such Patent Rights.
- (e) **Option Programs.** the Development, Commercialization, or other Exploitation of the Option Molecules and Option Products as contemplated herein will not conflict with any other license or agreement to which Junshi or any of its Affiliates is a party. In addition, Junshi Controls Know-How related to, and the Option Patent Rights that cover: (A) the recombinant cytokine that is known as of the Execution Date as JS018-1, which has the sequence set forth on Schedule 1.91 (Junshi IL-2 Molecule (JS018-1) Sequence); and (B) the monoclonal Antibody that is known as of the Execution Date as JS006, which has the sequence set forth on Schedule 1.94 (Junshi TIGIT Antibody (JS006) Sequence).
- (f) **Option Technology.** (i) Section 10.2(f) (Option Patent Rights) sets forth a complete and accurate list of all Patent Rights that are Controlled by Junshi or any of its Affiliates and that are necessary or reasonably useful to Develop, Manufacture, Commercialize, or otherwise Exploit any Option Molecule or Option Product in the Field in the Coherus Territory (the "**Option Patent Rights**"), (ii) Junshi does not own or hold rights to any Patent Rights that would otherwise fall within the foregoing clause (i) but for the fact that it does not Control such Patent Rights; and (iii) except as otherwise noted on Section 10.2(f) (Option Patent Rights), Junshi solely owns all rights, title, and interests in and to all Option Patent Rights.
- (g) **Third Party Agreements.** Neither Junshi nor any of its Affiliates have entered into any agreement with any Third Party pursuant to which Junshi Controls or grants any intellectual property rights with respect to the Licensed Technology, Option Patent Rights, or any Licensed Antibody or Option Molecule for the Field in the Coherus Territory other than those agreements that are set forth in Schedule 10.2(g) (Third Party Agreements) (the "**Third Party Agreements**"). Each Third Party Agreement is valid and binding.
- (h) **Licensed Antibody; Option Molecules.** Junshi has disclosed to Coherus all Antibodies that Junshi or any of its Affiliates owns or in-licenses that are the subject of the PD-1 Program (as of the Execution Date) or each Option Program, as applicable.
- (i) **Junshi Assignment.** Junshi or any of its Affiliates have secured from all employees, consultants, and contractors of Junshi or any of its Affiliates who have contributed to the Development, creation, conception or invention of any of the Licensed Patent Rights or Option Patent Rights a written agreement assigning to Junshi or any of its Affiliates all rights to such Developments, creations, conceptions or inventions, or Licensed Patent Rights or Option Patent Rights, and neither Junshi nor any of its Affiliates has received any written communication challenging Junshi's ownership or right to the Licensed Patent Rights or Option Patent Rights.



- (j) **All Material Information Furnished.**
- (i) As of the Execution Date, Junshi has furnished or made available to Coherus or its agents or representatives (A) all information requested by Coherus on or before January 27, 2021, (B) all material safety and efficacy data, and (C) all material regulatory filings and other material correspondence with Regulatory Authorities within or For the Coherus Territory, in each case ((A) through (C)) concerning the Licensed Antibodies, the Licensed Products, and the Licensed Technology, and as of each such date all such information and data, regulatory filings and other correspondence with Regulatory Authorities is accurate, complete, and true in all material respects.
  - (ii) As of the Option Data Package Delivery Date, Junshi has furnished or made available to Coherus or its agents or representatives (A) all information requested by Coherus, (B) all material safety and efficacy data, and (C) all material regulatory filings and other material correspondence with Regulatory Authorities within or For the Coherus Territory, in each case ((A) through (C)), concerning the Option Molecules and the Option Products, and as of each such date all such information and data, regulatory filings and other correspondence with Regulatory Authorities is accurate, complete, and true in all material respects.
- (k) **Conduct of Research and Development.** Junshi and its Affiliates have conducted all Development of Licensed Antibody and Licensed Products for the Coherus Territory in accordance with all applicable law.
- (l) **Upstream Licenses.** Junshi is in compliance with all material terms of the JS001 Upstream License and the JS018-1 Upstream License. The provisions listed in Section 2.4 (No Implied Licenses) are the only terms of the JS001 Upstream License and the JS018-1 Upstream License necessary for Junshi's grant of the sublicenses thereunder to Coherus upon the terms and conditions of this Agreement.
- (m) **Regulatory Materials.** Junshi maintains Control over all Regulatory Approvals and Regulatory Materials pertaining to the Licensed Products and Option Products in the Field in the Coherus Territory.

### 10.3 Junshi Covenants.

- (a) **Closing Disclosure Letter.** As of the Effective Date, Junshi will provide to Coherus a disclosure letter containing any additional information that is responsive to any of the representations and warranties set forth in Section 10.2 (Representations and Warranties) as if each such representation was made as of the Effective Date (the "**Closing Disclosure Letter**") an updated schedule reflecting the Patent Rights described in the first sentence of Section 10.2(d); *provided* that any representation that is to be made as of the Effective Date must be true and correct notwithstanding any such additional disclosures made in the Closing Disclosure Letter. To the extent not provided before the Execution Date, then Junshi will provide to Coherus the information requested by Coherus from Junshi on January 28, 2021 on or before the Effective Date.
- (b) **No Conflicting Grants.** Junshi will not, and will cause its Affiliates not to, enter into any agreement with any Affiliate or Third Party that conflicts with or contradicts the terms and conditions set forth in this Agreement, including any agreement that would limit the grant of licenses or rights hereunder to the Licensed Technology.

- (c) **Compliance with Applicable Law.** Junshi will comply with the applicable law (including applicable anti-corruption laws), including as applicable GLP, GCP, and cGMP and any applicable anti-corruption or anti-bribery laws or regulations of any governmental authority with jurisdiction over the activities performed by or on behalf of Junshi or its Affiliates in furtherance of such obligations, in each case, in the course of performing its obligations or exercising its rights pursuant to this Agreement. Neither Junshi nor its Affiliates will engage any agent to perform activities under this Agreement that has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual, or a Convicted Entity or Convicted Individual.
- (d) **Control of Licensed Technology.** During the period between the Execution Date and the Effective Date, Junshi and its Affiliates will (i) maintain (A) exclusive ownership and Control of all Licensed Technology, Know-How related to any Option Molecule, and Option Patent Right, in each case, owned by Junshi or its Affiliates as of the Execution Date and (B) Control of all Licensed Technology, Know-How related to any Option Molecule, and Option Patent Right, in each case, in-licensed by Junshi or its Affiliates as of the Execution Date. In addition, during the period between the Execution Date and the first to occur of the Option Exercise Date or expiration of the Option Term Junshi and its Affiliates will maintain (A) exclusive ownership and Control of all Know-How related to any Option Molecule and Option Patent Rights, in each case, owned by Junshi or its Affiliates at any time during such period and (B) Control of all Know-How related to any Option Molecule and Option Patent Rights, in each case, in-licensed by Junshi or its Affiliates at any time during such period, and (ii) not assign, transfer, encumber, or otherwise grant any Third Party any rights with respect to the Licensed Technology, Know- How related to any Option Molecule, or Option Patent Right, in each case, in any manner that would conflict with, limit the scope of, or adversely affect the rights granted to Coherus under this Agreement.
- (e) **Control of Upstream Licenses.** Junshi will not, without Coherus' prior written consent, (i) waive, amend, cancel, or terminate any material provision of, or fail to maintain, any JS001 Upstream License or JS018-1 Upstream License in any manner that would adversely affect the rights granted to Coherus hereunder or that would impose additional or greater obligations on Coherus, or (ii) take or fail to take any action that would give any counterparty to any JS001 Upstream License or JS018-1 Upstream License the right to terminate any rights under JS001 Upstream License or JS018-1 Upstream License applicable to the Field within or For the Coherus Territory. The foregoing obligation with respect to the JS018-1 Upstream License terminates if Coherus does not exercise its option with respect to the Junshi IL-2 Molecule within the applicable Option Term.
- (f) **Assignment of Inventions.** Junshi will, and will ensure that its Affiliates, licensees, and contractors, obtain written agreements from any and all Persons involved in or performing any activities under this Agreement by or on behalf of Junshi that assign such Persons' rights, title, and interests in and to any Licensed Technology to Junshi prior to any such Person performing such activities.
- (g) **Debarment.** In the performance of activities under this Agreement, Junshi will not employ or use any Person that: (i) has ever been Debarred or is subject to debarment or convicted of a crime for which a Person could be a Debarred Entity or Debarred Individual; or (ii) has ever been under indictment for a crime for which a Person could be so Debarred. Junshi will inform Coherus in writing immediately if it or any Person that is performing activities

under this Agreement is Debarred or is subject to debarment or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or threatened, relating to the debarment or conviction of Junshi or any Person used in any capacity by Junshi or any of its Affiliates with respect to this Agreement or the performance of its other obligations or exercise of its rights under this Agreement.

- (h) **CFIUS.** Notwithstanding any provision to the contrary in this Agreement or any other agreement between the Parties, Junshi will neither be permitted to nor will seek (i) control rights (as defined in 31 C.F.R. § 800.208) in respect of Coherus or any Coherus subsidiary; (ii) membership or observer rights on the board or equivalent governing body of any Coherus subsidiary; (iii) access to any material nonpublic technical information in the possession of Coherus or any Coherus subsidiary; or (iii) involvement, other than through voting of shares, in substantive decision making of Coherus or any Coherus subsidiary regarding: (A) the use, development, acquisition, safekeeping, or release of sensitive personal data of U.S. citizens maintained or collected by Coherus or any Coherus subsidiary; (B) the use, development, acquisition, or release of critical technologies; or (C) the management, operation, manufacture, or supply of covered critical infrastructure (in each case of (ii)-(iii), within the meaning of 31 C.F.R. § 800.211(b)). Junshi hereby waives any such rights to which it may be entitled under the this Agreement or any other agreement between the Parties or otherwise, including any statutory rights to such information as a stockholder of Coherus.
- (i) **Lonza Consents.** Junshi will, within 30 days of the Effective Date, use reasonable efforts to obtain from Lonza any consent, approval or authorization necessary or required from Lonza under the JS001 Upstream License to grant the licenses to Coherus under Section 2.1 (Licenses to Coherus).

#### 10.4 Coherus Covenants and CFIUS Representation.

- (a) **No Conflicting Grants.** Coherus will not, and will cause its Affiliates not to, enter into any agreement with any Affiliate or Third Party that conflicts with or contradicts the terms and conditions set forth in this Agreement, including any agreement that would limit the grant of licenses or rights hereunder to the Arising Technology.
- (b) **Compliance with Applicable Law.** Coherus will comply with the applicable law (including applicable anti-corruption laws), including as applicable GLP, GCP, and cGMP and any applicable anti-corruption or anti-bribery laws or regulations of any governmental authority with jurisdiction over the activities performed by or on behalf of Coherus or its Affiliates in furtherance of such obligations, in each case, in the course of performing its obligations or exercising its rights pursuant to this Agreement. Neither Coherus nor its Affiliates will engage any agent to perform activities under this Agreement that has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual, or a Convicted Entity or Convicted Individual.
- (c) **Assignment of Inventions.** Coherus will, and will ensure that its Affiliates, Sublicensees, and contractors, obtain written agreements from any and all Persons involved in or performing any activities under this Agreement by or on behalf of Coherus that assign such Persons' rights, title, and interests in and to any Arising Technology to Coherus prior to any such Person performing such activities on behalf of Coherus.

- (d) **Debarment.** In the performance of activities under this Agreement, Coherus will not employ or use any Person that: (i) has ever been Debarred or is subject to debarment or convicted of a crime for which a Person could be a Debarred Entity or Debarred Individual; or (ii) has ever been under indictment for a crime for which a Person could be so Debarred. Coherus will inform Junshi in writing immediately if it or any Person that is performing activities under this Agreement is Debarred or is subject to debarment or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or threatened, relating to the debarment or conviction of Coherus or any Person or entity used in any capacity by Coherus or any of its Affiliates with respect to this Agreement or the performance of its other obligations or exercise of its rights under this Agreement.
- (e) **CFIUS.** Coherus represents and warrant to Junshi as of the Execution Date and as of the Effective Date that Coherus is not a “TID business” as defined in 31 C.F.R. § 800.248.

10.5 **NO OTHER REPRESENTATIONS OR WARRANTIES.** EXCEPT AS EXPRESSLY STATED IN THIS Article 10 (REPRESENTATIONS, WARRANTIES AND COVENANTS), NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## ARTICLE 11 INDEMNIFICATION

- 11.1 **Indemnification by Junshi.** Subject to the remainder of this Article 11 (Indemnification), Junshi will defend, indemnify, and hold Coherus, its Affiliates, and its and their respective officers, directors, employees, and agents (the “**Coherus Indemnitees**”) harmless from and against any and all liabilities, losses, costs, damages, fees, expenses, or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation incurred by such Coherus Indemnitees, all to the extent resulting from claims, suits, proceedings, or causes of action brought by or on behalf of such Third Party against such Coherus Indemnitees that arise from or relate to: (a) the Exploitation of any Licensed Antibody, Licensed Product, Option Molecule, or Option Product by or on behalf of Junshi or any of its Affiliates or licensees (other than Coherus and its Sublicensees); (b) a breach of any of Junshi’s representations, warranties, or obligations under this Agreement; (c) the willful misconduct or grossly negligent acts of Junshi or any of its Affiliates; or (d) violation of applicable law by any Junshi Indemnitee; excluding, in each case ((a), (b), (c), and (d)), any damages or other amounts for which Coherus has an obligation to indemnify any Junshi Indemnitee pursuant to Section 11.2 (Indemnification by Coherus).
- 11.2 **Indemnification by Coherus.** Subject to the remainder of this Article 11 (Indemnification), Coherus will defend, indemnify, and hold Junshi, its Affiliates, and each of their respective officers, directors, employees, and agents (the “**Junshi Indemnitees**”) harmless from and against any and all liabilities, losses, costs, damages, fees, expenses, or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation incurred by such Junshi Indemnitees, all to the extent resulting from any claims, suits, proceedings, or causes of action brought by such Third Party against such Junshi Indemnitees that arise from or relate to: (a) the Exploitation of Licensed Antibody or Licensed Products by or on behalf of Coherus or any of its

Affiliates or Sublicensees; (b) a breach of any of Coherus' representations, warranties, or obligations under this Agreement; (c) the willful misconduct or grossly negligent acts of Coherus or any of its Affiliates; or (d) violation of applicable law by any Coherus Indemnatee; excluding, in each case ((a), (b), (c), and (d)), any damages or other amounts for which Junshi has an obligation to indemnify any Coherus Indemnatee pursuant to Section 11.1 (Indemnification by Junshi).

- 11.3 **Indemnification Procedures.** The Party claiming indemnity under this Article 11 (Indemnification) (the “**Indemnified Party**”) will give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought (“**Claim**”). The Indemnifying Party’s obligation to defend, indemnify, and hold harmless pursuant to Section 11.1 (Indemnification by Junshi) or Section 11.2 (Indemnification by Coherus), as applicable, will be reduced to the extent the Indemnified Party’s delay in providing notification pursuant to the previous sentence results in actual prejudice to the Indemnifying Party; *provided, however*, that the failure by an Indemnified Party to give such notice or otherwise meet its obligations under this Section 11.3 (Indemnification Procedures) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement. At its option, the Indemnifying Party may assume the defense and have exclusive control, at its own expense, of any Claim for which indemnity is being sought by giving written notice to the Indemnified Party within 30 days after receipt of the notice of the Claim. The assumption of defense of the Claim will not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Claim, nor will it constitute waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party’s claim for indemnification. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party’s expense, in connection with the defense. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided, however*, the Indemnifying Party will have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. The Indemnified Party will not settle any such Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnified Party reserves any right it may have under this Article 11 (Indemnification) to obtain indemnification from the Indemnified Party.
- 11.4 **Limitation of Liability.** IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR INDIRECT DAMAGES OF ANY KIND ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY CLAIMS ARISING HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 (INDEMNIFICATION BY LICENSOR) OR SECTION 11.2 (INDEMNIFICATION BY COHERUS), (B) DAMAGES AVAILABLE IN THE CASE OF A PARTY’S FRAUD, GROSS NEGLIGENCE, OR INTENTIONAL MISCONDUCT, OR (C) DAMAGES AVAILABLE TO A PARTY FOR A BREACH BY THE OTHER PARTY OF THE CONFIDENTIALITY OBLIGATIONS UNDER Article 12 (CONFIDENTIALITY),

MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OWNED OR CONTROLLED BY SUCH PARTY, OR THE OTHER PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTION 2.7 (EXCLUSIVITY).

- 11.5 **Insurance.** During the Term, each Party will obtain and maintain, at its individual sole expense, liability insurance in an amount adequate to cover its obligations under this Agreement during the Term. Each Party is required to obtain and maintain clinical trial insurance only for those trials they are sponsoring. Each Party will also maintain any mandatory insurance, including workers compensation coverage, in accordance with all applicable laws and regulations. Each Party will furnish to the other Party, on request, certificates of insurance evidencing the insurance, including notice of cancellation to be provided in accordance with the terms of the insurance policies. Such insurance will not be construed to create a limit of the insured Party's liability with respect to its indemnification obligations under this Article 11 (Indemnification).

## ARTICLE 12 CONFIDENTIALITY

- 12.1 **Confidentiality; Exceptions.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, during the Term and for 10 years thereafter, the Parties agree that the receiving Party will keep confidential and will not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any information and materials furnished to such Party or any of its Affiliates by or on behalf of the other Party or any of its Affiliates or generated pursuant to this Agreement (collectively, "**Confidential Information**"). For any Confidential Information that constitutes trade secrets of either Party, the foregoing non-disclosure obligations will continue for as long as such Confidential Information remains trade secrets.
- (a) **Specific Examples of Confidential Information.** Confidential Information of a Party or any of its Affiliates will include all information and materials disclosed by such Party or any of its Affiliates or their respective designees that (a) is marked as "Confidential," "Proprietary," or with similar designation at the time of disclosure or (b) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Know- How disclosed orally will not be required to be identified as such to be considered Confidential Information. The terms of this Agreement and all Licensed Know-How will be deemed to be the Confidential Information of both Parties. All reports delivered by one Party to the other Party hereunder will be the Confidential Information of the providing Party.
- (b) **Exceptions.** Notwithstanding the foregoing, Confidential Information will not include any information to the extent that it can be established by written documentation by the receiving Party that such information (a) was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement, (d) was independently developed by the receiving Party as demonstrated by written documentation prepared contemporaneously with such independent development, or (e) was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

## 12.2 Authorized Disclosure.

- (a) **Permitted Disclosure.** Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement (but of shorter duration, if customary): (A) in connection with the performance of its obligations or as necessary or useful in the exercise of its rights under this Agreement, including the right to grant licenses or sublicenses as permitted hereunder, (B) to the extent such disclosure is reasonably necessary or useful in conducting Clinical Trials under this Agreement, or (C) to actual or potential (sub)licensees, acquirers or assignees, collaborators, investment bankers, investors or lenders (including in connection with any royalty factoring transaction), or; (ii) to the extent such disclosure is to a governmental authority as reasonably necessary in filing or prosecuting Patent Right, copyright, and trademark applications in accordance with this Agreement, prosecuting or defending litigation related to this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement (including any disclosure to any securities exchange), obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for the Licensed Antibody or Licensed Products, or otherwise required by applicable law; *provided, however*, that if a Party is required by applicable law or the rules or requests of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information then it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), endeavor to give reasonable advance notice to the other Party of such disclosure requirement and, in each of the foregoing, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed and will limit the disclosure of that Confidential Information required to be disclosed; (iii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement, or (iv) to the extent agreed to by the Parties.
- (b) **Disclosure to SEC.** Each Party acknowledges and agrees that the other Party may submit this Agreement to the U.S. Securities and Exchange Commission (the "SEC") and if a Party does submit this Agreement to the SEC, then such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. If a Party is required by applicable law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC, and (i) such Party has provided copies of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, (ii) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (iii) such Party has given the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by applicable law. Notwithstanding any provision to the contrary herein, it is hereby understood and agreed that if a Party seeking to make a disclosure to the U.S. Securities and Exchange Commission as set forth in this Section 12.2 (Authorized Disclosure), and the other Party provides comments within the respective time periods or constraints specified herein or within the respective notice, the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith (A) consider incorporating such comments and (B) use



reasonable efforts to incorporate such comments, limit disclosure, or obtain confidential treatment to the extent reasonably requested by the other Party to the extent permitted by applicable law.

- (c) **Disclosure on HKSE and SSE.** Each Party acknowledges and agrees that the other Party may submit this Agreement to the Hong Kong Stock Exchange (“**HKSE**”) and the Shanghai Stock Exchange (“**SSE**”) and if a Party does submit this Agreement to HKSE or SSE, then such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. If a Party is required by applicable law, rules, or requests to make a disclosure or filing of this Agreement or the terms hereof, (i) such Party will, to the extent practicable, provide copies of the disclosure to the other Party as far in advance of such filing or other disclosure, and (ii) such Party will promptly notify the other Party in writing of such requirement and any respective timing constraints. Notwithstanding any provision to the contrary set forth in this Agreement, it is hereby understood and agreed that if a Party seeking to make a disclosure as set forth in this Section 12.2 (Authorized Disclosure), and the other Party provides comments within the respective time periods or constraints specified herein or within the respective notice, then the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith (A) consider incorporating such comments and (B) use reasonable efforts to incorporate such comments, limit disclosure, or obtain confidential treatment to the extent reasonably requested by the other Party to the extent permitted by applicable law.
- (d) **Press Release.** Other than public disclosure permitted by Section 12.2(a) (Permitted Disclosures), Section 12.2(b) (Disclosure to SEC), Section 12.2(c) (Disclosure on HKSE and SSE) and disclosures required by applicable law and rules of applicable stock exchanges, the Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information that is not already in the public domain, must be reviewed and discussed by both Parties. After a disclosure or other public announcement has been reviewed and approved by both Parties under this Section 12.2 (Authorized Disclosure), either Party may make subsequent public disclosures reiterating such information without having to obtain the other Party’s prior consent and approval, so long as the information in such disclosure or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein.

12.3 **Prior Agreement.** This Agreement supersedes the Existing Nondisclosure Agreement. All confidential information exchanged between the Parties under the Existing Nondisclosure Agreement will be deemed Confidential Information of the disclosing Party and will be subject to the terms of this Agreement.

12.4 **Residual Knowledge.** Notwithstanding any provision to the contrary set forth in this Agreement, use or disclosure by an authorized representative of a receiving Party of Confidential Information that is knowledge, technique, experience, or Know-How retained in the unaided memory of such authorized representative of the receiving Party that had authorized access to such Confidential Information (“**Residual Knowledge**”) will not violate the confidentiality, non-use and non-disclosure obligations set forth in this Article, *provided* that such authorized representative did not intentionally memorize such Confidential Information for use outside of this Agreement. Any use made by the receiving Party of any such Residual Knowledge is on an “as is, where is” basis, with all faults and all representations and warranties disclaimed and at its sole risk.

12.5 **Publications.**

- (a) **Coherus Publication Rights.** As between the Parties, Coherus will: (i) control and be responsible for the publication strategy and logistics for all publications with respect to the Licensed Antibodies and Licensed Products within the Coherus Territory, subject to any rights of investigators that conduct any of the Clinical Trials for any of the Licensed Antibodies or Licensed Products in the Coherus Territory, (ii) have the exclusive right to issue publications and make presentations with respect to the Licensed Antibodies and Licensed Products within or For the Coherus Territory authored solely by representatives of Coherus, and (iii) subject to any rights of investigators that conduct any of the Clinical Trials for any of the Licensed Antibodies or Licensed Products in the Coherus Territory, have the sole and exclusive right to author and publish data generated and observations arising from Clinical Trials conducted within or For the Coherus Territory involving monotherapy treatments of Licensed Antibodies and Licensed Products and Development associated with Independent Trials for which Coherus is the Developing Party, in each case, without the prior consent of Junshi, *provided* that no such publication may include the Confidential Information of Junshi; except that the Parties will jointly author and publish such data and observations arising from the Ongoing JS001 Clinical Trials or activities under the Optioned Licensed Product Development Plan as well as for Clinical Trials conducted jointly by the Parties, subject to Coherus' publication strategy and logistical control within or For the Coherus Territory.
- (b) **Junshi Publication Rights.** As between the Parties, Junshi will have the exclusive right to issue publications and make presentations with respect to the Licensed Antibodies and Licensed Products authored solely by representatives of Junshi and, before the Option Exercise, the Option Molecules. As between the Parties, and subject to any rights of investigators that conduct any of the Clinical Trials for any of the Licensed Antibodies or Licensed Products, Junshi will have the sole and exclusive right to author publish data generated and observations arising from Development of the Option Molecules Clinical Trials before the Option Exercise, Development conducted outside the Coherus Territory involving Licensed Antibodies and Licensed Products, and Development associated with Independent Trials within the Coherus Territory for which Junshi is the Developing Party, in each case, without the prior consent of Coherus, *provided* that no such publication may include the Confidential Information of Coherus.

#### ARTICLE 13

#### TERM AND TERMINATION

- 13.1 **Term.** This Agreement will commence on the Effective Date and, unless earlier terminated pursuant to this Article 13 (Term and Termination), will expire on a Licensed Product-by-Licensed Product and country-by-country basis at the end of the applicable Royalty Term (the "**Term**"). Following the end of the Term for a Licensed Product in a country by expiration of the applicable Royalty Term (but not earlier termination for any other reason) and payment of all amounts due with respect thereto, including milestones that first become due after a Royalty Term, the license granted to Coherus under Section 2.1 (Licenses to Coherus) will become perpetual, irrevocable, fully paid-up, and royalty-free.
- 13.2 **Termination by Coherus.** Coherus will have the right for any or no reason to terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product basis (a) prior to the first Regulatory Approval for a Licensed Product in the Field in the Coherus Territory, upon six months' prior written notice to Junshi; and (b) upon or after the first Regulatory Approval for a Licensed Product in the Field in the Coherus Territory, upon 12 months' prior written notice to Junshi.
- 13.3 **Termination for Cause.**

- (a) **By Coherus.** In the event of a material breach of this Agreement by Junshi, which material breach remains uncured for 90 days measured from the date of written notice of such material breach by Coherus that identifies the material breach and the actions or conduct that Coherus considers would be an acceptable cure of such material breach, Coherus may terminate this Agreement in whole or with respect to one or more Licensed Antibodies (and all Licensed Products that include such Licensed Antibody) at any time during the Term of this Agreement by written notice of termination to Junshi, *provided* that such 90- day cure period will be extended for a period of up to an additional 90 days so long as Junshi continues to use good faith efforts to cure such breach during such extension.
- (b) **By Junshi.** In the event of a material breach of this Agreement by Coherus with respect to any of the Licensed Antibodies or Licensed Products, which material breach remains uncured for 90 days measured from the date of written notice of such material breach by Junshi that identifies the material breach and the actions or conduct that it considers would be an acceptable cure of such material breach, Junshi may terminate this Agreement by notice (with immediate effect) solely with respect to the Licensed Antibody and corresponding Licensed Products that contributed to the breach and for which the Term has not yet expired, *provided* that such 90-day cure period will be extended for a period of up to an additional 90 days so long as Coherus continues to use good faith efforts to cure such breach during such extension.
- (c) **Disputes Regarding Material Breach.** In case the Party (the “**Defaulting Party**”) alleged by the other Party (the “**Non-Defaulting Party**”) to have committed a material breach under Section 13.3(a) (By Coherus) or Section 13.3(b) (By Junshi) disputes occurrence of such material breach, then the issue of whether the Non-Defaulting Party may properly terminate this Agreement on expiration of the applicable cure period will be resolved in accordance with Article 15 (Dispute Resolution). If as a result of such dispute resolution process, it is determined that the Defaulting Party committed a material breach of this Agreement and the Defaulting Party does not cure such material breach within 90 days after the date of such determination, (the “**Additional Cure Period**”), then such termination will be effective as of the expiration of the Additional Cure Period. If the Parties dispute whether such material breach was so cured, then such dispute will also be determined in accordance with Article 15 (Dispute Resolution). This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the cure periods set forth in Section 13.3(a) (By Coherus) or Section 13.3(b) (By Junshi), as applicable, and any Additional Cure Period, in each case, will be tolled during any such dispute resolution proceeding, such proceeding will not suspend any obligations of either Party hereunder, and each Party will use reasonable efforts to mitigate any damage. If as a result of such dispute resolution proceeding it is determined that the Defaulting Party did not commit such material breach (or such material breach was cured in accordance with this Section 13.3 (Termination for Cause)), then no termination will be effective, and this Agreement will continue in full force and effect.
- (d) **Competitive Change of Control of or by Coherus.** Without limiting Junshi’s rights under Section 13.3(b) (By Junshi), if Coherus does not comply with its obligations under the last sentence of Section 2.7(b) (Acquisition by Third Parties) with respect to a subset of Competitive Products described by clause (a), (b), or (c) in such definition, then Junshi may terminate this Agreement with respect to the Licensed Antibody and Licensed Products corresponding to such subset immediately by notice. Any such breach will be deemed a material breach but no cure period will apply.

13.4 **Effects of Termination.** Upon the termination of this Agreement (in addition to any other rights and obligations under this Article 13 (Term and Termination)):

- (a) **Licenses.** As of the effective date of termination of this Agreement with respect to a Licensed Product, all licenses and all other rights granted by Junshi to Coherus under Section 2.1 (Licenses to Coherus) with respect to such Licensed Product will terminate. If this Agreement is terminated by Coherus under Section 13.3(a) (By Coherus), then as of the effective date of such termination, the licenses granted by Coherus to Junshi under Section 2.3 (Licenses to Junshi) will terminate. If this Agreement is terminated for any other reason, then as of the effective date of termination with respect to the terminated Licensed Products, subject to the terms and conditions of this Agreement, Coherus hereby grants to Junshi an irrevocable, non-exclusive, royalty-free, worldwide license, with the right to sublicense in accordance with the terms and restrictions set forth in Section 2.3 (Licenses to Junshi), under the Coherus Arising Technology existing as of the effective date of such termination to Exploit the terminated Licensed Products in the Field in the form such products exist as of the effective date of such termination.
- (b) **Regulatory Materials.** Coherus will and hereby does, and will cause its Affiliates and Sublicensees to, no later than 30 days after the effective date of termination of this Agreement, assign and transfer to Junshi or its designee all of Coherus' rights, title, and interests in and to all Regulatory Approvals and Regulatory Materials for the terminated Licensed Products.
- (c) **Ongoing Clinical Trials.**
- (i) **Transfer to Junshi.** If, as of the effective date of termination of this Agreement with respect to a Licensed Product, Coherus or its Affiliates are conducting any Clinical Trials for such Licensed Product, then, at Junshi's election on a Clinical Trial-by-Clinical Trial basis, Coherus will either (A) reasonably cooperate, and ensure that its Affiliates reasonably cooperate, with Junshi to transfer the conduct of such Clinical Trial to Junshi or its designees, or (B) subject to Coherus' approval, continue to conduct such Clinical Trial, at Junshi's cost. Junshi will assume any and all liability for the conduct of such transferred Clinical Trial for such Licensed Products after the effective date of such transfer (except to the extent arising prior to the transfer date or from any willful misconduct or negligent act or omission by Coherus, its Affiliates or their respective employees, agents, and contractors).
- (ii) **Wind-Down.** If Junshi does not elect to assume control of any such Clinical Trials for any Licensed Product, then Coherus will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down the conduct of any such Clinical Trial in an orderly manner. Coherus will be responsible for any costs and expenses associated with such wind-down (unless this Agreement is terminated by Coherus pursuant to Section 13.3 (Termination for Cause), in which case Junshi will bear all such costs and expenses).
- (d) **Return of Confidential Information.** Each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing as to such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party hereunder that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that (a) such Party will have the right to retain one copy of intangible Confidential Information of such other Party for legal purposes and (b) Junshi will not be obligated to return or destroy any of Coherus' Confidential Information necessary or reasonably useful for Junshi to exercise the rights granted to it upon termination of this Agreement, *provided* that all such Confidential Information will continue to be subject to all confidentiality obligations under this

Agreement (with Coherus as the disclosing Party with respect to such Confidential Information). Notwithstanding any provision to the contrary set forth in this Agreement, the receiving Party of any Confidential Information will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

(e) **Other Remedies.** Termination or expiration of this Agreement for any reason will not release either Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason will not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

13.5 **Survival.** Termination or expiration of this Agreement will not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding any provision to the contrary, the following provisions will survive and apply after expiration or termination of this Agreement in its entirety: Article 1 (Definitions), Section 2.3 (Licenses to Junshi), Section 4.9 (Development Records), Section 8.4 (Royalties) (but only with respect to Net Sales made during the Term), Section 8.6 (Books and Records; Audit Rights) (but only with respect to payment obligations accruing during the Term and only for a period of three years after expiration or termination), Section 8.8 (Late Payments) (but only with respect to payment obligations accruing during the Term), Section 9.1 (Ownership), Section 10.5 (No Other Representations or Warranties), Article 11 (Indemnification), Article 12 (Confidentiality), Section 13.1 (Term), Section 13.4 (Effects of Termination), this Section 13.5 (Survival), Article 15 (Dispute Resolution), and Article 16 (Miscellaneous). In addition, the other applicable provisions of Article 8 (Financials) will survive such expiration or termination of this Agreement in their entirety to the extent required to make final reimbursements, reconciliations or other payments incurred or accrued prior to the date of termination or expiration. For any surviving provisions requiring action or decision by the JDC or an Executive Officer, each Party will appoint representatives to act as its JDC members or Executive Officer, as applicable. All provisions not surviving in accordance with the foregoing will terminate upon expiration or termination of this Agreement and be of no further force and effect.

#### **ARTICLE 14 EFFECTIVENESS**

14.1 **Effective Date.** Except for the Parties' obligations under Article 12 (Confidentiality) and this Article 14 (Effectiveness), which will be effective as of the Execution Date, this Agreement will not become effective until the first Business Day after the Antitrust Clearance Date (the "**Effective Date**"); *provided* that the Effective Date will not occur (a) if either Party exercises its termination right under Section 14.3 (Outside Date) prior to the Antitrust Clearance Date, or (b) if and for so long as there is in force any applicable law (i) enjoining or prohibiting the consummation of the transactions contemplated by this Agreement or (ii) imposing any conditions in connection with such effectiveness, and no action, proceeding, or investigation brought by a governmental authority is pending that would reasonably be expected to lead to any of the foregoing that would be material in the context of the transactions contemplated by this Agreement.

14.2 **Filings.** Each Party will unless otherwise agreed by the Parties, within 10 Business Days following the Execution Date, file those Antitrust Filings required under the applicable Antitrust Laws (the

“**Required Filings**”). The Parties will reasonably cooperate with one another to the extent necessary in the preparation and execution of all such documents that are required to be filed pursuant to the Required Filings. Each Party will be responsible for its own costs and expenses associated with any such Required Filing, including premerger filing fees incurred by each Party associated with any such Required Filing. With respect to the Required Filings, the Parties will use reasonable efforts to seek early termination of the applicable waiting period and each use reasonable efforts to ensure that any applicable waiting period under the applicable Antitrust Law expires or is terminated as soon as practicable and to obtain any necessary approvals or consents under such applicable Antitrust Law, at the earliest possible date after the date of filing. To the extent permitted under applicable law and by the applicable governmental authorities, the Parties will (a) provide each other reasonable advance written notice of any meetings or telephone conferences with a governmental authority under the HSR Act relating to the transactions contemplated by this Agreement, and (b) permit each other to attend and participate in those meetings and telephone conferences. Each Party will (i) provide the other with reasonable opportunity to review and comment on any written submissions, and will consider comments in good faith, and (ii) keep the other Party apprised of the status of any communications with, and any inquiries or requests for information from, any governmental authority under the HSR Act, regardless of whether such other Party declines to participate in any meetings or telephone conferences; *provided* that neither Party will be obligated to disclose any commercially sensitive or privileged information, and to the extent the Parties agree to share information of this nature, such exchange and review will be limited to the Parties’ outside counsel only. Notwithstanding any provision to the contrary set forth in this Agreement, nothing in this Agreement (including this Section 14.2 (Filings)) will require either Party or any of its Affiliates to (a) disclose to the other Party or any of its Affiliates any information that is subject to obligations of confidentiality or non use owed to Third Parties (nor will either Party be required to conduct joint meetings with any governmental authority in which such information might be shared with the other Party), (b) commit to any consent decree or similar undertaking, or any divestiture, license (in whole or in part), or any arrangement to hold separate (or any similar arrangement) with respect to any of its products or assets, or (c) litigate.

- 14.3 **Outside Date.** This Agreement will terminate at the election of either Party, immediately upon written notice to the other Party, (a) if any governmental authority in any Clearance Country seeks a permanent injunction under applicable Antitrust Laws against the Parties to enjoin the transactions contemplated by this Agreement; or (b) in the event that the Antitrust Clearance Date will not have occurred on or prior to 180 days after the submission of the Required Filing, and the Parties have not agreed in writing to extend the Antitrust Clearance Date. In the event of such termination, this Agreement will be of no further force and effect.

## **ARTICLE 15 DISPUTE RESOLUTION**

### **15.1 Dispute Resolution.**

- (a) In the event of any dispute between the Parties under this Agreement, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within 15 Business Days, either Party may refer the matter to the Executive Officers of the Parties for attempted resolution, whereupon the Executive Officers will confer and attempt in good faith to resolve such dispute by negotiation and consultation for a 30 day period following such referral.
- (b) Subject to the Section 4.3(b) (Restrictions on Additional Development), if the Executive Officers do not resolve such dispute within such thirty (30) day period, either Party may at

any time thereafter proceed to binding arbitration in accordance with this Section 15.1 (Dispute Resolution). A Party may submit such dispute to arbitration with JAMS New York (“**JAMS**”), and notify the other Party, in writing, of such dispute. Within thirty (30) days after receipt of such notice, the Parties will each designate in writing an arbitrator to resolve the dispute. Both of the designated arbitrators will elect a third arbitrator; *provided, however*, that if the designated arbitrators cannot agree on a third arbitrator within 20 days after both arbitrators have been designated, the third arbitrator will be selected by JAMS. The arbitrator will be a lawyer with biotechnology and/or pharmaceutical industry legal experience, and will not be an Affiliate, employee, consultant, officer, director or stockholder of any Party.

- (c) Within 30 days after the designation of the arbitrator, the arbitrator and the Parties will meet, at which time the Parties will be required to set forth in writing all disputed issues and a proposed ruling on the merits of each such issue. The Parties will have the right to be represented by counsel. Except as provided herein, the arbitration will be governed by the Comprehensive Arbitration Rules and Procedures (the “**JAMS Rules**”). The arbitration proceedings will be conducted in English.
- (d) The arbitrator will use his or her best efforts to rule on each disputed issue within 30 days after the completion of any hearings associated with the arbitration. The determination of the arbitrator as to the resolution of any dispute will be binding and conclusive upon all Parties. The arbitrator will issue a written award that contains a reasoned opinion setting forth the findings of fact and conclusions upon which the award is based, including the calculation of any damages awarded.
- (e) The (i) attorneys’ fees of the Parties in any arbitration, (ii) fees of the arbitrator and (iii) costs and expenses of the arbitration will be borne by the Parties as determined by the arbitrator.
- (f) Any arbitration pursuant to this Section 15.1 (Dispute Resolution) will be conducted in New York, NY.
- (g) The Parties intend that each award by an arbitrator in an arbitration pursuant to this Section 15.1(Dispute Resolution) will be rendered in accordance with the United Nations Convention on the Recognition and Enforcement of Arbitral Awards and will be enforceable in accordance therewith.
- (h) The arbitrator will take appropriate actions to prevent, remediate, and/or sanction abusive conduct or other actions that threaten to undermine the fair, speedy and cost-effective resolution of the matter.
- (i) In addition, during the pendency of any dispute under this Agreement initiated before the end of any applicable cure period under Section 13.3 (Termination for Cause), (i) this Agreement will remain in full force and effect, (ii) the provisions of this Agreement relating to termination for material breach will not be effective, (iii) the time periods for cure under 13.3 (Termination for Cause) as to any termination notice given prior to the initiation of the proceeding will be tolled, and (iv) neither Party will issue a notice of termination pursuant to this Agreement based on the subject matter of the proceeding (and no effect will be given to previously issued termination notices), until the arbitrator has confirmed the existence of the facts claimed by a Non-Defaulting Party to be the basis for the asserted material breach.



- 15.2 **Injunctive Relief.** Nothing in this Article 15 (Dispute Resolution) will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any proceeding if necessary to protect the interests of such Party or to preserve the status quo pending the proceeding. Therefore, in addition to its rights and remedies otherwise available at law, including the recovery of damages for breach of this Agreement, upon an adequate showing of material breach, and without further proof of irreparable harm other than this acknowledgement, such Non-Defaulting Party will be entitled to seek (a) immediate equitable relief, specifically including both interim and permanent restraining orders and injunctions, and (b) such other and further equitable relief as the court may deem proper under the circumstances. For clarity, nothing in this Section 15.2 (Injunctive Relief; Remedy for Breach of Exclusivity) will otherwise limit a Defaulting Party's opportunity to cure a material breach as permitted in accordance with 13.3 (Termination for Cause).

## ARTICLE 16 MISCELLANEOUS

- 16.1 **Entire Agreement; Amendment.** This Agreement, including the Schedules hereto, set 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 all prior agreements and understandings between the Parties existing as of the Execution Date with respect to the subject matter hereof. In the event of any inconsistency between any plan hereunder and this Agreement, the terms of this Agreement will prevail. 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 will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.
- 16.2 **Force Majeure.** Neither Party will be held liable to the other Party nor be deemed to have breached this Agreement for failure or delay performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, epidemics, pandemics, or quarantines ("**Force Majeure**") and for so long as such failure or delay continues to be caused by or result from such Force Majeure event. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Execution Date may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing to the extent those effects are not reasonably foreseeable by the Parties as of the Execution Date. The affected Party will notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then the affected Party will update such notice to the other Party on a weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume.
- 16.3 **Notices.** Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate Party at the address

specified below or such other address as may be specified by such Party in writing in accordance with this Section 16.3 (Notices), and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable international expedited delivery service, or (b) five Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested. This Section 16.3 (Notices) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to Junshi:

SHANGHAI JUNSHI BIOSCIENCES CO., LTD.  
Level 13, Building 2, Nos. 36 and 58, Hai Qu Road,  
Shanghai, China 201203

Attention: CEO

And to:

SHANGHAI JUNSHI BIOSCIENCES CO., LTD.  
Level 13, Building 2, Nos. 36 and 58, Hai Qu Road,  
Shanghai, China 201203

Attention: Board Secretary, Securities Department

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

Jones Day  
4655 Executive Drive, Suite 1500  
San Diego, CA 92130

Attention: Thomas A. Briggs

If to Coherus:

Coherus BioSciences, Inc.  
333 Twin Dolphin Drive, Suite 600  
Redwood City, CA 94065

Attention: CEO

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

Ropes & Gray  
800 Boylston Street  
Boston MA 02199  
Attention: David M. McIntosh and Hannah H. Freeman

- 16.4 **No Strict Construction; Headings.** This Agreement has been prepared jointly and will not be strictly construed against either Party. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section 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 in the particular Article or Section.
- 16.5 **Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation,” (c) the word “will” will be construed to have the same meaning and effect as the word “shall,” (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person’s or entity’s successors and assigns, (f) the words “herein,” “hereof,” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent,” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (including e-mail, but excluding instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then- current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or,” and (l) references to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered “Section 2.2” would be part of “Section 2”, and references to “Section 2.2” would also refer to material contained in the subsection described as “Section 2.2(a)”) Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.
- 16.6 **Assignment.** Neither this Agreement nor any interest hereunder is assignable by either Party without the prior written consent of the other Party, except as follows: (a) either Party may, subject to the terms of this Agreement, assign its rights and obligations under this Agreement in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, or similar transaction or series of related transactions, *provided* that such sale is not primarily for the benefit of its creditors, and (b) either Party may assign its rights and obligations under this Agreement to any of its Affiliates, *provided* that such Party will remain liable for all of its rights and obligations under this Agreement. A Party will promptly notify the other Party of any assignment or transfer under the provisions of this Section 16.6 (Assignment). This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names

of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.6 (Assignment) will be null, void and of no legal effect. If an assignment of this Agreement, in whole or in part, by either Party causes a higher withholding or direct tax rate than would be applicable absent such assignment, then such additional withholding or taxes will be borne by the assigning Party, including taxes resulting therefrom.

- 16.7 **Performance by Affiliates.** Each Party may perform any obligations and exercise any right hereunder through any of its Affiliates, *provided* that such Party will remain primarily responsible for the acts of such Affiliates to other Party hereunder. Each Party hereby guarantees the performance by any of its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate. If the performance of any obligations, in whole or in part, by an Affiliate of a Party causes a higher withholding or direct tax rate than would be applicable if such Party had performed such obligation, then such additional withholding or taxes will be borne by such Party, including taxes resulting therefrom.
- 16.8 **Further Actions.** Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 16.9 **Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken, then the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will 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 into this Agreement may be realized.
- 16.10 **No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.
- 16.11 **Independent Contractors.** Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein will be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.
- 16.12 **Counterparts.** This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.
- 16.13 **Choice of Law.** This Agreement will be governed by, and enforced and construed in accordance with, the laws of the State of New York, without regard to its conflicts of law provisions.

*[Signature Page Follows]*

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the Execution Date.

SHANGHAI JUNSHI BIOSCIENCES CO., LTD.

COHERUS BIOSCIENCES, INC.

By: /s/ Ning Li  
Name: Ning Li  
Title: CEO

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the Execution Date.

**SHANGHAI JUNSHI BIOSCIENCES CO., LTD.**

**COHERUS BIOSCIENCES, INC.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

By: /s/ Dennis M. Lanfear  
Name: Dennis M. Lanfear  
Title: Chairman & Chief Executive

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**SCHEDULE 1.93**

**Junshi IL-2 Molecule (JS018-1) Sequence**

As of the Execution Date, Junshi has not selected the clinical candidate for JS018-1. Junshi expects to select such candidate within about 6 months after the Execution Date.

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**SCHEDULE 1.96**

Junshi TIGIT Antibody (JS006) Sequence

Heavy chain :

QVQLVQSGAEVKKPGASVKVSCKTSGYAFTEYTMHWVRQAPGKGLEWMGGINPNTGGTTYNQ  
KFQGRVTLTVDKSSSTAYMELSSLRSEDTVVYYCAKLLRLMYFFDYWGQGLVTVSSASTKGP  
SVFPLAPCSRSTSESTAALGCLVKDYFPEPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVTVP  
SSSLGTKTYTCNVDPKPSNTKVDKRVESKYGPPCPPAPEFLGGPSVFLFPPKPKDTLMISRTPE  
VTCVVVDVSDPEVQFNWYVDGVEVHNAKTKPREEQFNSTYRVVSVLTVLHQDWLNGKEYK  
CKVSNKGLPSSIEKTISKAKGQPREPQVYTLPPSQEEMTKNQVSLTCLVKGFYPSDIAVEWESNG  
QPENNYKTTTPVLDSDGSFFLYSRLTVDKSRWQEGNVFSCSVMHEALHNHYTQKSLSLGLGK

Light chain :

DIQMTQSPSSLSASVGDRVTITCQASQDVRTAVAWYQQKPGKAPKLLIYSASYRYTGVP  
SRFSGSGSGTDFTFTISLQPEDATYYCHQHYPWTFGGGTKVEIKRTVAAPSVFIFPPS  
DEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKDSSTYSSTL  
TLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC

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## SCHEDULE 1.99

### JS001 Sequence

#### Heavy chain

QGQLVQSGAE VKKPGASVKV SCKASGYTFT DYEMHWVRQA PIHGLEWIGV 50  
IESETGGTAY NQKFKGRVTI TADKSTSTAY MELSSLRSED TAVYYCAREG 100  
ITTVATTYYW YFDVWGQGT VTVSSASTKG PSVFPLAPCS RSTSESTAAL 150  
GCLVKDYFPE PVTVSWNSGA LTSGVHTFPA VLQSSGLYSL SSVVTVPSSS 200  
LGTKTYTCNV DHKPSNTKVD KRVESKYGPP CPPCPAPEFL GGPSVFLFPP 250  
KPKDTLMISR TPEVTCVVVD VSQEDPEVQF NWYVDGVEVH NAKTKPREEQ 300  
FNSTYRVVSV LTVLHQDWLN GKEYKCKVSN KGLPSSIEKT ISKAKGQPRE 350  
PQVYTLPPSQ EEMTKNQVSL TCLVKGFYPS DIAVEWESNG QPENNYKTP 400  
PVLDSGDSFF LYSRLTVDKS RWQEGNVFSC SVMHEALHNNH YTQKSLSLSL 450  
GK 452

#### Light chain

DVVMTQSPLS LPVTLGQPAS ISCRSSQSIV HSNNGNTYLEW YLQKPGQSPQ 50  
LLIYKVSNRG SGVPDRFSGS GSGTDFTLKI SRVEAEDVGV YYCFQGSHP 100  
LTFGQGTKLE IKRTVAAPSV FIFPPSDEQL KSGTASVVCL LNNFYPRK 150  
VQWKVDNALQ SGNSQESVTE QDSKDYSTYSL SSTLTLSKAD YEKHKVYACE 200  
VTHQGLSSPV TKSFNREGC 219

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**SCHEDULE 1.113**

**Ongoing JS001 Clinical Trials**

**Twenty-four Ongoing and Five Planned Toripalimab Clinical Trials**

<b>NO.</b>	<b>Brief Title</b>	<b>ClinicalTrials.gov ID</b>	<b>Trial Phase</b>
CT10	A Phase I open label study to evaluate Toripalimab concurrent with Radiotherapy in Patients with Advanced Triple-Negative Breast Cancer	NCT03151447	I
CT13	A Phase Ib, Open label, Dose-escalation Clinical Study Investigating the Tolerability and Pharmacokinetics of Toripalimab Combined with Axitinib in Patients with Advanced Renal Carcinoma and Melanoma	NCT03086174	I
TAB001-01	A Multi-Center, Open Label Phase I study to Evaluate the Safety, Tolerability and Pharmacokinetics of Toripalimab in Subjects with Advanced Malignancies	NCT03474640	I
CT5	A Multi-Center, Open Label Phase Ib/II Clinical Study to Evaluate Toripalimab in Patients with Advanced Gastric Adenocarcinoma, Esophageal Squamous Cell Carcinoma, Nasopharyngeal Carcinoma and Head and Neck Squamous Cell Carcinoma	NCT02915432	Ib/II
CT20	An Open-Label Study Evaluating the Efficacy and Safety of Toripalimab versus Placebo as Neoadjuvant Therapy in Resectable Hepatocellular Carcinoma or Intrahepatic Cholangiocarcinoma	NCT03867370	Ib
CT8	A Randomized, Controlled, Multi-Center Phase II Study of Toripalimab versus High-Dose Interferon in Patients With Completely surgical resected Mucosal Melanoma	NCT03178123	II
CT12	A Single-arm, Open-label, Multi-center Phase II Study to evaluate the Safety and Efficacy of Toripalimab for Patients with Locally Advanced or Metastatic Bladder Urothelial Carcinoma after Standard Treatment Failed	NCT03113266	II
CT18	A Study of Toripalimab in combination with Pemetrexed and Carboplatin in Patients With EGFR-mutation Positive and T790M Negative NSCLC After Progression on EGFR-TKI Treatment	NCT03513666	II

CT33	A Single-arm, Open-label, Multi-center Phase II Study to Evaluate the Efficacy and Safety of Toripalimab in the Patients with Recurrent or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Who Have Failed At least Two Prior Lines of Therapy and Are Positive for Specific Biomarkers	NCT04603040	II
CT34	A Single-arm, Open-label, Multi-center Phase II Clinical Study to Evaluate the Safety and Efficacy of Toripalimab in Combination with Bevacizumab as the First- line Therapy for Advanced Hepatocellular Carcinoma	NCT04605796	II
CT16	A Phase II/III, Randomized, Double-Blind, Placebo-Controlled Study evaluating the Efficacy and Safety of Toripalimab versus Placebo as Adjuvant Therapy in Patients with Local Advanced Hepatocellular Carcinoma after Curative Hepatic Surgery.	NCT03859128	III
CT15	A Randomized, Placebo-Controlled, Multicenter, Double-Blind, Phase III Study Comparing Toripalimab versus Placebo in Combination with Chemotherapy as 1 <sup>st</sup> line treatment of Recurrent or Metastatic Nasopharyngeal Cancer	NCT03581786	III
CT17	A Randomized, Multi-center, Phase III Study to Compare Toripalimab Versus Dacarbazine as First Line Therapy for Unresectable or Metastatic Melanoma	NCT03430297	III
CT19	A Randomized, Controlled, Multi-center, Phase III Study to Evaluate the Efficacy and Safety of Toripalimab Versus Placebo Combined with Chemotherapy in Patients with Treatment-naive Advanced NSCLC	NCT03856411	III
CT21	A Randomized, Controlled, Multi-center, Phase III Study to Compare Toripalimab Versus Placebo in combination with Paclitaxel and Cisplatin as First Line Therapy in Patients with Advanced or Metastatic Esophageal Squamous Cell Cancer	NCT03829969	III
CT25	A Randomized, Controlled, Multi-center, Phase III Study to Evaluate Toripalimab Versus Placebo in combination with Pemetrexed and Carboplatin in Patients With EGFR-mutated NSCLC After Progression on EGFR-TKI Treatment	NCT03924050	III

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CT26	A Randomized, Controlled, Multi-center, Phase III Study to Evaluate Toripalimab Versus Placebo in Combination with Nab- Paclitaxel In Patients With Metastatic or Recurrent Triple-Negative Breast Cancer	NCT04085276	III
CT27	A Randomized, Controlled, Multi-center, Phase III Study to Evaluate toripalimab + Lenvatinib vs. Lenvatinib alone as a 1st line treatment for patients with advanced HCC	NCT04523493	III
CT28	A Randomized, Controlled, Multi-center, Phase III Study to Evaluate Toripalimab Versus Placebo in Combination with Platinum and Etoposide in Patients with Extensive-Stage Small Cell Lung Cancer	NCT04012606	III
CT29	A randomized, double-blind, placebo- controlled, multicenter, phase III clinical study of Toripalimab Versus Placebo combined with platinum-based doublet chemotherapy as Neoadjuvant/adjuvant Therapy in Patients with resectable stage IIIA NSCLC	NCT04158440	III
CT35	A randomized, double-blind, placebo- controlled, multicenter, phase III Study to Evaluate Toripalimab Versus Placebo in Combination with Bevacizumab as the First-line Therapy for Advanced Hepatocellular Carcinoma	NCT04723004	III
CT36	A randomized, multicenter, phase III Study to Evaluate the Efficacy and Safety of Toripalimab in Combination with Axitinib Versus Sunitinib Monotherapy as first line treatment in Advanced Renal Cell Carcinoma	NCT04394975	III
CT38	A Multi-center, Randomized, Phase III Study to Evaluate Toripalimab Versus Placebo in Combination with Standard Chemotherapy as a First-line Treatment for Locally Advanced or Metastatic Urothelial Carcinoma	NCT04568304	III
CT43	A Multi-center, Randomized, Open-label Phase III Study to Evaluate Toripalimab + Axitinib versus Pembrolizumab as First-line Therapy in Patients with Unresectable, Locally Advanced or Metastatic Mucosal Melanoma	IND Approved	III
CT37	A Phase II Study to Evaluate Toripalimab plus Cetuximab in patients with head and neck squamous cell carcinoma (HNSCC)	IND Stage	II

CT41	A Phase II Study to Evaluate Toripalimab+ Anlotinib with or without chemo as the first line therapy for advanced or metastatic colorectal cancer	IND Stage	II
CT39	A Multi-center, Randomized Phase III Study to Evaluate Toripalimab in combination with Lenvatinib and GEMOX versus GEMOX to as first-line treatment for advanced or unresectable intrahepatic cholangiocarcinoma	IND Stage	III
CT42	A Multi-center, Randomized Phase III Study to Evaluate Toripalimab versus Placebo Plus Chemotherapy as Neoadjuvant/adjvant Therapy in Patients with Resectable Esophageal Squamous Cell Carcinoma	IND Stage	III
CT44	A Multi-center, Randomized Phase III Study to Evaluate Toripalimab versus Placebo as Neoadjuvant/adjvant Therapy in Patients with Resectable Gastric Cancer	IND Stage	III

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## SCHEDULE 1.116

### Option Data Package

1. A detailed description of all Option Molecules and Option Products that are the subject of such Option Program.
  2. Copies of all (a) communications from any patent authority and (b) applications, filings, and responses made to any patent authority and instructions relating thereto, in each case ((a) and (b)) regarding or otherwise relating to any Licensed Patent Rights with respect to such Option Program.
  3. All documents (including briefing documents), meeting minutes, correspondence, and information provided (a) by or on behalf of Junshi or its Affiliates to any Regulatory Authority, or (b) by or on behalf of any Regulatory Authority to Junshi or its Affiliates, in each case ((a) and (b)) in connection with (i) any Option Product that is the subject of such Option Program or (ii) any product that is referenced in any regulatory material with respect to such Option Product (a "**Referenced Product**").
  4. A summary of all relevant safety concerns with respect to the applicable Option Products, if an IND were to have been open at the time of observation.
  5. All available (a) draft or final molecular characterization, preclinical and non-clinical efficacy/safety study reports, including non-GLP and GLP toxicology, drug metabolism, pharmacokinetics, and pharmacodynamics study data and reports, from pre-IND and IND-enabling studies for the applicable Option Products and Referenced Products, and (b) data tables and completed data sets from any other non-clinical or preclinical experiments that evaluate the mechanism of action, dose range, pharmacokinetics, pharmacodynamics, or biochemical/functional efficacy of such Option Products or Referenced Products.
  6. The complete data set from the applicable Phase I Clinical Trial.
  7. A finalized statistical analysis plan and the dataset therefor.
  8. All available (a) CMC records, including all analytical method development and validation reports, certificates of analysis, and accompanying release test reports, and all related starting materials (e.g., cell lines, plasmids, and primers), (b) manufacturing process development, characterization, and validation reports, (c) drug substance and drug product stability reports, and (d) batch records and manufacturing cost records, in each case ((a)-(d)) for the applicable Option Products.
  9. Update as to the status of the Manufacturing of the applicable Option Products, including where such Option Products are Manufactured, and current quantities available.
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**SCHEDULE 2.6(b)**

**Manufacturing Technology Transfer Additional Terms**

- Under the oversight of the JDC there will be a Technology Transfer Plan outlining the technology transfer key timelines, roles and responsibilities of JDC and subordinate teams. This is deemed a project management document.
- In coordination with Junshi current technology transfer procedures the following framework is used for technology transfers to internal and external parties. This consists of a 7 **Element** framework. Junshi will provide latest bilingual (Chinese/English) working drafts of these documents for any given transfer which can then be used as a starting point for the **Coherus CMO** implementation of the technology transfer for a given molecule. The Manufacturing partner will generate local English Language equivalents (or functional equivalents) to these items.

<i><b>Element</b></i>	<i><b>Stage of Transfer</b></i>	
	<b>Engineering Runs</b>	<b>PPQ Runs</b>
Process Transfer Protocol	TTP – Technology Transfer Protocol	PQMP - Process Qualification Master Plan
Analytical Methodology	AMTP – Analytical Method Transfer Plan	
Control of Process	PCS - Process Control Strategy	
Measure Outcome	C&S Plan – Comparability and Stability Plan	
Process Fit	Material Balance	
Risk Management	QRA – Quality Risk Assessment (for Process)	
Reporting	ESR – Engineering Summary Report	VSR – Validation Summary Report

- For each transfer to a given manufacturing site or specific scale at a given site, the **Element** documents listed (or their functional equivalent) will be subject to Junshi’s review and approval. These include for Engineering Runs: TTP, AMTP, PCS, C&S Plan, QRA, ESR. These include for the PPQ Runs: PQMP, PCS, C&S Plan, QRA, VSR. While it is understood different formats for these documents may be currently used by Lonza or other Coherus CMOs, the intention is to follow the above framework in spirit inasmuch as Junshi is provided technology oversight and approval to the **Element** documents (or their functional equivalent) in the reaching of a validated process “state”.

4. **Coherus CMO** data as it relates to manufacturing including and not limited to all CPPs and CQAs for any Engineering and Validation Runs will be shared in a timely manner with Junshi in order to assure consistent and transparent process lifecycle management knowledge is maintained inside Junshi. All release testing data for all Engineering and PPQ batches will be shared with Junshi in a timely manner.
  5. Process changes that affect regulatory filing established ranges or change previously developed QbD based PCS ranges must be reviewed and approved by Junshi in advance.
  6. Annual reports content filed with the Regulatory Authorities at **Coherus CMO** that pertain to manufacturing data for Junshi processes will be shared with Junshi when submitted to the relevant authorities.
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**SCHEDULE 4.2**  
**Ongoing JS001 Development Plan**

Investigational product: Toripalimab Injection (JS001)

English name of  
investigational product: Toripalimab Injection

Company: Shanghai Junshi Biosciences Co., Ltd.  
Floor 13, Building 2, No. 36 and 58 Haiqu Road, Pudong New District, Shanghai, China  
201203

Version date: Jan 30, 2021, Version 2.0

**1. Clinical development of Toripalimab Injection**

**1.1 Summary**

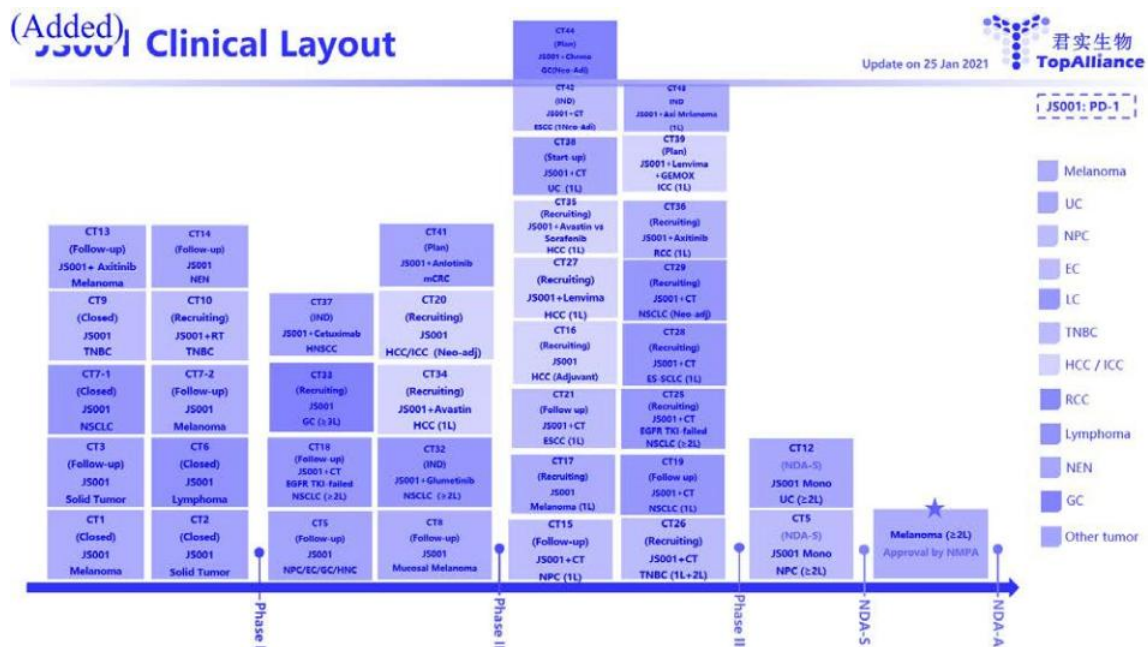
Toripalimab, also known as JS001 or TAB001, is a humanized IgG4 $\kappa$  monoclonal antibody specific for human programmed death-1 (PD-1). It binds to PD-1 with high affinity and selectively blocks the binding of PD-1 to its ligands PD-L1 and PD-L2, which leads to activation of T-lymphocytes and enhanced proliferation of T-lymphocytes and secretion of cytokines, especially IFN- $\gamma$ . For nonclinical pharmacology results of toripalimab including pharmacology, PK, and toxicology data please refer to the toripalimab Investigator's Brochure.

On December 27, 2018, toripalimab received marketing approval in China for the treatment of patients with advanced or metastatic melanoma who had failed 1st line therapy. The approved dose is toripalimab 3 mg/kg Q2W.

As of 16 December 2019, 26 Phase I-III clinical trials of toripalimab have been conducted in China and US. The summary of trials was shown in Figure 1. The safety profile observed with toripalimab is

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consistent with other PD-1 inhibitors. Please see the Investigator's Brochure for further information.



## 1.2 Overall of Clinical studies of Toripalimab

The clinical studies conducted with toripalimab have evaluated the efficacy and safety of toripalimab alone or toripalimab in combination with other drugs. As of Jan 30, 2021, there have been a total of 9 completed clinical studies and 24 ongoing clinical studies. It is estimated that 1546 subjects were exposed to Toripalimab, of which 1189 subjects were exposed to Toripalimab monotherapy and 358 subjects were exposed to Toripalimab combination therapy. It is estimated that 2128 subjects have been randomized to double blinded studies. In addition, approximately 1225 patients were enrolled in collaborative clinical studies sponsored by partners or investigator sponsored studies. For a complete list of completed, on- going and planned study list of company sponsored studies, please see Table 1.

**Table 1: Overview of ongoing and completed clinical studies with JS001 by Jan 30, 2021**

Study number	Study phase	Study population	Number of enrolled subjects Planned /actual	Study Status
Advanced solid tumors				
CT1	I	Advanced solid tumors	36 /36	Completed
CT2	I	Advanced solid tumors	12/25	Completed
CT3	I	Advanced solid tumors	36/33	Completed
Lymphoma				
CT6	I	Recurrent/refractory malignant lymphoma	12/13	Completed
Neuroendocrine tumor				
CT14	I	Advanced neuroendocrine tumor	40/40	Completed

Study number	Study phase	Study population	Number of enrolled subjects Planned /actual	Study Status
		after failure of standard of care		
Multiple types of tumor, multiple cohorts				
CT5	Ib/II	Advanced gastric adenocarcinoma, esophageal squamous cell carcinoma, nasopharyngeal carcinoma, and squamous cell carcinoma of head and neck	<p>Enrollment closed</p> <p>Monotherapy for nasopharyngeal carcinoma (180/190 subjects) Combined therapy for nasopharyngeal carcinoma (12/12 subjects)</p> <p>Monotherapy for esophageal squamous cell carcinoma (58/60 subjects) Combined therapy for esophageal squamous cell carcinoma (12/12 subjects)</p> <p>Monotherapy for gastric cancer (58/58 subjects) Combined therapy for gastric cancer (36/33 subjects)</p> <p>Monotherapy for squamous cell carcinoma of head and neck (30/34 subjects) Combined therapy for squamous cell carcinoma of head and neck (12/3 subjects)</p>	Follow up NPC arm under NDAs
Triple negative breast cancer				
CT9	I	Advanced triple Negative Breast Cancer	24/20 subjects	Completed
CT10	I	Advanced triple Negative Breast Cancer (combined with radiotherapy)	6/36 subjects	Enrollment ongoing
CT26	III	As 1st/2nd-line therapy for triple Negative Breast Cancer.	528/284	Enrollment ongoing
Melasma				
CT4	II	Locally advanced or metastatic melanoma	120/128 subjects	Completed

Study number	Study phase	Study population	Number of enrolled subjects Planned /actual	Study Status
		after failure of standard of care		
CT7-2	I	To examine the pharmacokinetic similarity before and after process change in patients with advanced melanoma	24/26 subjects	Completed
CT8	II	As adjuvant therapy for completely resected mucosal melanoma	Enrollment closed 145 subjects (73 subjects in JS001 group, 72 subjects in control group)	Follow up
CT13	I	Advanced melanoma (combined with Axitinib)	24/33 subjects	Data clean
CT17	III	As 1st-line therapy for unresectable or metastatic melanoma	230/168	Enrollment ongoing
CT43	III	As First-line Therapy in Patients with Unresectable, Locally Advanced or Metastatic Mucosal Melanoma	220	IND approved
Urothelial carcinoma				
CT12	II	Locally advanced or metastatic urothelial carcinoma after failure of standard of care	150/151	Follow up
Nasopharyngeal carcinoma				
CT15	III	As 1st-line therapy for nasopharyngeal carcinoma	280/289	Follow up
Esophageal cancer				
CT21	III	Systematic chemotherapy-naïve advanced or metastatic esophageal squamous cell carcinoma	500/514	Enrollment completed and follow up Follow up
HCC				
CT16	III	Post-operative adjuvant therapy for liver cancer	402/278	Enrollment ongoing

Study number	Study phase	Study population	Number of enrolled subjects Planned /actual	Study Status
CT20	Ib	As neoadjuvant therapy for hepatocellular carcinoma	40/20	Enrollment ongoing
CT27	III	As 1st-line therapy for advanced hepatocellular carcinoma(+Lev)	519/45	Enrollment ongoing
CT34	II	As 1st-line therapy for advanced hepatocellular carcinoma (+Bev)	50/50	Follow up
CT35	III	As 1st-line therapy for advanced hepatocellular carcinoma(+Bev)	280/1	Enrollment ongoing
NSCLC				
CT7-1	I	To examine the pharmacokinetic similarity before and after process change in patients with advanced NSCLC	30/41	Completed
CT18	II	EGFR mutation positive advanced NSCLC after failure of EGFR-TKI therapy	40 /40	Follow up
CT19	III	As 1st-line therapy for NSCLC (squamous cell carcinoma + adenocarcinoma)	450/465	Enrollment completed and follow up
CT25	III	As 1st-line therapy for NSCLC after failure of EGFR-TKI therapy	350/262	Enrollment ongoing
CT29	III	Perioperative systematic therapy for stage IIIA NSCLC	406/167	Enrollment ongoing
SCLC				
CT28	III	As 1st-line therapy for SCLC	420/310	Enrollment ongoing
GC				
CT33	II	Failed at least two prior lines of GC	100/1	Enrollment ongoing



Study number	Study phase	Study population	Number of enrolled subjects Planned /actual	Study Status
RCC				
CT36	III	As 1st-line therapy for RCC	380/54	Enrollment ongoing
UC				
CT38	III	As 1 <sup>st</sup> line therapy for Pd-L1+ UC	364/0	Enrollment ongoing
Clinical trial conducted in US				
TAB00 1-01	I	Advanced solid tumors	Enrollment ongoing	Enrollment ongoing

### 1.3 Proposed study of JS001

Two Phase II clinical trial for HNSCC and mCRC and three Phase III registration studies in ICC, EC and GC will be initiated in Q2 & Q3 in 2021 .

Study number	Study phase	Study population	Number of enrolled subjects Actual/planned	Study Status
CT37	II	head and neck squamous cell carcinoma (HNSCC)	40	IND stage
CT41	II	JS001 plus Anlotinib with or without chemo as first line in mCRC	208	IND stage
CT39	III	Intrahepatic cholangiocarcinoma ICC (1 <sup>st</sup> line) JS001+TKI/GEMOX	285	IND stage
CT42	III	EC (neoadjuvant and adjuvant)	500	IND stage
CT44	III	GC (neoadjuvant and adjuvant)	1000	IND stage

Note: The budget calculation is based on the ongoing and planned trials (listed in the above tables)

(Added)udget -Summary

Unit in USD (Exchange Rate: 1USD=6.5CNY)

Pipeline	Budget R&D Expnese (2021-2025 TBD)	TopAlliance Biosciences Inc. (US)	%	Shanghai Junshi Biosciences Co., Ltd.(CN)	Sum (USD)
JS001	2021	39,327,081.68	22%	137,449,703.19	176,776,784.87
	2022	39,327,081.68	23%	133,959,156.80	173,286,238.47
	2023	39,327,081.68	34%	76,499,909.43	115,826,991.11
	2024	13,109,027.23	12%	93,032,387.66	106,141,414.89
	2025	-	0%	12,918,247.45	12,918,247.45
	<b>Amount</b>		<b>131,090,272.25</b>		<b>453,859,404.53</b>
	<b>%</b>		<b>22%</b>	<b>78%</b>	<b>100%</b>

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**Schedule 10.2(d) Existing Patent Rights**

US Patent No. 10,066,013

US Patent No. 10,815,302

US Patent Application No. 17022719

PCT/CN2020/085046

CN2020100908290

CN202010090965X

CN2020100822088

CN2020108796448

CN2020108839123

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**Schedule 10.2(f)**  
**Option Patent Rights**

IL-2 Program: Certain Patent Rights are not owned by Junshi but are licensed to Junshi pursuant to the JS018-1 Upstream License.

JS006: PCT application No. PCT/CN2020/101883

JS018-1: PCT Application No. PCT/CN2020/070748 (licensed from Beijing Zhidao)

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**Schedule 10.2(g) Third Party Agreements**

JS001 Upstream License

JS018-1 Upstream License

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## STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (“*Agreement*”) is entered into as of February 2, 2021 (the “*Execution Date*”), by and between Shanghai Junshi Biosciences Co., Ltd., a company organized under the laws of the People’s Republic of China, having its place of business at Level 13, Building 2, Nos. 36 and 58, Hai Qu Road, China (Shanghai) Pilot Free Trade Zone, the PRC (“*Junshi*”), and Coherus BioSciences, Inc., a Delaware corporation having its principal place of business at 333 Twin Dolphin Drive, Suite 600 Redwood City, CA 94065 (“*Coherus*”). The capitalized terms used herein and not otherwise defined have the meanings given to them in Appendix 1.

## RECITALS

Coherus has agreed to sell, and Junshi has agreed to purchase, shares of Common Stock subject to and in accordance with the terms and provisions of this Agreement.

## AGREEMENT

For good and valuable consideration, the Parties agree as follows:

## Section 1. SALE AND PURCHASE OF STOCK

**1.1 Purchase of Stock.** Subject to the terms and conditions of this Agreement, at the Closing, Coherus will issue and sell to Junshi, and Junshi will purchase from Coherus 2,491,988 shares of Common Stock, which number of shares of Common Stock is equal to the quotient of (a) \$50,000,000 divided by (b) \$20.0643, being the daily weighted average price per share of the Common Stock on Nasdaq over the ten (10) trading day period ending on and including the last trading day prior to the execution date of the Collaboration Agreement (the “*Per Share Price*”), rounded down to the nearest whole number of shares of Common Stock, (the shares of Common Stock represented by such formula, the “*Shares*”) for an aggregate purchase price equal to \$50,000,000 (the “*Purchase Price*”).

**1.2 Payment.** At the Closing, Junshi will pay the Purchase Price by wire transfer of immediately available funds in accordance with wire instructions provided by Coherus to Junshi at least seven (7) Business Days prior to the Closing, and Coherus will deliver the Shares in book-entry form to Junshi upon receipt of the Purchase Price.

**1.3 Closing.**

(a) Closing. The closing of the transaction contemplated by Section 1.1 (the “*Closing*”) will be held within seven (7) Business Days after the conditions to closing set forth in Section 7 are satisfied or waived for the Closing (other than those conditions that by their nature are to be satisfied or waived at the Closing) or at such other time and/or date as may be jointly designated by Junshi and Coherus for the Closing.

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(b) Closing Deliverables.

(i) At the Closing, Coherus will deliver to Junshi:

(1) a duly executed cross-receipt for the Purchase Price in exchange for the issuance of the Shares in form and substance reasonably satisfactory to each party; and

(2) a certificate in form and substance reasonably satisfactory to Junshi and duly executed on behalf of Coherus by an authorized officer of Coherus, certifying that the conditions to Closing set forth in Section 7.2 have been fulfilled.

(ii) At the Closing, Junshi will deliver to Coherus:

(1) the Purchase Price by wire transfer of immediately available funds pursuant to Section 1.2;

(2) a duly executed cross-receipt for the Shares in exchange for the receipt of the Purchase Price; and

(3) a certificate in form and substance reasonably satisfactory to Coherus and duly executed on behalf of Junshi by an authorized officer of Junshi, certifying that the conditions to Closing set forth in Section 7.1 have been fulfilled.

(iii) As promptly as practicable following the Closing, Coherus will deliver to Junshi evidence from its transfer agent that the Shares have been issued to Junshi in book-entry form.

## **Section 2. REPRESENTATIONS AND WARRANTIES OF COHERUS**

Except as otherwise specifically contemplated by this Agreement, Coherus hereby represents and warrants to Junshi that:

**2.1 Private Placement; No General Solicitation.** Subject to the accuracy of the representations made by Junshi in Section 3, the offer, issuance and sale of the Shares to Junshi as contemplated hereby are exempt from the registration requirements of the Securities Act. Coherus has not engaged any brokers, finders, placement agents or other agents, or incurred, or will incur, directly or indirectly, any liability for brokerage or finder's or financial advisory fees or agents' commissions or any similar charges in connection with this Agreement and the transactions contemplated hereby. Coherus has not engaged in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) in connection with the offer or sale of the Shares.

**2.2 Organization and Qualification.** Each of Coherus and its subsidiaries is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, with full corporate, limited liability company or similar organizational power and authority to conduct its business as currently conducted. Each of Coherus and its subsidiaries is duly

qualified to do business and is in good standing in every jurisdiction in which the nature of the business conducted by it or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not reasonably be expected to have a Material Adverse Effect.

**2.3 Authorization; Enforcement.** Coherus has all requisite corporate power and authority to enter into and to perform its obligations under this Agreement, to consummate the transactions contemplated hereby and to issue the Shares in accordance with the terms hereof. The execution, delivery and performance of this Agreement by Coherus and the consummation by it of the transactions contemplated hereby (including the issuance of the Shares at the Closing in accordance with the terms hereof) have been duly authorized by the Board and no further consent or authorization of Coherus, the Board or its stockholders is required. This Agreement has been duly executed by Coherus and constitutes a legal, valid and binding obligation of Coherus enforceable against Coherus in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization or moratorium or similar laws affecting creditors' and contracting parties' rights generally, and except as enforceability may be subject to general principles of equity and except as rights to indemnity and contribution may be limited by state or federal securities laws or public policy underlying such laws.

**2.4 Issuance of Shares.** The Shares are duly authorized and, upon issuance in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, free and clear of all Liens (except for the restrictions set forth in this Agreement or under applicable securities laws) and will not be subject to preemptive rights or other similar rights of stockholders of Coherus.

**2.5 SEC Documents, Financial Statements.**

**(a)** The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act. Coherus has delivered or made available (by filing on the SEC's electronic data gathering and retrieval system (EDGAR)) to Junshi complete copies of its most recent Annual Report on Form 10-K and its most recent Quarterly Report on Form 10-Q, and any report on Form 8-K, in each case filed with the SEC after January 1, 2020 and prior to the Execution Date (the "**SEC Documents**"). As of its respective date, each SEC Document complied as to form in all material respects with the requirements of the Exchange Act and, as of its respective date, each SEC Document did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

**(b)** As of its respective date, the financial statements, together with the related notes and schedules, of Coherus included in the SEC Documents complied as to form in all material respects with all applicable accounting requirements and the published rules and regulations of the SEC and all other applicable rules and regulations with respect thereto. Such financial statements, together with the related notes and schedules, have been prepared in accordance with GAAP applied on a consistent basis during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto or (ii) in the case of unaudited interim statements, to the extent they may not include footnotes or may be condensed



or summary statements), and fairly present in all material respects the financial condition of Coherus and its consolidated subsidiaries as of the dates thereof and the results of operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments). Except as disclosed on or reflected or reserved against in, the financial statements, Coherus has not, and is not subject to any material liabilities of the type required to be disclosed in the financial statements, except (i) liabilities incurred in the ordinary course of business since the date of its most recent financial statements (none of which is resulting from a breach of contract, breach of warranty, tort, infringement, claim or lawsuit), (ii) liabilities that were incurred under any contract or agreement to which Coherus is a party (but, in each case, none of which resulted from a breach thereof), or (iii) liabilities incurred as a result of or arising out of the transactions contemplated under this Agreement.

(c) The Common Stock is listed on Nasdaq, and Coherus has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from Nasdaq. Coherus has not received any notification that, and has no knowledge that, the SEC or Nasdaq is contemplating terminating such registration or listing.

**2.6 Internal Controls; Disclosure Controls and Procedures.** Coherus maintains internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Coherus has implemented the “disclosure controls and procedures” (as defined in Rules 13a- 15(e) and 15d-15(e) under the Exchange Act) required in order for the principal executive officer and principal financial officer of Coherus to engage in the review and evaluation process mandated by the Exchange Act, and is in compliance with such disclosure controls and procedures in all material respects. Each of the principal executive officer and the principal financial officer of Coherus has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 with respect to all reports, schedules, forms, statements and other documents required to be filed by Coherus with the SEC after January 1, 2020. Since January 1, 2020, neither Coherus, nor, to Coherus’ knowledge, any of Coherus’ employees or independent auditors, has identified or been made aware of (a) any significant deficiency or material weakness (as defined in Rule 12b-2 under the Exchange Act) in the system of internal accounting controls utilized by Coherus, (b) any fraud, whether or not material, that involves Coherus’ management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by Coherus or (c) any claim or allegation regarding any of clauses (a) and (b), in each case, except to the extent disclosed in the SEC Documents.

## **2.7 Capitalization and Voting Rights**

(a) The authorized capital of Coherus as of the date hereof consists of: (i) 300,000,000 shares of Common Stock of which, as of January 23, 2021, (w) 72,681,383 shares were issued and outstanding, which excludes 1,833,640 shares of unvested restricted stock subject to repurchase, (x) 5,531,162 shares were available for future issuance pursuant to Coherus’s stock-based compensation plans, (y) 20,348,826 shares were issuable upon the exercise of stock options outstanding as of such date and (z) 16,416,023 shares were available for were issuable upon exercise of outstanding convertible notes issued by Coherus, and (ii)

5,000,000 shares of Preferred Stock, of which no shares are issued and outstanding. All of the issued and outstanding shares of Common Stock (A) have been duly authorized and validly issued, (B) are fully paid and non-assessable and (C) were issued in compliance with all applicable federal and state securities laws and not in violation of any preemptive rights.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(c) As of January 23, 2021, there were not any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which Coherus is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of Coherus other than options granted pursuant to its stock-based compensation plans, which plans are described in the SEC Documents.

(d) Except pursuant to this Agreement or as described in this Section 2.7, Coherus is not a party to or subject to any agreement or understanding relating to (i) the voting of shares of capital stock of Coherus or the giving of written consents by a stockholder or director of Coherus, (ii) the issuance, sale, transfer or other disposition of or the repurchase, redemption or other acquisition of the equity interests of Coherus, (iii) any preemptive right, right of participation, right of maintenance, right of first refusal or any similar right with respect to equity interests of Coherus, (iv) the registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any equity interest of Coherus.

(e) Except for customary adjustments as a result of stock dividends, stock splits, combinations of shares, reorganizations, recapitalizations, reclassifications or other similar events, there are no anti-dilution or price adjustment provisions contained in any equity interest issued by Coherus and the issuance and sale of the Shares will not obligate Coherus to issue shares of Common Stock or other equity interests to any Person (other than Junshi) and will not result in a right of any holder of securities to adjust the exercise, conversion, exchange or reset price under any equity interests.

(f) To Coherus' knowledge, except as set forth in the SEC Documents or any schedules filed with the SEC pursuant to Rule 13d-1 of the Exchange Act by reporting persons, no Person or group of related Persons "beneficially owns," or has the right to acquire, by agreement with or by obligation binding upon Coherus, "beneficial ownership" of in excess of five percent (5%) of the outstanding Common Stock. For the purpose of this Section 2.7(f), (a) the terms "beneficial own" and "beneficially ownership" will have meanings correlative to that of "beneficial owner" as determined in accordance with Rule 13d-3 under the Exchange Act.

## **2.8 No Conflicts; Government Consents and Permits.**

(a) The execution, delivery and performance of this Agreement by Coherus and the consummation by Coherus of the transactions contemplated hereby (including the issuance of the Shares) will not (i) conflict with or result in a violation of any provision of (a) Coherus's Certificate of Incorporation or Bylaws or (b) any organizational documents of any of its subsidiaries, (ii) violate or conflict with, or result in a breach of any provision of or constitute

a default under, any agreement, indenture or instrument to which Coherus or any of its subsidiaries is a party or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including United States federal and state securities laws and regulations and regulations of any self-regulatory organizations) applicable to Coherus any of its subsidiaries, except in the case of clauses (i)(b), (ii) and (iii) only, for such conflicts, breaches, defaults and violations as would not reasonably be expected to be, have a Material Adverse Effect or result in a liability for Junshi.

(b) Coherus is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self regulatory agency in order for it to execute, deliver or perform any of its obligations under this Agreement in accordance with the terms hereof, or to issue and sell the Shares in accordance with the terms hereof other than such as have been made or obtained, and except for (i) any post- signing filings required to be made under federal or state securities laws or (ii) any required filings or notifications regarding the issuance or listing of additional shares with Nasdaq.

**2.9 Litigation.** Other than as set forth in the SEC Documents filed prior to the Execution Date, there is no action, suit, proceeding or investigation pending (of which Coherus has received notice or otherwise has knowledge) or, to Coherus's knowledge, threatened, against Coherus or any of its subsidiaries or which Coherus or any of its subsidiaries intends to initiate, except where such action, suit, proceeding or investigation, as the case may be, would not reasonably be expected to have a Material Adverse Effect.

**2.10 Licenses and Other Rights; Compliance with Laws.** Each of Coherus and its subsidiaries has all franchises, permits, licenses and other rights and privileges ("**Permits**") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance would not reasonably be expected to have a Material Adverse Effect. Neither Coherus nor any of its subsidiaries has taken any action that would interfere with its ability to renew all such Permit(s) when required, except where the failure to renew such Permit(s) would not reasonably be expected to have a Material Adverse Effect. Each of Coherus and its subsidiaries is and has been in compliance with all laws applicable to its business, properties and assets, except where the failure to be in compliance has not been and would not reasonably be expected to be, material to Coherus and its subsidiaries, taken as a whole.

**2.11 Absence of Certain Changes.**

(a) Except as disclosed in the SEC Documents filed prior to the Execution Date, since September 30, 2020, no change or event has occurred, except where such change or event has not and would not reasonably be expected to have a Material Adverse Effect.

(b) Except as set forth in the SEC Documents filed prior to the Execution Date or as contemplated by this Agreement or the Collaboration Agreement, since September 30, 2020, Coherus has not (i) declared or paid any dividends, or authorized or made any distribution upon or with respect to any class or series of its capital stock, or (ii) sold, exchanged or otherwise disposed of any of its material assets or rights.

(c) Since September 30, 2020, neither Coherus nor any of its subsidiaries has (i) admitted in writing its inability to pay its debts generally as they become due, filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency act, made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, or had a petition in bankruptcy filed against it, been adjudicated bankrupt or filed a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws or any other laws of the United States or any other jurisdiction, (ii) experienced any loss, damage or destruction to, or any interruption in the use of, any of the assets of Coherus or its such subsidiary (whether or not covered by insurance) or incurred any material liabilities other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice, and (B) liabilities not required to be reflected in Coherus' financial statements pursuant to GAAP or required to be disclosed in filings made with the SEC, or (iii) altered its method of accounting or changed its auditors, except in the case of clauses (ii) and (iii) any such loss, damage, destruction, interruption or alteration that would not reasonably be expected to have a Material Adverse Effect.

**2.12 Not an Investment Company.** Coherus is not, and solely after receipt of the Purchase Price, will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.

**2.13 No Integration.** Coherus has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.

**2.14 Transactions With Affiliates.** Except as set forth in the SEC Documents filed prior to the Execution Date, none of the officers or directors of Coherus or any of its subsidiaries is presently a party to any transaction with Coherus or any of its subsidiaries (other than for ordinary course services as employees, officers or directors) that would be required to be reported on its Annual Report on Form 10-K.

**2.15 Manipulation of Price.** Coherus has not, and to Coherus' knowledge no one acting on its behalf has, since January 1, 2020 (a) taken, directly or indirectly, any action designed to cause or to result, or that would reasonably be expected to cause or result, in the stabilization or manipulation of the price of any security of Coherus to facilitate the sale or resale of any of the Shares, (b) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares, or (c) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of Coherus, in each case in violation of any federal or state securities law.

**2.16 Not a TID Business.** Coherus is not, and will not immediately following the Closing be, a "TID business" as defined in 31 C.F.R. § 800.248.

### Section 3. REPRESENTATIONS AND WARRANTIES OF JUNSHI

Except as otherwise specifically contemplated by this Agreement, Junshi hereby represents and warrants to Coherus that:

**3.1 Authorization; Enforcement.** Subject to the receipt of the PRC Approvals, Junshi (a) has the requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby, and (b) has taken all necessary corporate action to authorize the execution, delivery and performance of this Agreement. Upon the execution and delivery of this Agreement, this Agreement will constitute a valid and binding obligation of Junshi enforceable against Junshi in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally, and except as enforceability may be subject to general principles of equity and except as rights to indemnity and contribution may be limited by state or federal securities laws or public policy underlying such laws.

#### **3.2 No Conflicts; Government Consents and Permits.**

(a) The execution, delivery and performance of this Agreement by Junshi and the consummation by Junshi of the transactions contemplated hereby (including the purchase of the Shares) will not (i) conflict with or result in a violation of any provision of Junshi's articles of association, (ii) violate or conflict with, or result in a breach of any provision of, or constitute a default under, any agreement, indenture or instrument to which Junshi is a party or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including United States federal and state securities laws and regulations and regulations of any self-regulatory organizations) applicable to Junshi, except in the case of clauses (ii) and (iii) only, for such conflicts, breaches, defaults and violations as would not reasonably be expected to affect the ability of Junshi to consummate the transactions contemplated hereby or perform its obligations hereunder or result in a liability for Coherus.

(b) Junshi is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self regulatory agency in order for it to execute, deliver or perform any of its obligations under this Agreement in accordance with the terms hereof, or to purchase the Shares in accordance with the terms hereof other than such as have been made or obtained, except for any consent required under the PRC Approvals.

**3.3 Investment Purpose.** Junshi is purchasing the Shares for its own account and not with a present view toward the public distribution thereof and has no arrangement or understanding with any other persons regarding the distribution of the Shares. Junshi will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the Shares except in accordance with the Securities Act and to the extent permitted by Section 6.1 and Section 6.2.

**3.4 Reliance on Exemptions.** Junshi understands that Coherus intends for the Shares to be offered and sold to it in reliance upon specific exemptions from the registration

requirements of United States federal and state securities laws and that Coherus is relying upon the truth and accuracy of, and Junshi's compliance with, the representations, warranties, agreements, acknowledgments and understandings of Junshi set forth herein in order to determine the availability of such exemptions and the eligibility of Junshi to acquire the Shares.

**3.5 Accredited Investor; Access to Information.** Junshi is an "accredited investor" as defined in Regulation D under the Securities Act and is knowledgeable, sophisticated and experienced in making, and is qualified to make, decisions with respect to investments in shares presenting an investment decision like that involved in the purchase of the Shares. Junshi has been furnished with materials relating to the offer and sale of the Shares that have been requested by Junshi, including Coherus's SEC Documents, and Junshi has had the opportunity to review the SEC Documents. Junshi has been afforded the opportunity to ask questions of Coherus.

**3.6 Brokers and Finders.** No person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon Coherus for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of Junshi.

**3.7 Governmental Review.** Junshi understands that no United States federal or state agency or any other government or governmental agency has passed upon or made any recommendation or endorsement of the Shares or an investment therein.

#### **Section 4. STANDSTILL AGREEMENT.**

**4.1** Prior to the three (3) year anniversary of the Closing Date (the "**Standstill Period**"), Junshi and its Affiliates will not, directly or indirectly, except as expressly approved or invited by Coherus:

(a) effect or seek, offer or propose (whether publicly or otherwise) to effect, or cause or participate in or in any way advise, assist or encourage any other person to effect or seek, offer or propose (whether publicly or otherwise) to effect or participate in, (i) any acquisition of any securities (or beneficial ownership thereof) or material assets of Coherus, (ii) any tender or exchange offer, merger or other business combination involving Coherus, (iii) any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to Coherus or (iv) any "*solicitation*" of "*proxies*" (as such terms are used in the proxy rules of the SEC) or consents to vote any voting securities of Coherus;

(b) form, join or in any way participate in a "*group*" (as defined under the Exchange Act) with respect to any securities of Coherus;

(c) otherwise act, alone or in concert with others, to seek to control or influence the management, Board or policies of Coherus;

(d) take any action that would reasonably be expected to require Coherus to make a public announcement regarding any of the types of matters set forth in clause (a) above; or

(e) enter into any discussions or arrangements with any person with respect to any of the foregoing.

4.2 Junshi also agrees during the Standstill Period not to request Coherus (or its representatives), directly or indirectly, to amend or waive any provision of this Section 4, other than by means of a confidential communication to the Coherus Chairman of the Board or Chief Executive Officer; provided that such communication will not require public disclosure. Junshi represents and warrants that, as of the Execution Date, neither Junshi nor any of its Affiliates owns, of record or beneficially, any voting securities of Coherus, or any securities convertible into or exercisable for any voting securities of Coherus.

4.3 Notwithstanding the provisions set forth in Sections 4.1 and 4.2 (the “**Standstill Provisions**”), Junshi shall immediately, and without any other action by Coherus, be released from its obligations under the Standstill Provisions if: (a) Coherus executes a definitive agreement with a third party providing for an acquisition (by way of merger, tender offer or otherwise), of more than 50% of Coherus’s outstanding Common Stock or all or substantially all of Coherus’s assets or (b) a third party commences a tender offer seeking to acquire beneficial ownership of more than 50% of Coherus’s outstanding Common Stock and the Board recommends that the stockholders tender their Common Stock in such tender offer.

### **Section 5. VOTING AGREEMENT.**

5.1 If the Proxyholder instructs Junshi in writing to vote in favor of, or against, any matter, action, ratification or other event for which approval of the holders of Coherus’s stock is sought (either by vote or written consent) or upon which such holders are otherwise entitled to vote, including the election of directors, but excluding any Extraordinary Matter (collectively, a “**Coherus Stockholder Matter**”), then Junshi will (i) after receiving proper notice of any meeting of stockholders of Coherus related to such Coherus Stockholder Matter (or, if no notice is required or such notice is properly waived, after notice from the Proxyholder is given), be present, in person or by proxy, as a holder of Shares at all such meetings and be counted for the purposes of determining the presence of a quorum at such meetings and (ii) vote (in person, by proxy or by action by written consent, as applicable) all Shares as to which Junshi has beneficial ownership or as to which Junshi otherwise exercises voting or dispositive authority in the manner directed by the Proxyholder.

5.2 Extraordinary Matters. Junshi may vote or execute a written consent with respect to, any or all of the voting securities of Coherus as to which they are entitled to vote or execute a written consent, as it may determine in its sole discretion, with respect to the following matters, if presented to Coherus’s stockholders for approval (each such matter being an “**Extraordinary Matter**”):

- (i) any transaction which would result in a Change of Control of Coherus;
- (ii) the payment of any dividends to any class of stockholders of Coherus;

(iii) any matter relating to or arising from the transactions contemplated by the Collaboration Agreement; or

(iv) any liquidation or dissolution of Coherus.

**5.3 Appointment of Proxy.** To secure Junshi's obligations to vote the Shares in accordance with this Agreement and to comply with the other terms hereof, Junshi hereby appoints the Proxyholder, or his designees, as Junshi's true and lawful proxy and attorney, with the power to act alone and with full power of substitution, to vote or act by written consent with respect to all of Junshi's Shares in accordance with the provisions set forth in this Agreement, and to execute all appropriate instruments consistent with this Agreement on behalf of Junshi. The proxy and power granted by Junshi pursuant to this Section 5 are coupled with an interest and are given to secure the performance of Junshi's duties under this Agreement. Each such proxy and power will be irrevocable until the agreements contained in this Section 5 expire in accordance with Section 5.5. The proxy and power will survive the merger, consolidation, conversion or reorganization of Junshi or any other entity holding any Shares (other than any Shares sold by Junshi in compliance with Section 6). For the avoidance of doubt, the proxy granted by this Section 5 shall not apply to any Extraordinary Matter.

**5.4 No Revocation.** The voting agreements contained in this Section 5 are coupled with an interest and may not be revoked prior to their expiration in accordance with Section 5.5.

**5.5 Expiration.** The agreements contained in this Section 5 will expire (i) in part, solely with respect to any Shares sold by Junshi in an arm's length sale to a non-Affiliate in compliance with this Agreement upon the execution of the sale of such Shares, and (ii) as a whole on the earlier of (a) the three (3) year anniversary of the Closing Date and (b) the date the Collaboration Agreement is terminated; provided, however, that in no event shall such expiration date be prior to the one-year anniversary of the Closing Date. For the avoidance of doubt, the agreements contained in this Section 5 shall not limit Junshi's ability to transfer or resell any Shares, provided that such transfers or resales are done in accordance with Section 6.

## **Section 6. TRANSFER, RESALE, LEGENDS.**

**6.1 Transfer or Resale.** Junshi understands that:

(a) the Shares have not been and are not being registered under the Securities Act or any applicable state securities laws and, consequently, Junshi may have to bear the risk of owning the Shares for an indefinite period of time because the Shares may not be transferred unless (i) the resale of the Shares is registered pursuant to an effective registration statement under the Securities Act; (ii) Junshi has delivered to Coherus an opinion of counsel (in form, substance and scope customary for opinions of counsel in comparable transactions) to the effect that the Shares to be sold or transferred may be sold or transferred pursuant to an exemption from such registration; or (iii) the Shares are sold or transferred pursuant to Rule 144; and

(b) any sale of the Shares made in reliance on Rule 144 may be made only in accordance with the terms of Rule 144 and, if Rule 144 is not applicable, any resale of the Shares under circumstances in which the seller (or the person through whom the sale is made) may be



deemed to be an underwriter (as that term is defined in the Securities Act) may require compliance with some other exemption under the Securities Act or the rules and regulations of the SEC thereunder.

**6.2 Lock-Up.** Junshi agrees that it will hold and will not sell any of the Shares (or otherwise make any short sale of, grant any option for the purchase of or enter into any hedging or similar transaction with the same economic effect as a sale of the Shares) until the earlier of (a) the day following the two (2) year anniversary of the Closing Date and (b) the date the Collaboration Agreement is terminated (the “**Holding Period**”). In addition, after the expiration of the Holding Period, in any single trading day Junshi will not (i) sell an amount of Shares that exceeds 5% of the average daily trading volume of the Common Stock on Nasdaq over the five (5) trading day period ending on the trading day immediately prior to such trading date (the “**Volume Limitation**”) or (ii) knowingly sell, and will instruct its broker not to sell, any Shares to a Competitor (unless the identity of the purchaser is not known to Junshi or the broker). Notwithstanding the foregoing, this Section 6.2 will not preclude, and the Volume Limitation shall not apply to, sales of Shares by Junshi to a third party pursuant to a tender offer made by such third party.

**6.3 Legends.** Junshi understands the Shares will bear a restrictive legend in substantially the following form (and a stop-transfer order may be placed against transfer of the Shares):

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

If such Shares may be transferred pursuant to Section 6.2, Junshi may request that Coherus remove, and Coherus agrees to authorize and instruct (including by causing any required legal opinion to be provided) the removal of any legend from the Shares, if permitted by applicable securities law, within two (2) Business Days of any such request; provided, however, each party will be responsible for any fees it incurs in connection with such request and removal.

## **Section 7. CONDITIONS TO CLOSING**

**7.1 Conditions to Obligations of Coherus.** Coherus’s obligation to complete the purchase and sale of the Shares and deliver the Shares to Junshi is subject to the fulfillment or waiver of the following conditions at or prior to the Closing:

(a) Representations and Warranties. The representations and warranties made by Junshi in Section 3 will be true and correct in all material respects as of the Closing Date,

except to the extent such representations and warranties are made as of another date, in which case such representations and warranties will be true and correct in all material respects as of such other date.

(b) Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by Junshi on or prior to the Closing Date shall have been performed or complied with in all material respects.

(c) Absence of Litigation. No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, will have been instituted or be pending before any court, arbitrator, governmental body, agency or official.

(d) No Governmental Prohibition. The sale of the Shares by Coherus and the purchase of the Shares by Junshi will not be prohibited by any applicable law or governmental order or regulation or by any Governmental Authority.

(e) PRC Approvals. The PRC Approvals shall have been obtained and shall remain valid.

(f) Collaboration Agreement. Junshi shall have duly executed and delivered the Collaboration Agreement to Coherus, and subject to execution by Junshi, such agreement shall be in full force and effect pursuant to its terms.

(g) Closing Deliverables. All closing deliverables as required under Section 1.3(b) shall have been delivered by Junshi to Coherus.

**7.2 Conditions to Junshi's Obligations at the Closing.** Junshi's obligation to complete the purchase and sale of the Shares is subject to the fulfillment or waiver of the following conditions at or prior to the Closing:

(a) Representations and Warranties. The representations and warranties made by Coherus in Section 2 will be true and correct in all material respects as of the Closing Date, except to the extent such representations and warranties are made as of another date, in which case such representations and warranties will be true and correct in all material respects as of such other date.

(b) Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by Coherus on or prior to the Closing Date shall have been performed or complied with in all material respects.

(c) Transfer Agent Instructions. Coherus will have delivered to its transfer agent irrevocable written instructions to issue the Shares to Junshi in a form and substance acceptable to such transfer agent.

(d) Nasdaq Qualification. The Shares will be duly authorized for listing by Nasdaq, subject to official notice of issuance.

(e) Absence of Litigation. No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, will have been instituted or be pending before any court, arbitrator, governmental body, agency or official.

(f) PRC Approvals. The PRC Approvals shall have been obtained and shall remain valid.

(g) Collaboration Agreement. Coherus shall have duly executed and delivered the Collaboration Agreement to Junshi, and subject to execution by Coherus, (i) such agreement shall be in full force and effect pursuant to its terms, and (ii) the Upfront Payment (as defined in the Collaboration Agreement) shall have been fully paid by Coherus pursuant to its terms.

(h) No Governmental Prohibition. The sale of the Shares by Coherus, and the purchase of the Shares by Junshi will not be prohibited by any applicable law or governmental order or regulation or by any Governmental Authority.

(i) Closing Deliverables. All closing deliverables as required under Section 1.3(b) shall have been delivered by Coherus to Junshi.

## **Section 8. TERMINATION.**

**8.1** Ability to Terminate. This Agreement may be terminated:

(a) at any time by mutual written consent of Coherus and Junshi;

(b) by Coherus, upon written notice to Junshi, so long as Coherus is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1, as applicable, could not be satisfied by the Termination Date, (i) upon a breach of any covenant or agreement on the part of Junshi set forth in this Agreement or (ii) if any representation or warranty of Junshi shall have been or become untrue, in each case such that any of the conditions set forth in Section 7.1 could not be satisfied by the Termination Date;

(c) by Junshi, upon written notice to Coherus, so long as Junshi is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.2, as applicable, could not be satisfied by the Termination Date, (i) upon a breach of any covenant or agreement on the part of Coherus set forth in this Agreement, or (ii) if any representation or warranty of Coherus shall have been or become untrue, in each case such that any of the conditions set forth in Section 7.2 could not be satisfied by the Termination Date.

(d) by either Coherus or Junshi, upon written notice to the other, if the Closing has not occurred on or before the date six (6) months after the Execution Date (the "**Termination Date**"). In such event, neither party shall have any further obligations under this Agreement.

**8.2 Automatic Termination.** In the event that the Collaboration Agreement is terminated prior to the Closing Date, this Agreement shall terminate automatically.

**8.3 Effect of Termination.** In the event of the termination of this Agreement pursuant to Section 8.1 or Section 8.2, (a) this Agreement (except for this Section 8.3 and Section 9, and any definitions set forth in this Agreement and used in such Sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (b) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 8.3 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

## **Section 9. GOVERNING LAW; MISCELLANEOUS.**

**9.1 Governing Law; Jurisdiction.** This Agreement will be governed by and interpreted in accordance with the laws of the State of Delaware without regard to the principles of conflict of laws.

**9.2 Market Listing.** Coherus shall use reasonable best efforts to (a) maintain the listing and trading of the Common Stock on Nasdaq and (b) effect the listing of the Shares on Nasdaq.

**9.3 CFIUS.** Notwithstanding anything to the contrary in this Agreement, the Collaboration Agreement or any other agreement between the parties, Junshi shall neither be permitted nor seek (a) control rights (as defined in 31 C.F.R. § 800.208) in respect of Coherus or any Coherus subsidiary; (b) membership or observer rights on, or the right to nominate an individual to a position on, the Board or equivalent governing body of any Coherus subsidiary; (c) access to any material nonpublic technical information (as defined at 31 C.F.R. § 800.232) in the possession of Coherus or any Coherus subsidiary; or (d) any involvement, other than through voting of shares, in substantive decision making of Coherus or any Coherus subsidiary regarding: (i) the use, development, acquisition, safekeeping, or release of sensitive personal data of U.S. citizens (as defined at 31 C.F.R. § 800.241) maintained or collected by Coherus or any Coherus subsidiary; (ii) the use, development, acquisition, or release of critical technologies (as defined at 31 C.F.R. § 800.215); or (iii) the management, operation, manufacture, or supply of covered critical infrastructure, in each case of (b)-(d), within the meaning of 31 C.F.R. § 800.211(b). Junshi hereby waives any such rights to which it may be entitled under this Agreement, the Collaboration Agreement or any other agreement between the parties or otherwise, including any statutory rights to such information as a stockholder of Coherus.

**9.4 PRC Approvals.** Junshi shall, (a) as promptly as practicable following the date hereof (but in any event within ten (10) Business Days after the date of this Agreement), file all documentation necessary to be filed with MOFCOM and NDRC in connection with the PRC Approvals, and (b) within five (5) Business Days after Junshi obtains the necessary approval from MOFCOM and NDRC (whichever is later) in connection with the PRC Approvals, file the documentation necessary to be filed with a bank designated to handle the foreign exchange

affairs for the transaction contemplated hereunder in connection with the PRC Approval by SAFE. Junshi shall (i) use its reasonable best efforts to take all actions required by law and otherwise reasonably necessary to obtain the PRC Approvals as promptly as practicable; (ii) provide Coherus with reasonable opportunity to review and comment on any written submissions, which comments will be considered in good faith; and (iii) keep Coherus reasonably apprised of the status of inquiries from, and communications with, any Governmental Authority with respect to the PRC Approvals.

**9.5 Counterparts; Electronic Signatures.** This Agreement may be executed in two counterparts, both of which are considered one and the same agreement and will become effective when the counterparts have been signed by each party and delivered to the other party hereto. This Agreement, once executed by a party, may be delivered to the other party hereto by electronic PDF of a copy of this Agreement bearing the signature of the party so delivering this Agreement.

**9.6 Headings.** The headings of this Agreement are for convenience of reference only, are not part of this Agreement and do not affect its interpretation.

**9.7 Severability.** If any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

**9.8 Entire Agreement; Amendments.** This Agreement (including any schedules and exhibits hereto) and the Collaboration Agreement constitute the entire agreement between the parties hereto with respect to the subject matter hereof and thereof. There are no restrictions, promises, warranties or undertakings, other than those set forth or referred to herein or therein. This Agreement (including any schedules and exhibits hereto) and the Collaboration Agreement supersede all prior agreements and understandings between the parties hereto with respect to the subject matter hereof. No provision of this Agreement may be waived or amended other than by an instrument in writing signed by the party to be charged with enforcement. Any amendment or waiver effected in accordance with this Section 9.8 will be binding upon Junshi and Coherus.

**9.9 Notices.** All notices required or permitted hereunder will be in writing and will be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed email if sent during normal business hours of the recipient, if not, then on the next Business Day, or (c) one Business Day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. The addresses for such communications are:

If to Coherus, addressed to:

Coherus BioSciences, Inc.  
333 Twin Dolphin Drive, Suite 600  
Redwood City, CA 94065  
Attention: Chief Executive Officer  
E-mail: DML152@coherus.com

with a copy to:

Coherus BioSciences, Inc.  
333 Twin Dolphin Drive, Suite 600  
Redwood City, CA 94065  
Attention: Chief Legal Officer  
E-mail: tfitzpatrick@coherus.com

Ropes & Gray LLP  
800 Boylston Street  
Prudential Tower  
Boston, Massachusetts 02199  
Attention: Zachary R. Blume  
E-mail: Zachary.Blume@ropesgray.com

If to Junshi, addressed to:

Shanghai Junshi Biosciences Co., Ltd.  
Level 13, Building 2, Nos. 36 and 58, Hai Qu  
Road  
Shanghai, China 201203  
Attention: CEO

And to:

Shanghai Junshi Biosciences Co., Ltd.  
Level 13, Building 2, Nos. 36 and 58, Hai Qu  
Road  
Shanghai, China 201203  
Attention: Board Secretary, Securities Department

with a copy to:

Jones Day  
51 Louisiana Avenue, N.W.  
Washington, DC 20001  
Attention: Daniel J. Michaels  
E-mail: dmichaels@jonesday.com

**9.10 Successors and Assigns.** This Agreement is binding upon and inures to the benefit of the parties and their successors and assigns. Coherus will not assign this Agreement or any rights or obligations hereunder without the prior written consent of Junshi, and Junshi will not assign this Agreement or any rights or obligations hereunder without the prior written consent of Coherus; provided, however, that Junshi may assign this Agreement together with all of the Shares it then owns (subject to Section 4, Section 5 and Section 6) to any wholly-owned subsidiary and any such assignee may assign the Agreement together with all of the Shares it then owns (subject to Section 4, Section 5 and Section 6) to Junshi or any other subsidiary wholly-owned by Junshi, in any such case, without such consent provided that the assignee agrees to assume Junshi's obligations under Section 4, Section 5 and Section 6 of this Agreement.

**9.11 Third Party Beneficiaries.** This Agreement is intended for the benefit of the parties hereto, their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

**9.12 Further Assurances; Survival.** Each party will do and perform, or cause to be done and performed, all such further acts and things, and will execute and deliver all other agreements, certificates, instruments and documents, as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby. The provisions of this Agreement will survive termination.

**9.13 No Strict Construction.** The language used in this Agreement is deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against a party.

**9.14 Equitable Relief.** Coherus recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to Junshi. Coherus therefore agrees that Junshi is entitled to seek temporary and permanent injunctive relief or specific performance in any such case. Junshi also recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to Coherus. Junshi therefore agrees that Coherus is entitled to seek temporary and permanent injunctive relief or specific performance in any such case.

**9.15 Expenses.** Coherus and Junshi are each liable for, and will pay, their own expenses incurred in connection with the negotiation, preparation, execution and delivery of this Agreement, including attorneys' and consultants' fees and expenses.

[Remainder of page intentionally left blank.]

**IN WITNESS WHEREOF**, Junshi and Coherus have caused this Agreement to be duly executed as of the date first above written.

**COHERUS BIOSCIENCES, INC.**

By: /s/ Dennis M. Lanfear  
Name: Dennis M. Lanfear  
Title: Chairman & Chief Executive

**SHANGHAI JUNSHI BIOSCIENCES CO., LTD.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

[Signature page to Stock Purchase Agreement]

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**IN WITNESS WHEREOF**, Junshi and Coherus have caused this Agreement to be duly executed as of the date first above written.

**COHERUS BIOSCIENCES, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**SHANGHAI JUNSHI BIOSCIENCES CO., LTD.**

By: /s/ Ning Li  
Name: Ning Li  
Title: CEO

[Signature page to Stock Purchase Agreement]

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## APPENDIX 1

### DEFINED TERMS

**“Affiliate”** means with respect to any Person, any Person controlling, controlled by or under common control with such first Person. For purposes of this definition, “control” means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such laws; provided, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

**“Board”** means the board of directors of Coherus.

**“Business Day”** means any day other than a Saturday or a Sunday on which the banks in New York, New York, Shanghai, the PRC and the Hong Kong Special Administrative Region are open for business.

**“Change of Control”** means, with respect to a party, any of the following events occurring after the Closing Date: (a) any “person” or “group” (as such terms are defined below) (i) is or becomes the “beneficial owner” (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (**“Voting Stock”**) of such party representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such party or (ii) has the power, directly or indirectly, to elect a majority of the members of the party’s board of directors, or similar governing body; (b) such party enters into a merger, consolidation or similar transaction with another person (whether or not such party is the surviving entity), and as a result of such merger, consolidation or similar transaction (i) the members of the board of directors of such party immediately prior to such transaction constitute less than a majority of the members of the board of directors of such party or such surviving Person immediately following such transaction or (ii) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such party representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person or the ultimate parent entity of such surviving Person in substantially the same proportions as their ownership of Voting Stock of such party immediately prior to such transaction; (c) such party sells or transfers to any third party, in one (1) or more related transactions, properties or assets representing all or substantially all of such party’s consolidated total assets; or (d) the holders of capital stock of such party approve a plan or proposal for the liquidation or dissolution of such party. For the purpose of this definition of Change of Control: (a) “person” and “group” have the meanings given such terms under Section 13(d) and 14(d) of the Exchange Act and the term “group” includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the exchange Act; (b) a “beneficial owner” will be determined in accordance with Rule

13d-3 under the Exchange Act; and (c) the terms “beneficially owned” and “beneficially own” will have meanings correlative to that of “beneficial owner.”

“**Closing Date**” means the date on which the Closing actually occurs.

“**Coherus’ knowledge**” means the actual knowledge of Coherus’s Chief Executive Officer or Chief Financial Officer.

“**Collaboration Agreement**” means that certain Exclusive License and Commercialization Agreement, dated February 1, 2021, by and between Coherus and Junshi.

“**Common Stock**” means shares of Coherus’s common stock, par value \$0.0001 per share.

“**Competitor**” means any operating company with a biopharmaceutical business, or any other Person that directly or indirectly beneficially owns a majority of the voting securities of or voting interests in such a company, or any direct or indirect majority-owned subsidiary of such a company or of such a Person.

“**DOJ**” means the U.S. Department of Justice.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC thereunder.

“**FTC**” means the United States Federal Trade Commission or any successor agency thereto.

“**GAAP**” means generally accepted accounting principles in the United States of America as applied by Coherus.

“**Governmental Authority**” means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government and including any stock exchange on which the shares of Coherus or Junshi are listed.

“**Lien**” means any lien, charge, claim, security interest, encumbrance, right of first refusal or other restriction.

“**Material Adverse Effect**” means any change, effect or circumstance, individually or in the aggregate, (a) the business, properties or financial condition of Coherus and its subsidiaries on a consolidated basis, or (b) Coherus’s ability to issue the Shares hereunder; provided that none of the following shall be taken into account in determining whether there is a Material Adverse Effect: (i) any change in the market price or trading volume of Coherus’s stock; (ii) any event, circumstance, change or effect in the industries in which Coherus or its subsidiaries operates or the United States or European economy generally, in financial markets or in political conditions generally; (iii) any act of terrorism, military action or war (whether or not declared), national or international calamity or similar event, any natural disasters, acts of God or comparable events,

epidemic, pandemic or disease outbreak (including the COVID-19 virus), or any escalation or worsening thereof; (iv) any event, circumstance, change or effect arising from or relating to any change in legal requirements or GAAP (or interpretations of any legal requirements thereof); (v) any study results from clinical trials or preclinical/non-clinical trials of Coherus's drug candidates; or (vi) any change or effect attributable to the consummation of the transactions contemplated hereby, or the public announcement of the execution of, this Agreement (provided any such public announcement is not in breach of this Agreement or the Collaboration Agreement); provided, further that the exceptions set forth in clauses (i)-(iv) shall only apply to the extent that the effect of the event, circumstance, change or effect is not disproportionately more adverse to Coherus and its subsidiaries in any material respect, taken as a whole, than the effect of the change on comparable businesses or companies in the industry in which Coherus and its subsidiaries operate.

**"MOFCOM"** means the Ministry of Commerce of the PRC or its competent local counterparts.

**"Nasdaq"** means The Nasdaq Global Select Market.

**"NDRC"** means the National Development and Reform Commission of the PRC or its competent local counterparts.

**"Person"** means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

**"PRC"** means the People's Republic of China, but solely for purposes of this Agreement, excluding the Hong Kong Special Administrative Region, the Macau Special Administrative Region and the Islands of Taiwan.

**"PRC Approvals"** means (a) the issuance of a certificate of outbound investment by enterprises by MOFCOM, (b) the approval by NDRC pursuant to the Measures for the Administration of Overseas Investment of Enterprises (Order of the National Development and Reform Commission (No. 11)) (《企业境外投资管理办法》(国家发展和改革委员会令第11号)),

(c) the approval or consent by SAFE, and pursuant to any other applicable PRC laws and regulations, in each case of (a)-(c), with respect to the transactions contemplated hereby.

**"Preferred Stock"** means shares of Coherus's preferred stock, par value \$0.0001 per share.

**"Proxyholder"** means Coherus and its Chief Executive Officer in his capacity as an officer of Coherus.

**"SAFE"** means the State Administration of Foreign Exchange of the PRC (or its competent local counterparts).

**"SEC"** means the United States Securities and Exchange Commission or any successor entity.

**"Securities Act"** means the Securities Act of 1933, as amended, and the rules and regulations of the SEC thereunder.

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO  
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Dennis M. Lanfear, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, 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 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 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: May 6, 2021

/s/ Dennis M. Lanfear

Dennis M. Lanfear

President and Chief Executive Officer

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO  
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, McDavid Stilwell, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, 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 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 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: May 6, 2021

/s/ McDavid Stilwell  
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McDavid Stilwell  
Chief Financial Officer

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**CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Quarterly Report of Coherus BioSciences, Inc. on Form 10-Q for the quarterly period ended March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.

Date: May 6, 2021

By: /s/ Dennis M. Lanfear  
Name: Dennis M. Lanfear  
Title: President and Chief Executive Officer

Date: May 6, 2021

By: /s/ McDavid Stilwell  
Name: McDavid Stilwell  
Title: Chief Financial Officer

*A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.*

*This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.*

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