

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2022

OR

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

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

Commission File Number: 001-38582

**Allakos Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**825 Industrial Road, Suite 500**  
**San Carlos, California**  
(Address of principal executive offices)

**45-4798831**  
(I.R.S. Employer  
Identification No.)

**94070**  
(Zip Code)

**975 Island Drive, Suite 201**  
**Redwood City, California 94065**  
(Former name, former address and former fiscal year, if changed since last report)

**(650) 597-5002**

**Registrant's telephone number, including area code**

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001	ALLK	The Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 May 2, 2022, the registrant had 54,776,915 shares of common stock outstanding.

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## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements (unaudited).

**ALLAKOS INC.**  
**BALANCE SHEETS**  
(in thousands, except per share data)

	March 31, 2022 (unaudited)	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,294	\$ 152,822
Investments in marketable securities	210,407	271,416
Prepaid expenses and other current assets	11,466	27,343
Total current assets	258,167	451,581
Property and equipment, net	43,933	43,100
Operating lease right-of-use assets	31,294	31,707
Other long-term assets	12,389	8,436
Total assets	\$ 345,783	\$ 534,824
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 9,128	\$ 13,692
Accrued expenses and other current liabilities	28,424	26,557
Total current liabilities	37,552	40,249
Operating lease liabilities, net of current portion	48,355	49,099
Total liabilities	85,907	89,348
Contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 20,000 shares authorized as of March 31, 2022 and December 31, 2021; no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value per share; 200,000 shares authorized as of March 31, 2022 and December 31, 2021; 54,761 and 54,622 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	54	54
Additional paid-in capital	1,070,138	1,058,399
Accumulated other comprehensive loss	(469)	(153)
Accumulated deficit	(809,847)	(612,824)
Total stockholders' equity	259,876	445,476
Total liabilities and stockholders' equity	\$ 345,783	\$ 534,824

*See accompanying notes to unaudited interim financial statements*

**ALLAKOS INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(in thousands, except per share data)  
(unaudited)

	Three Months Ended	
	March 31,	
	2022	2021
Operating expenses		
Research and development	\$ 176,807	\$ 38,915
General and administrative	18,844	16,670
Total operating expenses	195,651	55,585
Loss from operations	(195,651)	(55,585)
Interest income	83	130
Other expense, net	(1,455)	(103)
Net loss	(197,023)	(55,558)
Unrealized gain (loss) on marketable securities	(316)	80
Comprehensive loss	\$ (197,339)	\$ (55,478)
Net loss per common share:		
Basic and diluted	\$ (3.60)	\$ (1.04)
Weighted-average number of common shares outstanding:		
Basic and diluted	54,686	53,186

*See accompanying notes to unaudited interim financial statements*

**ALLAKOS INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands)  
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2021</b>	54,622	\$ 54	\$ 1,058,399	\$ (153)	\$ (612,824)	\$ 445,476
Stock-based compensation expense	—	—	11,392	—	—	11,392
Issuance of common stock upon exercise of stock options	34	—	104	—	—	104
Issuance of common stock upon 2018 ESPP purchase	42	—	243	—	—	243
Issuance of common stock upon vesting of restricted stock units	63	—	—	—	—	—
Unrealized loss on marketable securities	—	—	—	(316)	—	(316)
Net loss	—	—	—	—	(197,023)	(197,023)
<b>Balance at March 31, 2022</b>	<u>54,761</u>	<u>\$ 54</u>	<u>\$ 1,070,138</u>	<u>\$ (469)</u>	<u>\$ (809,847)</u>	<u>\$ 259,876</u>

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2020</b>	53,081	\$ 53	\$ 997,298	\$ 8	\$ (342,964)	\$ 654,395
Stock-based compensation expense	—	—	12,354	—	—	12,354
Issuance of common stock upon exercise of stock options	321	—	3,788	—	—	3,788
Issuance of common stock upon 2018 ESPP purchase	17	—	995	—	—	995
Issuance of common stock upon vesting of restricted stock units	38	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	80	—	80
Net loss	—	—	—	—	(55,558)	(55,558)
<b>Balance at March 31, 2021</b>	<u>53,457</u>	<u>\$ 53</u>	<u>\$ 1,014,435</u>	<u>\$ 88</u>	<u>\$ (398,522)</u>	<u>\$ 616,054</u>

*See accompanying notes to unaudited interim financial statements*

**ALLAKOS INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

	Three Months Ended	
	March 31,	
	2022	2021
<b>Cash flows from operating activities</b>		
Net loss	\$ (197,023)	\$ (55,558)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,123	372
Stock-based compensation	11,392	12,354
Net amortization of premiums and discounts on marketable securities	1,130	465
Noncash lease expense	413	807
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	14,637	(2,458)
Other long-term assets	(3,151)	—
Accounts payable	(5,053)	(6,791)
Accrued expenses and other current liabilities	1,825	3,823
Operating lease liabilities, net of current portion	(580)	727
Net cash used in operating activities	(174,287)	(46,259)
<b>Cash flows from investing activities</b>		
Purchases of marketable securities	(19,988)	(174,797)
Proceeds from sales of marketable securities	19,989	—
Proceeds from maturities of marketable securities	60,000	180,000
Purchases of property and equipment	(2,589)	(915)
Net cash provided by investing activities	57,412	4,288
<b>Cash flows from financing activities</b>		
Proceeds from exercise of stock options	104	3,788
Proceeds from issuance of common stock under the 2018 ESPP	243	995
Net cash provided by financing activities	347	4,783
Net increase (decrease) in cash, cash equivalents and restricted cash	(116,528)	(37,188)
Cash, cash equivalents and restricted cash, beginning of period	155,097	209,452
Cash, cash equivalents and restricted cash, end of period	\$ 38,569	\$ 172,264
<b>Supplemental disclosures</b>		
Noncash investing and financing items:		
Property and equipment purchased, not yet paid	\$ 367	\$ 3,266

*See accompanying notes to unaudited interim financial statements*

**ALLAKOS INC.**  
**NOTES TO UNAUDITED INTERIM FINANCIAL STATEMENTS**

**1. Organization and Business**

Allakos Inc. (“Allakos” or the “Company”) was incorporated in the state of Delaware in March 2012. Allakos is a clinical stage biopharmaceutical company focused on the development of lrintelimumab (AK002) for the treatment of eosinophil and mast cell related diseases. The Company’s primary activities to date have included establishing its facilities, recruiting personnel, conducting research and development of its product candidates and raising capital. The Company’s operations are located in San Carlos, California. The Company operates in one reportable segment.

**Liquidity Matters**

Since inception, the Company has incurred net losses and negative cash flows from operations. During the three months ended March 31, 2022, the Company incurred a net loss of \$197.0 million and used \$174.3 million of cash in operations. At March 31, 2022, the Company had an accumulated deficit of \$809.8 million and does not expect to experience positive cash flows from operating activities in the foreseeable future. The Company has financed its operations to date primarily through the sale of common stock. Management expects to incur additional operating losses in the future as the Company continues to further develop, seek regulatory approval for and, if approved, commence commercialization of its product candidates.

Due to the clinical study results released in December 2021, our Board of Directors approved in February 2022 plans to reduce our contractual commitments and a reorganization plan (the “Reorganization Plan”) to reduce operating costs and better align our workforce with the clinical development plans of our business. As part of this, the Company entered into a termination agreement (the “Termination Agreement”) with Lonza AG, Lonza Sales Ltd and Lonza Sales AG (collectively, “Lonza”) regarding all outstanding manufacturing service agreements in February 2022.

The Company had \$246.7 million of cash, cash equivalents and marketable securities at March 31, 2022. Management believes that this amount is sufficient to fund the Company’s operations for at least the next 12 months from the issuance date of these financial statements.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The unaudited interim financial statements 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 management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes.

The interim balance sheet as of March 31, 2022, the statements of operations and comprehensive loss, statements of stockholders’ equity and statements of cash flows for the three months ended March 31, 2022 and 2021 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company’s financial position as of March 31, 2022 and its results of operations and comprehensive loss for the three months ended March 31, 2022 and 2021 and its cash flows for the three months ended March 31, 2022 and 2021. Certain information and note disclosures normally included in annual audited financial statements prepared in accordance with U.S. GAAP have been omitted. The financial data and the other financial information disclosed in these notes to the interim financial statements are also unaudited. The results of operations for any interim period are not necessarily indicative of the results to be expected for the entire year or for any other future annual or interim period. The balance sheet as of March 31, 2022 included herein was derived from the audited financial statements as of that date. These interim financial statements should be read in conjunction with the Company’s audited financial statements included in the Company’s Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the “SEC”) on March 1, 2022.

**Use of Estimates**

Management uses significant judgment when making estimates related to common stock valuation and related stock-based compensation expense, accrued research and development expense, and lease-related assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions, and those differences could be material to the financial position and results of operations.

**Concentration of Credit Risk and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to credit risk principally consist of cash, cash equivalents and marketable securities. These financial instruments are held in accounts at a single financial institution that management believes



possesses high credit quality. Amounts on deposit with this financial institution have and will continue to exceed federally-insured limits. The Company has not experienced any losses on its cash deposits. Additionally, the Company's investment policy limits its investments to certain types of securities issued by or backed by the U.S. government and its agencies.

The Company is subject to a number of risks similar to that of other early stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of current or future clinical trials, its reliance on third-parties to conduct its clinical trials, the need to obtain regulatory and marketing approvals for its product candidates, competitive developments, the need to successfully commercialize and gain market acceptance of the Company's product candidates, its right to develop and commercialize its product candidates pursuant to the terms and conditions of the licenses granted to the Company, protection of proprietary technology, the ability to make milestone, royalty or other payments due under licensing agreements, and the need to secure and maintain adequate manufacturing arrangements with third-parties. If the Company does not successfully commercialize or partner its product candidates, it will be unable to generate product revenue or achieve profitability.

### **Cash, Cash Equivalents and Restricted Cash**

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Company's balance sheets and which, in aggregate, represent the amounts reported in the accompanying statements of cash flows (in thousands):

	March 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 36,294	\$ 152,822
Restricted cash in other long-term assets	1,472	2,275
Restricted cash in prepaid and other current assets	803	—
Total	<u>\$ 38,569</u>	<u>\$ 155,097</u>
	March 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 169,989	\$ 207,177
Restricted cash	2,275	2,275
Total	<u>\$ 172,264</u>	<u>\$ 209,452</u>

Restricted cash at March 31, 2022 represents \$1.5 million in security deposits for the lease of the Company's facilities in Redwood City, California and San Carlos, California. Both security deposits are in the form of letters of credit secured by restricted cash. As of March 31, 2022, \$0.8 million of restricted cash amounts are included within prepaid expenses and other current assets and \$1.5 million within other long-term assets on the Company's balance sheets.

### **Marketable Securities**

The Company invests in marketable securities, primarily securities issued by the United States government and its agencies. The Company's marketable securities are considered available-for-sale and are classified as current assets even when the stated maturities of the underlying securities exceed one year from the date of the current balance sheet being reported. This classification reflects management's ability and intent to utilize proceeds from the sale of such investments to fund ongoing operations. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated other comprehensive gain. The cost of securities sold is determined using the specific-identification method. Interest earned and adjustments for the amortization of premiums and discounts on investments are included in interest income, net, on the statements of operations and comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on investments in marketable securities are included in other expense, net, on the statements of operations and comprehensive loss.

### **Operating Leases**

The Company accounts for its leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, "Leases" ("ASC 842"). Right-of-use assets represent the Company's right to use an underlying asset over the lease term and include any lease payments made prior to the lease commencement date and are reduced by lease incentives. Lease liabilities represent the present value of the total lease payments over the lease term, calculated using the Company's incremental borrowing rate. In determining the Company's incremental borrowing rate, consideration is given to the term of the lease and the Company's credit risk. The Company recognizes options to extend a lease when it is reasonably certain that it will exercise such

extension. The Company does not recognize options to terminate a lease when it is reasonably certain that it will not exercise such early termination options. Lease expense is recognized on a straight-line basis over the expected lease term.

### ***Accrued Research and Development Expense***

Service agreements with contract development and manufacturing organizations (“CDMOs”), clinical contract research organizations (“CROs”) and clinical investigative sites comprise a significant component of the Company’s research and development activities. External costs for these vendors are recognized as the services are incurred. The Company accrues for expenses resulting from obligations under agreements with its third-parties for which the timing of payments does not match the periods over which the materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CDMOs, clinical CROs, clinical investigative sites and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services.

The Company makes judgements and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CDMO, clinical CRO, clinical investigative site or other outside service provider, the payments are recorded within prepaid expenses and other current assets or other long-term assets, as appropriate, and subsequently recognized as research and development expense when the associated services have been performed. As actual costs become known, the Company adjusts its liabilities and assets. Inputs, such as the extent of services received and the duration of services to be performed, may vary from the Company’s estimates, which will result in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company’s accruals could materially affect the Company’s results of operations. The Company’s historical estimates have not been materially different from actual amounts recorded.

### ***Research and Development Expense***

Research and development costs are expensed as incurred. Research and development costs include, among others, consulting costs, salaries, benefits, travel, stock-based compensation, laboratory supplies and other non-capital equipment utilized for in-house research, allocation of facilities and overhead costs and external costs paid to third-parties that conduct research and development activities on the Company’s behalf. Costs to terminate commitments with third-party suppliers performing research and development activities and amounts incurred in connection with license agreements, including milestone payments, are also included in research and development expense.

Advance payments for goods or services to be rendered in the future for use in research and development activities are deferred and included in prepaid expenses, and other current assets or other long-term assets, as appropriate. The deferred amounts are expensed as the related goods are delivered or the services are performed.

### ***Comprehensive Loss***

Comprehensive loss is defined as the change in stockholders’ equity during a period from transactions and other events and circumstances from non-owner sources. The differences between net loss and comprehensive loss for the three months ended March 31, 2022 and 2021 are a result of unrealized gains and losses on the Company’s investments in marketable securities included in current assets on the Company’s balance sheets.

### ***Net Loss per Share***

The Company calculates basic net loss per share by dividing the net loss attributable to common stockholders by the weighted-average shares of common stock outstanding during the period. The Company calculates diluted net loss per share after giving consideration to all potentially dilutive securities outstanding during the period using the treasury-stock and if-converted methods, except where the effect of including such securities would be anti-dilutive. Because the Company has reported net losses since inception, the effect from potentially dilutive securities would have been anti-dilutive and therefore has been excluded from the calculation of diluted net loss per share.

Basic and diluted net loss per share was calculated as follows (in thousands, except per share data):

	Three Months Ended March 31,	
	2022	2021
<b>Numerator:</b>		
Net loss	\$ (197,023)	\$ (55,558)
<b>Denominator:</b>		
Weighted-average shares of common stock outstanding, basic and diluted	54,686	53,186
Net loss per share, basic and diluted	\$ (3.60)	\$ (1.04)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2022	2021
Options to purchase common stock	5,380	6,251
Unvested restricted stock units	5,267	1,093
Unvested performance stock units	4,216	—
Shares issuable under employee stock purchase plans	17	4
Total	14,880	7,348

### Recently Issued and Adopted Accounting Pronouncements

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

### 3. Fair Value Measurements

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The Company's financial assets measured at fair value on a recurring basis were as follows (in thousands):

	March 31, 2022			
	Level 1	Level 2	Level 3	Total
<b>Cash equivalents</b>				
Money market funds	\$ 33,493	\$ —	\$ —	\$ 33,493
Total cash equivalents	33,493	—	—	33,493
<b>Short-term marketable securities</b>				
U.S. treasuries	210,407	—	—	210,407
Total short-term marketable securities	210,407	—	—	210,407
Total cash equivalents and short-term marketable securities	\$ 243,900	\$ —	\$ —	\$ 243,900
	December 31, 2021			
	Level 1	Level 2	Level 3	Total
<b>Cash equivalents</b>				
Money market funds	\$ 150,781	\$ —	\$ —	\$ 150,781
Total cash equivalents	150,781	—	—	150,781
<b>Short-term marketable securities</b>				
U.S. treasuries	271,416	—	—	271,416
Total short-term marketable securities	271,416	—	—	271,416
Total cash equivalents and short-term marketable securities	\$ 422,197	\$ —	\$ —	\$ 422,197

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the three months ended March 31, 2022 and 2021.

#### 4. Marketable Securities

All marketable securities were considered available-for-sale at March 31, 2022. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type at March 31, 2022 and December 31, 2021 are summarized in the table below (in thousands):

	March 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities				
U.S. treasuries classified as investments	\$ 210,876	\$ —	\$ (469)	\$ 210,407
Total available-for-sale securities	<u>\$ 210,876</u>	<u>\$ —</u>	<u>\$ (469)</u>	<u>\$ 210,407</u>

  

	December 31, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities				
U.S. treasuries classified as investments	\$ 271,570	\$ 2	\$ (156)	\$ 271,416
Total available-for-sale securities	<u>\$ 271,570</u>	<u>\$ 2</u>	<u>\$ (156)</u>	<u>\$ 271,416</u>

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. As of March 31, 2022 and December 31, 2021, the aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months was \$210.4 million and \$241.4 million, respectively. All of these securities had remaining maturities of less than one year. The Company has the intent and ability to hold such securities until recovery and has determined that there has been no material change to their credit risk. As a result, the Company determined it did not hold any investments with a credit loss at March 31, 2022 and December 31, 2021.

There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities during the three months ended March 31, 2022 and 2021, and as a result, there were no material reclassifications out of accumulated other comprehensive gain (loss) for the same periods.

#### 5. Balance Sheet Components and Supplemental Disclosures

##### Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Laboratory equipment	\$ 6,161	\$ 4,676
Furniture and office equipment	5,205	1,947
Capitalized software	4,032	—
Leasehold improvements	36,466	4,581
Construction-in-progress	—	37,704
	<u>51,864</u>	<u>48,908</u>
Less accumulated depreciation	<u>(7,931)</u>	<u>(5,808)</u>
Property and equipment, net	<u>\$ 43,933</u>	<u>\$ 43,100</u>

Depreciation and amortization expense for the three months ended March 31, 2022 and 2021 was \$2.1 million and \$0.4 million, respectively. Assets included within construction-in-progress primarily related to leasehold improvements and other equipment relating to our new San Carlos headquarters and were placed into service during the first quarter of 2022.

##### Other Long-Term Assets

Other long-term assets were \$12.4 million and \$8.4 million as of March 31, 2022 and December 31, 2021, respectively. Other long-term assets at March 31, 2022 and December 31, 2021 included \$9.3 million and \$5.9 million in advance payments to CDMOs for development and manufacturing services to be provided more than one year from now.

### Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Accrued contract research and development expense	\$ 14,441	\$ 16,215
Accrued compensation and benefits expense	6,095	3,172
Current portion of operating lease liabilities	2,915	2,316
Other current liabilities	4,973	4,854
Total	<u>\$ 28,424</u>	<u>\$ 26,557</u>

## 6. Leases

### Operating Leases

The Company's lease obligations primarily relate to leased office and laboratory space under noncancelable operating leases. In accordance with ASC 842, the Company has performed an evaluation of its other contracts with vendors and has determined that, except for the leases described below, none of its other contracts contain a material lease.

#### 2018 Redwood City Lease

In January 2018, the Company entered into an operating lease agreement for approximately 25,000 square feet of office and laboratory space in Redwood City, California (the "2018 Redwood City Lease"). The contractual term of the 2018 Redwood City Lease was 10.75 years beginning from the substantial completion and delivery of the premises, which occurred in November 2018, and originally terminating in July 2029.

The 2018 Redwood City Lease included monthly base rent amounts escalating over the term of the lease. In addition, the lessor provided for a tenant improvement allowance ("TIA") of up to \$1.4 million, which was fully utilized. The TIA was recorded as leasehold improvements, with offsetting adjustments recorded to the associated operating lease right of use asset included on the Company's balance sheets as of March 31, 2022 and December 31, 2021.

In November 2021 the Company entered into a lease termination agreement (the "Termination Agreement") with respect to the 2018 Redwood City Lease. Pursuant to the Termination Agreement, the 2018 Redwood City Lease was terminated effective April 30, 2022. The Company accounted for this change in lease term as a modification of the original lease. As a result of the modification, the operating right-of-use asset and lease liability were remeasured during the fourth quarter of 2021.

In connection with the early termination and upon satisfaction of certain conditions including the delivery of certain equipment and other assets related to the building, the landlord agreed to pay to the Company \$1.1 million.

#### 2019 San Carlos Lease

In December 2019, the Company entered into an additional operating lease agreement for approximately 98,000 square feet of office and laboratory space in San Carlos, California (the "2019 San Carlos Lease"). The contractual term of the 2019 San Carlos Lease is 10.25 years from August 2021 until October 2031. The 2019 San Carlos Lease provides rent abatements and includes a one-time option to extend the lease term for five years. This option to extend the lease term was not determined to be reasonably certain and therefore has not been included in the Company's calculation of the associated operating lease liability under ASC 842.

The 2019 San Carlos Lease includes monthly base rent amounts escalating over the term of the lease. In addition, the lessor provided for a TIA of up to \$14.7 million, which was fully utilized and are recorded in lease obligations.

The Company utilized its incremental borrowing rate to calculate the present value of the lease payments for the 2019 San Carlos Lease based on information available on November 1, 2020, the lease commencement date for accounting purposes, which was the date the Company was deemed to have obtained control of the premises. Calculation of the operating lease liability also included estimated future TIA reimbursements that had not yet been received as of the lease commencement date. TIA reimbursements received subsequent to lease commencement date are recorded as reductions to the operating lease liability.

### Classification of Operating Leases

The 2018 Redwood City Lease and the 2019 San Carlos Lease required security deposits of \$0.8 million and \$1.5 million, respectively, which the Company satisfied by establishing letters of credit secured by restricted cash. Restricted cash related to the Company's lease agreements are recorded in other long-term assets or other current assets on the Company's balance sheets depending on the timing in which the security deposit is expected to be returned.

Classification of the Company's operating lease liabilities included on the Company's balance sheets at March 31, 2022 and December 31, 2021 was as follows (in thousands):

	March 31, 2022	December 31, 2021
Operating lease liabilities		
Current portion included in accrued expenses and other current liabilities	\$ 2,915	\$ 2,316
Operating lease liabilities, net of current portion	48,355	49,099
Total operating lease liabilities	<u>\$ 51,270</u>	<u>\$ 51,415</u>

The components of lease costs included in operating expenses in the Company's statements of operations and comprehensive loss were as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Operating lease costs	\$ 1,454	\$ 1,734
Variable costs	683	87
Total lease costs	<u>\$ 2,137</u>	<u>\$ 1,821</u>

Variable costs included in the table above represent amounts the Company pays related to property taxes, insurance, maintenance and repair costs.

Cash paid for amounts included in the measurement of the Company's operating lease liabilities and presented within cash used in operating activities in the statements of cash flows was \$2.0 million and \$0.3 million for the three months ended March 31, 2022 and 2021, respectively.

Cash received for amounts related to tenant improvement allowances from lessors was \$1.0 million and \$0.4 million for the three months ended March 31, 2022 and 2021, respectively.

### Operating Lease Obligations

Future lease payments required under operating leases included on the Company's balance sheet at March 31, 2022 are as follows (in thousands):

<b>Fiscal Year Ending December 31,</b>		
2022 (remaining 9 months)	\$	5,272
2023		7,061
2024		7,273
2025		7,492
2026		7,716
Thereafter		40,667
Total future lease payments		<u>75,481</u>
Less:		
Present value adjustment		24,211
Present value of future lease incentives		—
Operating lease liabilities	<u>\$</u>	<u>51,270</u>

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate based on the information available

at the lease commencement date. As of March 31, 2022, the weighted-average remaining lease term of the Company's leases was 9.6 years and the weighted-average discount rate used to determine the operating lease liabilities included on the balance sheet was 8.5%.

As of March 31, 2022, the Company was not party to any lease agreements containing material residual value guarantees or material restrictive covenants.

## **7. Contingencies**

### ***In-Licensing Agreements***

The Company has entered into exclusive and non-exclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements, the Company is obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Research and development expense associated with the Company's milestone payments are recognized when such milestone has been achieved. Actual amounts due under the license agreements will vary depending on factors including, but not limited to, the number of products developed and the Company's ability to further develop and commercialize the licensed products. The Company is also subject to future royalty payments based on sales of the licensed products. In-licensing payments to third-parties for milestones are recognized as research and development expense in the period of achievement.

The Company did not recognize any milestone expense for the three months ended March 31, 2022 and 2021. As of March 31, 2022, the Company has not incurred any royalty liabilities related to its license agreements, as product sales have not yet commenced.

#### *Exclusive License Agreement with The Johns Hopkins University*

In December 2013, the Company entered into a license agreement with The Johns Hopkins University ("JHU") for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including lirinlimab, which was amended in September 2016. Under the terms of the agreement, the Company has made upfront and milestone payments of \$0.7 million through March 31, 2022 and may be required to make aggregate additional milestone payments of up to \$1.8 million. The Company also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, the Company is also subject to low single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by the Company and its affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

#### *Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG*

In October 2013, the Company entered into a tripartite agreement with BioWa Inc. ("BioWa"), and Lonza Sales AG ("Lonza"), for the non-exclusive worldwide license to develop and commercialize product candidates including lirinlimab that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, the Company has made milestone payments of \$3.4 million through March 31, 2022 and may be required to make aggregate additional milestone payments of up to \$38.0 million. In addition to milestone payments, the Company is also subject to minimum annual commercial license fees of \$40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by the Company and its affiliates and sublicensees.

### ***Indemnification Agreements***

The Company has entered into indemnification agreements with certain directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no such matters have arisen and the Company does not believe that the outcome of any claims under indemnification arrangements will have a material adverse effect on its financial positions, results of operations or cash flows. Accordingly, the Company has not recorded a liability related to such indemnifications at March 31, 2022.

### ***Legal Contingencies***

On March 10, 2020, a putative securities class action complaint captioned Kim v. Allakos et al., No. 20-cv-01720 (N.D. Cal.) was filed in the United States District Court for the Northern District of California against the Company, its Chief Executive Officer, Dr. Robert Alexander, and its former Chief Financial Officer, Mr. Leo Redmond. The complaint asserts claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder and seeks damages based on alleged material misrepresentations and omissions concerning its Phase 2 clinical trials of lirinlimab. The proposed class period is August 5, 2019, through December 17, 2019, inclusive. On August 28, 2020, the plaintiff filed an amended complaint, adding as defendants Adam Tomasi, the Company's President and Chief Operating Officer, and Henrik Rasmussen, the Company's former Chief Medical Officer.

On March 31, 2022, the Court granted the defendants' motion to dismiss, with leave to amend. On April 29, 2022, the plaintiffs filed a second amended complaint which extended the proposed class period from December 17, 2019 to December 21, 2021 and added additional claims related to the Company's Phase 3 ENIGMA clinical trial. The defendants intend to file a further motion to dismiss. Given the early stage of this litigation matter, the Company cannot reasonably estimate a potential future loss or a range of potential future losses, if any, and has not recorded a contingent liability accrual as of March 31, 2022.

## 8. Stock-Based Compensation

Total stock-based compensation expense recognized is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 4,435	\$ 5,063
General and administrative	6,957	7,291
Total	\$ 11,392	\$ 12,354

No income tax benefits for stock-based compensation expense have been recognized for the three months ended March 31, 2022 and 2021 as a result of the Company's full valuation allowance applied to net deferred tax assets and net operating loss carryforwards.

### Equity Incentive Plans

In July 2018, the Board of Directors adopted the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units ("RSUs"), stock appreciation rights, performance-based awards ("PSUs") and other stock-based awards. The number of shares of common stock that may be issued under the 2018 Plan will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 5,000,000 shares, (ii) 5% of the outstanding shares of common stock as of the last day of the preceding fiscal year and (iii) such other amount as the Board of Directors may determine. Stock options and RSUs granted under the 2018 Plan generally vest over four years and expire no more than 10 years from the date of grant.

Following the IPO and upon the effectiveness of the 2018 Plan, the Company's 2012 Equity Incentive Plan, as amended, (the "2012 Plan"), terminated and no further awards will be granted thereunder. All outstanding awards under the 2012 Plan will continue to be governed by their existing terms. Any shares subject to awards granted under the 2012 Plan that, on or after the termination of the 2012 Plan, expire or terminate and shares previously issued pursuant to awards granted under the 2012 Plan that, on or after the termination of the 2012 Plan, are forfeited or repurchased by the Company will be transferred into the 2018 Plan. As of March 31, 2022, the maximum number of shares that may be added to the 2018 Plan pursuant to the preceding clause is 3,546,887 shares.

Prior to its termination, the 2012 Plan provided for the grant of stock options, stock appreciation rights, restricted stock and restricted stock units to employees, directors and consultants. Stock options granted under the 2012 Plan generally vest over four years and expire no more than 10 years from the date of grant.

#### Stock Options

The following weighted-average assumptions were used to calculate the fair value of stock options granted during the periods indicated:

	Three Months Ended March 31,	
	2022	2021
Risk-free interest rate	1.88 %	0.77 %
Expected volatility	72.81 %	69.57 %
Expected dividend yield	—	—
Expected term (in years)	6.08	6.06



The Company's stock option activity during the three months ended March 31, 2022 is summarized as follows (number of shares in thousands):

	Options Outstanding	Weighted- Average Exercise Price
Balance at December 31, 2021	5,530	\$ 21.51
Granted	135	\$ 5.62
Exercised	(34)	\$ 3.00
Expired	(59)	\$ 36.48
Forfeited	(192)	\$ 66.69
Balance at March 31, 2022	<u>5,380</u>	\$ 3.66
Options exercisable	<u>4,695</u>	\$ 13.75
Options vested and expected to vest	<u>5,368</u>	\$ 19.37

During the three months ended March 31, 2022 and 2021, the Company did not grant any stock options with performance-based or market-based vesting conditions.

As of March 31, 2022, total unrecognized stock-based compensation expense relating to unvested stock options was \$20.0 million. This amount is expected to be recognized over a weighted-average period of 2.5 years.

*Restricted Stock Units ("RSUs")*

RSU activity under the 2018 Plan during the three months ended March 31, 2022 is summarized as follows (in thousands, except per share data):

	Shares	Weighted- Average Grant Date Fair Value
Balance at December 31, 2021	1,506	\$ 93.14
Granted	4,189	\$ 5.58
Vested	(63)	\$ 103.48
Forfeited	(365)	\$ 91.46
Balance at March 31, 2022	<u>5,267</u>	\$ 23.50

The weighted-average fair value of RSUs granted during the three months ended March 31, 2022 and 2021 was \$5.58 and \$127.96, respectively.

As of March 31, 2022, total unrecognized stock-based compensation expense relating to unvested RSUs was \$113.6 million and the weighted-average remaining vesting period was 3.2 years.

*Performance-based Restricted Stock Units ("PSUs")*

PSU activity under the 2018 Plan during the three months ended March 31, 2022 is summarized as follows (in thousands, except per share data):

	Shares	Weighted- Average Grant Date Fair Value
Balance at December 31, 2021	113	\$ 79.60
Granted	4,103	\$ 5.58
Balance at March 31, 2022	<u>4,216</u>	\$ 7.57

As of March 31, 2022, total unrecognized stock-based compensation expense relating to unvested PSUs was \$31.9 million and the weighted-average remaining vesting period was 1.8 years.

**Employee Stock Purchase Plan**

In July 2018, the Company's Board of Directors and stockholders approved the 2018 Employee Stock Purchase Plan (the "2018 ESPP"). The number of shares of common stock that may be issued under the 2018 ESPP shall automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 1,000,000 shares, (ii) 1% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year and (iii) such other amount determined by the 2018 ESPP administrator. Under the 2018 ESPP, employees may purchase shares of the Company's common stock at a price per share equal to 85% of the lower of the fair market value of the common stock on the first trading day of the offering period or on the exercise date. The 2018 ESPP provides for consecutive, overlapping 24-month offering periods, each of which will include four 6-month purchase periods. The Company's first offering period under the 2018 ESPP commenced on July 18, 2018. During each of the three months ended March 31, 2022 and 2021, stock-based compensation expense related to the 2018 ESPP was \$0.2 million.

**9. Defined Contribution Plans**

In January 2018, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) plan"). The 401(k) plan covers all employees who meet defined minimum age and service requirements. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under U.S. federal tax regulations. The Company makes matching contributions of up to 4% of the eligible employees' compensation to the 401(k) plan. During the three months ended March 31, 2022 and 2021, the Company made contributions to the 401(k) plan of \$0.5 million and \$0.2 million, respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. These statements generally relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The following discussion and analysis contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results and the timing of events may differ materially from those discussed in our forward-looking statements as a result of various factors, including those discussed below and those discussed in the section entitled “Risk Factors” included in this Quarterly Report on Form 10-Q. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. Additional information concerning these and other risks and uncertainties is contained in our other periodic filings with the SEC.

Forward-looking statements include, but are not limited to, statements about:

- risks related to the COVID-19 pandemic;
- our plans and ability to manufacture, or have manufactured, sufficient quantities of lirentelimab for preclinical studies and to conduct clinical trials and to eventually commercialize the product, and our reliance on third parties in relation to the foregoing;
- the impact that the adoption of new accounting pronouncements will have on our financial statements;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing lirentelimab, if approved, including the geographic areas of focus and sales strategy;
- the size of the market opportunity for lirentelimab in each of the diseases we are targeting;
- the number of diseases represented in the patient population enrolled in our clinical trials, and our ability to evaluate response to treatment of lirentelimab in diseases other than the primary indication in our clinical trials;
- our estimates of the number of patients in the United States who suffer from the diseases we are targeting and the number of patients that will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of lirentelimab;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for lirentelimab or our other product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of lirentelimab or our other product candidates;
- our plans relating to the further development of lirentelimab and our other product candidates;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our continued reliance on third-parties to conduct additional clinical trials of lirentelimab and our other product candidates;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements; and
- our anticipated uses of our existing cash, cash equivalents and investments in marketable securities.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in “Risk Factors”. In some cases, you can identify these statements by terms such as “anticipate,” “believe,”

“could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled “Risk Factors” included in Part II, Item 1A and elsewhere in this Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

## Overview

We are a clinical stage biotechnology company developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergy, inflammatory and proliferative diseases. Our most advanced antibodies are lirentelimab (AK002) and AK006. Lirentelimab targets Siglec-8, an inhibitory receptor expressed selectively on eosinophils and mast cells. Lirentelimab has been studied in a number of human clinical studies and has shown the ability to deplete eosinophils inhibit mast cell activation, and improve patient reported symptoms. We are developing lirentelimab for the treatment of eosinophilic gastritis (“EG”) /eosinophilic duodenitis (“EoD”), eosinophilic esophagitis (“EoE”), atopic dermatitis, chronic spontaneous urticaria and potentially additional indications. AK006 targets Siglec-6, an inhibitory receptor selectively expressed on mast cells. AK006 appears to have the potential to provide deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, reduce mast cell numbers. We plan to begin human studies with AK006 in the first half of 2023.

Lirentelimab selectively targets both mast cells and eosinophils, two types of white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated mast cells and eosinophils have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. To date, lirentelimab completed a randomized, double-blind, placebo-controlled Phase 2 study (ENIGMA 1) and Phase 3 study (ENIGMA 2) in patients with EG and/or EoD, a Phase 2/3 study in patients with EoE (KRYPTOS), as well as proof of concept studies in chronic spontaneous urticaria, severe allergic conjunctivitis, and indolent systemic mastocytosis. Lirentelimab has received orphan disease status for EG, EoD, and EoE from the U.S. Food and Drug Administration (the “FDA”).

The Phase 2 EG and/or EoD study with lirentelimab (ENIGMA 1) met all prespecified primary and secondary endpoints when compared to placebo and results were published in The New England Journal of Medicine. More recently, the ENIGMA 2 study met the histologic co-primary endpoint but failed to meet the symptomatic co-primary endpoint when compared to placebo in the fourth quarter of 2021. Similarly, the KRYPTOS study met the histologic co-primary endpoint but failed to meet the symptomatic co-primary endpoint when compared to placebo. After conducting post-hoc analyses, we believe that the trials missed their symptomatic co-primary endpoints due to the inclusion of mild patients and/or patients who had not failed standard of care. Although post-hoc analyses cannot be used to establish efficacy, these analyses can be helpful in generating hypothesis for future clinical studies. Based on these analyses, we believe that lirentelimab may have potential to treat the more severe EG/EoD and EoE patient populations. As a result, we plan to conduct additional studies with lirentelimab in these indications after discussions with the FDA.

Beyond EoE, EG and EoD, additional lirentelimab clinical testing is ongoing or planned. Allakos initiated a randomized, double-blind, placebo controlled Phase 2 clinical trial of subcutaneous (SC) lirentelimab in adult patients with moderate-to-severe atopic dermatitis. The company also announced plans to initiate a randomized, double-blind, placebo-controlled trials of SC lirentelimab in patients with chronic spontaneous urticaria in the middle of 2022. Both diseases are complex, chronic inflammatory skin diseases believed to be driven by activated eosinophils and mast cells.

Since our inception in 2012, we have devoted substantially all of our resources and efforts towards the research and development of our product candidates. Our lead product candidate, lirentelimab, a monoclonal antibody targeting Siglec-8, entered clinical trials in 2016. In addition to activities conducted internally at our facilities, we have utilized significant financial resources to engage contractors, consultants and other third parties to conduct various preclinical and clinical development activities on our behalf.

To date, we have not had any products approved for sale and have not generated any revenue nor been profitable. Further, we do not expect to generate revenue from product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one of our product candidates. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We have incurred significant operating losses to date and expect to incur significant operating losses for the foreseeable future. Our net losses were \$197.0 million and \$55.6 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of \$809.8 million.

In February 2022, we began implementing a reorganization plan (the “Reorganization Plan”) to reduce operating costs, contractual commitments and better align our workforce with the clinical development plans of our business. As a result, we entered into the Termination Agreement with Lonza and reduced our workforce by approximately 35%. While this will result in increased near-term costs, primarily in the first and second quarters of 2022, we believe that the Reorganization Plan will reduce our overall spending in subsequent quarters subject to periodic fluctuations caused by the timing of ongoing manufacturing development efforts.

As of March 31, 2022, we had cash, cash equivalents and marketable securities of \$246.7 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our financial statements.

#### **Vendor Termination Agreement**

Approximately \$231.2 million of the \$284.8 million total noncancellable purchase obligations as of December 31, 2021 related to various manufacturing services agreements with Lonza AG or affiliates (such agreements, the “MSAs”). On February 14, 2022 (the “Effective Date”), the Company entered into a termination agreement (the “Termination Agreement”) with Lonza AG, Lonza Sales Ltd and Lonza Sales AG (collectively, “Lonza”) regarding all outstanding manufacturing service agreements. Lonza will continue to provide certain services to us, including completion of cGMP batches already underway and other services to assist with the transition post-termination. The Termination Agreement provides that the Company shall pay 126 million Swiss Francs, approximately \$137 million (the “Termination Amount”) to Lonza, as a result of such termination. In accordance with the terms of the Termination, we paid 95% of the Termination Amount (approximately \$130 million) during the first quarter of 2022. The remaining 5% (approximately \$7 million) is to be paid within 30 days of the release of the remaining cGMP batches expected to occur around the middle of 2022. The Termination Agreement contains mutual releases by all parties thereto, for all claims known and unknown, relating and arising out of, or connected with, the MSAs and the subject matter(s) thereof, subject to certain exceptions.

In addition, Lonza held or had placed orders for raw materials to be used in the course of services Lonza was to provide to the Company. Pursuant to the Termination Agreement, the cost of such raw materials was included in the Termination Amount. The Company will hold title to such raw materials and may repurpose these items through use elsewhere or resale to the extent possible.

As the agreement was terminated on February 14, 2022, the Company recognized the costs associated with the Termination Agreement during the first quarter of 2022 in accordance with ASC 420 except for approximately \$6.0 million attributed to services remaining to be rendered by Lonza and therefore to be expensed in future periods as the services are performed.

#### **Reorganization Plan**

Under the Reorganization Plan, the Company reduced its workforce by approximately 35%. Impacted employees received notice that their positions will be eliminated on February 16, 2022. At the time of departure from the Company, impacted employees were eligible to receive severance benefits and Company funded COBRA premiums, contingent upon an impacted employee’s execution (and non-revocation) of a customary separation agreement, which includes a general release of claims against the Company.

In connection with the Reorganization Plan, the Company recognized restructuring charges of approximately \$5.2 million during the first quarter of 2022, related to severance payments and other employee-related separation costs, of which \$2.6 million was unpaid as of March 31, 2022 and reflected in accrued expenses and other current liabilities. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the reduction in workforce.

In addition, the Board determined that it was in the best interests of the Company and its stockholder to put in place arrangements designed to provide that the Company will have the continued dedication and commitment of those employees, including executives, determined to be key to the planned go-forward operations. The Board approved, and management implemented a retention program for employees staying with the company and includes cash retention bonuses totaling \$3.1 million for certain retained employees and grants of RSUs totaling 8.2 million awards in aggregate to all employees. Half of these RSUs are time-based RSUs with four-year vesting and half are performance-based with full vesting occurring only if the Company achieves all primary endpoints in any of its Phase 2/3 clinical studies other than the Phase 3 Eosinophilic Duodenitis study expected to readout data in Q3 2022. The cash retention bonuses are required to be repaid in full if the employee leaves the Company prior to December 31, 2023. As a result, these cash retention bonuses are being amortized over the requisite service period, with \$0.1 million expense recorded during the three months ended March 31, 2022.

## Components of Operating Results

### Revenue

We have not generated any revenue from product sales or otherwise, and do not expect to generate any revenue for at least the next several years.

### Operating Expenses

We classify operating expenses into two categories: (i) research and development and (ii) general and administrative.

#### Research and Development Expenses

Research and development expenses represent the following costs incurred by us for the discovery, development and manufacturing of our product candidates:

- consultant and personnel-related costs including consulting fees, employee salaries and benefits, travel and stock-based compensation expense;
- costs incurred under service agreements with contract research organizations (“CROs”) that conduct nonclinical research and development activities on our behalf;
- costs incurred under service agreements with clinical CROs and clinical investigative sites to conduct our clinical studies;
- costs incurred under service agreements with contract development and manufacturing organizations (“CDMOs”) for the manufacture and fill finish of our product candidates, as well as any costs required to cancel any related purchase obligations;
- costs related to in-house research and development activities conducted at our facilities including laboratory supplies, non-capital laboratory equipment and depreciation of capital laboratory equipment and leasehold improvements;
- costs incurred under exclusive and non-exclusive license agreements with third-parties; and
- allocated facility and other costs including the rent and maintenance of our facilities, insurance premiums, depreciation of shared-use leasehold improvements and general office supplies.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, patient enrollment or information provided to us by our clinical CROs and clinical investigative sites, along with analysis by our in-house clinical operations personnel. Advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized as prepaid expenses, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Prior to the regulatory approval of our product candidates, we recognize expenses incurred with our CDMOs for the manufacture of product candidates that could potentially be available to support future commercial sales, if approved, in the period in which they have occurred. To date, we have not yet capitalized any costs to inventory as we are unable to determine if these costs will provide a future economic benefit, given the unapproved nature of our product candidates.

The successful development of our product candidates is highly uncertain. Accordingly, it is difficult to estimate the nature, timing and extent of costs necessary to complete the remainder of the development of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty surrounding:

- demonstrating sufficient safety and tolerability profiles of product candidates;
- successful enrollment and completion of clinical trials;
- requisite clearance and approvals from applicable regulatory authorities;
- establishing and maintaining commercial manufacturing capabilities with CDMOs;
- obtaining and maintaining protection of intellectual property; and
- commercializing product candidates, if and when approved, alone or in collaboration with third-parties.

A change pertaining to any of these variables would significantly impact the timing and extent of costs incurred with respect to the development and commercialization of our product candidates.

External costs incurred from CDMOs, clinical CROs and clinical investigative sites have comprised a significant portion of our research and development expenses since inception. We track these costs on a program-by-program basis following the advancement of a product candidate into clinical development. Consulting and personnel-related costs, laboratory supplies and non-capital equipment utilized in the conduct of in-house research, in-licensing fees and general overhead, are not tracked on a program-by-program basis, nor are they allocated, as they commonly benefit multiple projects, including those still in our pipeline.

We anticipate that our research and development expenses will decrease compared to the three months ended March 31, 2022 and will fluctuate from quarter-to-quarter in the future, primarily driven by the timing of costs associated with the manufacturing of our lead product candidate, lirentelimab, as we refine the frequency and increase the scale of our manufacturing batches. Additionally, we expect costs to fluctuate from quarter-to-quarter associated with our ongoing and future early, mid and late-stage clinical trials for various indications.

#### *General and Administrative Expenses*

General and administrative expenses consist of fees paid to consultants, salaries, benefits and other personnel-related costs, including stock-based compensation, for our personnel in executive, finance, accounting and other administrative functions, legal costs, fees paid for accounting and tax services, costs associated with pre-commercialization activities and facility costs not otherwise included in research and development expenses. Legal costs include general corporate and patent legal fees and related costs.

We anticipate that our general and administrative expenses will fluctuate from quarter-to-quarter in the future to support our continued research and development activities, as well as progress on our preliminary commercial development activities, including costs related to personnel, outside consultants, attorneys and accountants, stock-based compensation, among others. Additionally, we expect to incur costs associated with continuing to operate as a public company, including expenses related to maintaining compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance premiums, investor relations activities and other ancillary administrative and professional services.

#### **Interest Income**

Interest income primarily consists of interest and investment income earned on our cash, cash equivalents and marketable securities included on the balance sheets.

#### **Other Expense, Net**

Other expense, net, primarily consists of amounts realized from gains and losses related to fluctuations in foreign currencies.

#### **In-Licensing Agreements**

We have entered into a number of exclusive and nonexclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements described below, we are obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Research and development expense associated with the Company's milestone payments are recognized when such milestone has been achieved. Actual amounts due under the license agreements vary depending on factors including, but not limited to, the number of product candidates we develop and our ability to successfully develop and commercialize our product candidates covered under the respective agreements. In addition to milestone payments, we are also subject to future royalty payments based on sales of our product candidates covered under the agreements, as well as certain minimum annual royalty and commercial reservation fees. Because the achievement of milestones and the timing and extent of future royalties is not probable, these contingent amounts have not been included on our balance sheets or as part of Contractual Obligations and Commitments discussion below.

We did not incur any milestone expense for the three months ended March 31, 2022 and 2021. As of March 31, 2022, we have not incurred any royalty liabilities related to our license agreements, as product sales have not yet commenced.

#### *Exclusive License Agreement with The Johns Hopkins University*

In December 2013, we entered into a license agreement with JHU for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including lirentelimab, which was amended in September 2016. Under the terms of the agreement, we have made upfront and milestone payments of \$0.7 million through March 31, 2022. We may be required to make

aggregate additional milestone payments of up to \$1.8 million. We also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, we are also subject to low single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by us and our affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

#### *Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG*

In October 2013, we entered into a tripartite agreement with BioWa and Lonza for the non-exclusive worldwide license to develop and commercialize product candidates including lirentelimab that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, we have made milestone payments of \$3.4 million through March 31, 2022 and we may be required to make aggregate additional milestone payments of up to \$38.0 million. In addition to milestone payments, we are also subject to minimum annual commercial license fees of \$40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by us and our affiliates and sublicensees.

#### **Critical Accounting Policies and Use of Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. During the three months ended March 31, 2022, there were no other changes to our critical accounting policies and estimates as disclosed in our 2021 Annual Report on Form 10-K.

#### **Recent Accounting Pronouncements**

See Note 2 to our unaudited financial statements for recently issued accounting pronouncements, including the respective effective dates of adoption and effects on our results of operations and financial condition.



## Results of Operations

### Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2022	2021
Operating expenses		
Research and development	\$ 176,807	\$ 38,915
General and administrative	18,844	16,670
Total operating expenses	195,651	55,585
Loss from operations	(195,651)	(55,585)
Interest income	83	130
Other expense, net	(1,455)	(103)
Net loss	(197,023)	(55,558)
Unrealized loss on marketable securities	(316)	80
Comprehensive loss	\$ (197,339)	\$ (55,478)

#### Research and Development Expenses

Research and development expenses were \$176.8 million for the three months ended March 31, 2022 compared to \$38.9 million for the three months ended March 31, 2021, an increase of \$137.9 million. The first quarter of 2022 includes \$130.5 million related to the Lonza Termination agreement and \$4.6 million of costs as a result of the Reorganization Plan. Additionally, the period-over-period increase in research and development expenses included an additional \$3.1 million of equipment and overhead related costs primarily due to the new corporate facility and \$2.3 million of additional contract research and development and clinical costs primarily relating to lirentelimab (AK002). This was offset by a decrease of \$1.0 million in personnel-related costs after excluding the costs relating to the Reorganization Plan and a decrease of \$1.8 million in professional and other research and development expenses.

#### General and Administrative Expenses

General and administrative expenses were \$18.8 million for the three months ended March 31, 2022 compared to \$16.7 million for the three months ended March 31, 2021, an increase of \$2.1 million. The period-over-period increase in general and administrative expenses was primarily due to the \$4.3 million related to costs as a result of the Reorganization Plan incurred in the first quarter of 2022 offset by \$1.1 million decrease in other personnel-related costs and \$1.1 million decrease in marketing, professional and other general and administrative expenses.

#### Other Expense, Net

A loss of \$1.5 million was recognized in other expense, net for the three months ended March 31, 2022 compared to a loss of \$0.1 million for the three months ended March 31, 2021. The fluctuation was primarily attributed to foreign currency charges associated with payments made under the Termination Agreement with Lonza.

## Liquidity and Capital Resources

### Sources of Liquidity

As of March 31, 2022, we had cash, cash equivalents and marketable securities of \$246.7 million. Based on our existing business plan, we believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our anticipated level of operations through at least the next 12 months from the issuance of our financial statements.

We are a clinical stage biotechnology company with a limited operating history. As a result of our significant research and development expenditures, we have generated net losses since our inception. We have financed our operations primarily through equity offerings.

### July 2018 Initial Public Offering

On July 23, 2018, we completed an IPO, selling 8,203,332 shares of common stock at \$18.00 per share (the "July 2018 IPO"). Proceeds from our July 2018 IPO, net of underwriting discounts and commissions, were \$137.3 million. Concurrently with our July

2018 IPO, we completed a private placement of 250,000 shares of common stock at \$18.00 per share to an existing stockholder. Proceeds from this private placement were \$4.5 million.

In connection with the completion of the July 2018 IPO, all then outstanding shares of convertible preferred stock converted into 30,971,627 shares of common stock.

#### **August 2019 Follow-On Offering**

On August 9, 2019, we closed an underwritten public offering (the “August 2019 Offering”) under our shelf registration statement on Form S-3 (File No. 333-233018) pursuant to which we sold an aggregate of 5,227,272 shares of our common stock at a public offering price of \$77.00 per share. We received aggregate net proceeds of \$377.5 million, after deducting the underwriting discounts and commissions and offering expenses.

#### **November 2020 Follow-On Offering**

On November 2, 2020, we closed an underwritten public offering (the “November 2020 Offering”) under our shelf registration statement on Form S-3 (File No. 333-233018) pursuant to which we sold an aggregate of 3,506,098 shares of our common stock at a public offering price of \$82.00 per share. We received aggregate net proceeds of \$271.7 million, after deducting the underwriting discounts and commissions.

#### **“At-the-Market” Equity Offering**

On May 10, 2021, we entered into a Sales Agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”). Pursuant to the terms of the Sales Agreement, we may sell, from time to time up to an aggregate of \$400.0 million of our common stock through an “at-the-market” offering as defined in Rule 415 under the Securities Act of 1933, as amended. We will pay Cowen a commission equal to 3.0% of the gross proceeds from the sale of shares of our common stock under the Sales Agreement and reimburse up to \$60,000 of legal expenses incurred by Cowen.

We were not obligated to and did not make any sales of shares of our common stock under the Sales Agreement. The Sales Agreement was terminated effective February 24, 2022.

#### **Summary Cash Flows**

##### **Comparison of the Three Months Ended March 31, 2022 and 2021**

The following table summarizes the primary sources and uses of our cash, cash equivalents, and restricted cash for the periods indicated (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Net cash used in operating activities	\$ (174,287)	\$ (46,259)
Net cash provided by investing activities	57,412	4,288
Net cash provided by financing activities	347	4,783
Net increase in cash, cash equivalents and restricted cash	<u>\$ (116,528)</u>	<u>\$ (37,188)</u>

#### **Cash Used in Operating Activities**

Net cash used in operating activities was \$174.3 million for the three months ended March 31, 2022, which was primarily attributable to our net loss of \$197.0 million adjusted for net noncash charges of \$15.1 million and net changes in operating assets and liabilities of \$7.7 million. Noncash charges included approximately \$11.4 million in stock-based compensation expense, \$2.1 million in depreciation and amortization expense, \$1.1 million in amortization of premiums and discounts on marketable securities and \$0.4 million in noncash lease expense.

Net cash used in operating activities was \$46.3 million for the three months ended March 31, 2021, which was primarily attributable to our net loss of \$55.6 million adjusted for net noncash charges of \$14.0 million and net changes in operating assets and liabilities of \$4.7 million. Noncash charges included approximately \$12.4 million in stock-based compensation expense, \$0.4 million in depreciation and amortization expense, \$0.5 million in amortization of premiums and discounts on marketable securities and \$0.8 million in noncash lease expense.

### *Cash Provided by Investing Activities*

Net cash provided by investing activities was \$57.4 million for the three months ended March 31, 2022, which consisted of \$60.0 million in proceeds from maturities of marketable securities and \$20.0 million in proceeds from sales of marketable securities, partially offset by \$20.0 million for the purchases of marketable securities and \$2.6 million for the purchases of property and equipment.

Net cash provided by investing activities was \$4.3 million for the three months ended March 31, 2021, which consisted of \$180.0 million in proceeds from maturities of marketable securities, partially offset by \$174.8 million for the purchases of marketable securities and \$0.9 million for the purchases of property and equipment.

### *Cash Provided by Financing Activities*

Net cash provided by financing activities was \$0.3 million for the three months ended March 31, 2022 primarily related to proceeds of \$0.1 million received from employees for the exercise of stock options and \$0.2 million received from employees for the purchase of common stock through the 2018 ESPP.

Net cash provided by financing activities was \$4.8 million for the three months ended March 31, 2021 primarily related to proceeds of \$3.8 million received from employees for the exercise of stock options and \$1.0 million received from employees for the purchase of common stock through the 2018 ESPP.

### **Funding Requirements**

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise funding through private or public equity or debt financings, or other sources such as strategic collaborations. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies.

The timing and amount of our capital expenditures will depend on many factors, including:

- the number and scope of clinical indications and clinical trials we decide to pursue;
- the scope and costs of manufacturing activities;
- the extent to which we acquire or in-license other product candidates and technologies, if any;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities for product candidates receiving marketing approval, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development efforts. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

The issuance of additional equity securities may cause our stockholders to experience dilution. Future equity or debt financings may contain terms that are not favorable to us or our stockholders including debt instruments imposing covenants that restrict our operations and limit our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation, licensing or asset sale transactions.

### **Contractual Obligations and Commitments**

Our contractual obligations and commitments relate primarily to our operating leases and non-cancelable purchase obligations under agreements with various research and development organizations and suppliers in the ordinary course of business.

In the normal course of business, we enter into contracts with clinical CROs, clinical investigative sites and other counterparties assisting with our preclinical studies and clinical trials. Such contracts are generally cancellable, with varying provisions regarding

termination. In the event of a contract being terminated, we would only be obligated for services received as of the effective date of the termination, along with cancellation fees, as applicable. Additionally, we have entered into agreements with certain vendors for the provision of goods and services, which includes development and manufacturing services with CDMOs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payment for the cancellation of committed purchase obligations or for early termination of the agreements. The amounts of the cancellation or termination payments may vary and are based on the timing of the cancellation or termination and the specific terms of the agreements. The Company expects to enter into additional collaborative research, contract research, clinical and commercial manufacturing, and supplier agreements in the future, which may require significant upfront payments and long-term commitments of capital resources. Additionally, see Note 6, Leases, and Note 7, Contingencies, to our unaudited interim financial statements for further information relating to lease commitments, indemnification obligations and other commitments.

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

Since our inception, we have not entered into any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

#### ***Interest Rate Sensitivity***

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in money market funds that invest in U.S. Treasury obligations. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Due to the short-term maturities and low credit risk profile of our balances held in money market funds, a hypothetical 10% change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities.

#### ***Foreign Currency Sensitivity***

Our primary operations are transacted in U.S. Dollars, however, certain service agreements with third parties are denominated in currencies other than the U.S. Dollar, primarily the British Pound and Euro. As such, we are subject to foreign exchange risk and therefore, fluctuations in the value of the U.S. Dollar against the British Pound and Euro may impact the amounts reported for expenses and obligations incurred under such agreements. We do not currently engage in any hedging activity to reduce our potential exposure to currency fluctuations, although we may choose to do so in the future. Excluding the portion of the Termination Amount paid during the three months ended March 31, 2022, a hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial condition or results of operations.

### **Item 4. Controls and Procedures.**

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

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act 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 the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. As of March 31, 2022, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies 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 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

As a result of COVID-19, including the related stay-at-home and shelter-in-place orders mandated by state and local governments in which we operate, most of our employees, including those responsible for financial reporting, have or continue to work remotely a significant amount of time. As part of our Company's transition to a hybrid/remote workforce, we took precautionary actions to re-evaluate our financial reporting process to provide assurance that we could report our financial results accurately and timely. We will continue to monitor and assess new potential impacts of COVID-19 on the design and operating effectiveness of our internal controls going forward.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

Information on our legal proceedings is set forth in Note 7 to the Unaudited Interim Financial Statements included under Part I, Item 1.

### Item 1A. Risk Factors.

*Except as set forth below, the Company's risk factors have not materially changed from those previously disclosed in Part 1, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021.*

#### ***We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.***

We have incurred net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through the sale and issuance of common stock and preferred stock. Our net losses were \$269.9 million for the year ended December 31, 2021 and \$197.0 million for the three months ended March 31, 2022. As of March 31, 2022, we had an accumulated deficit of \$809.8 million. We have devoted substantially all of our resources and efforts to research and development. Our lead compound, lirentelimab, is in clinical development, and our other product candidates are in preclinical development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

#### ***We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.***

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, lirentelimab and our other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. We have also incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of March 31, 2022, we had \$246.7 million in cash, cash equivalents and investments in marketable securities, which includes proceeds from our July 2018 initial public offering and concurrent private placement that we completed on July 23, 2018 and from our subsequent follow-on offerings in August 2019 and November 2020, after deducting underwriting discounts and commissions. We believe that our existing cash, cash equivalents and investments in marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Our estimate as to how long we expect our existing cash, cash equivalents and investments in marketable securities to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our existing cash, cash equivalents and investments in marketable securities to fund our development of lirentelimab and for other research and development activities, working capital and other general corporate purposes. This may include additional research, hiring additional personnel, capital expenditures and the costs of operating as a public company. Advancing the development of lirentelimab and any other product candidates will require a significant amount of capital. Our existing cash, cash equivalents and investments in marketable securities will not be sufficient to fund all of the actions that are necessary to complete the development of lirentelimab or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders

or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

***We are currently and may in the future be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are currently and may in the future be the target of this type of litigation. For example, on March 10, 2020, a putative securities class action complaint captioned Kim v. Allakos et al., No. 20-cv-01720 (N.D. Cal.) was filed in the United States District Court for the Northern District of California against us, our Chief Executive Officer, Dr. Robert Alexander, and our former Chief Financial Officer, Mr. Leo Redmond. The complaint asserts claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder and seeks damages based on alleged material misrepresentations and omissions concerning our Phase 2 clinical trials of lirentelimab. The proposed class period is August 5, 2019, through December 17, 2019, inclusive. This or other securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. On March 31, 2022, the Court granted the defendants' motion to dismiss, with leave to amend. On April 29, 2022, the plaintiffs filed a second amended complaint which extended the proposed class period from December 17, 2019 to December 21, 2021 and added additional claims related to the Company's Phase 3 ENIGMA clinical trial. The defendants intend to file a further motion to dismiss. This or other securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

**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.**

None



Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Number	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant.</a>	8-K	001-38582	3.1	7/24/2018
3.2	<a href="#">Amended and Restated Bylaws of the Registrant.</a>	8-K	001-38582	3.2	7/24/2018
10.1*#	<a href="#">Master Development Services Agreement between the Registrant and Samsung Biologics Co., Ltd., dated March 31, 2022.</a>				
10.2*+	<a href="#">Outside Director Compensation Policy.</a>				
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
32.1**	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
32.2**	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	The cover page for the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, has been formatted in Inline XBRL.				

\* Filed herewith.

\*\* Furnished herewith.

+ Indicates management contract or compensatory plan.

# Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

**SIGNATURES**

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

Allakos Inc.

Date: May 6, 2022

By: /s/ Robert Alexander  
**Robert Alexander, Ph.D.**  
**Chief Executive Officer and Director**  
**(Principal Executive Officer)**

Date: May 6, 2022

By: /s/ H. Baird Radford, III  
**H. Baird Radford, III**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

Certain identified information in this document has been excluded because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed, and has been marked with “[\*\*\*]” to indicate where omissions have been made.

**MASTER DEVELOPMENT SERVICES AGREEMENT**

**Between**

**SAMSUNG BIOLOGICS CO., LTD.**

**and**

**ALLAKOS INC.**

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## MASTER DEVELOPMENT SERVICES AGREEMENT

This Master Development Services Agreement (this “**MDSA**”) is made and entered into as of March 31, 2022 (the “**Effective Date**”) by and between Allakos Inc., a Delaware corporation having its principal place of business at 825 Industrial Road, Suite 500, San Carlos, CA 94070, USA (“**Client**”), and Samsung Biologics Co., Ltd., a Korean corporation having its principal place of business at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea (“**SBL**”). Client and SBL are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

**WHEREAS**, Client and SBL wish to enter into a business relationship whereby SBL or through its Affiliate will provide Client with certain services related to biologics development and/or manufacturing;

**NOW, THEREFORE**, in consideration of the mutual promises, covenants and agreements hereinafter set forth and for other valuable consideration, the Parties agree as follows:

### **SECTION 1 DEFINITIONS**

Each of the following capitalized terms as used in this MDSA, whether in the singular or plural, shall have the respective meanings set forth below. Other capitalized terms are defined elsewhere in this MDSA.

**1.1 “Acceptance Procedure”** means the review of the Batch Related Documents and any reasonably necessary test(s) of a Batch of Product which are performed to verify that the Product delivered meets the Specifications and complies with Regulatory Authority requirements, which are conducted by Client before or after SBL’s release of a Batch of Product in accordance with the applicable PSA and QAG.

**1.2 “Affected Party”** means the Party affected by Force Majeure under Section 16.3.

**1.3 “Affiliate”** means any corporation, company, partnership or other entity which directly or indirectly, controls, is controlled by or is under common control with either Party hereto. A corporation or other entity shall be regarded as controlling another corporation or other entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other entity, or if possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other entity.

**1.4 “Annual Service Fees”** means the total Service Fees paid or payable by Client to SBL in a given calendar year (excluding costs of Raw Materials, Handling Fees, and other expense or cost reimbursements) pursuant to a particular Product Specific Agreement.

**1.5 “Applicable Laws”** means any and all laws, rules, or regulations of any jurisdiction which are applicable to the Parties in carrying out activities described in this MDSA or any PSAs that may be in effect from time to time.

**1.6 “Background IP”** means any Intellectual Property related to a Product or its use, or the Manufacture of such Product, in each case, which is owned or controlled by a Party prior to the Effective Date or

developed independently from the Services by a Party without using or reference to any Confidential Information or Intellectual Property of the other Party.

- 1.7 “Batch”** means a cGMP batch of Clinical Product Manufactured by SBL which results from a single run of the applicable Manufacturing Process.
- 1.8 “Batch Failure”** means that a Batch is Non-Conforming Product as determined as set forth in Section 4.6 during Manufacture of a Batch and prior to SBL’s batch release.
- 1.9 “Batch Record”**, if not defined in the applicable QAG, means the document, proposed by SBL and approved by Client (which approval will be in the reasonable discretion of Client), which defines the manufacturing methods, test methods, and other procedures, direction, and controls associated with the Manufacture and testing of Product.
- 1.10 “Batch Related Documents”** means Manufacturing Documentation in support of SBL’s release of a Product.
- 1.11 “Cancellation Fees”** means any fees set forth in a PSA that shall be paid to SBL by Client upon Client’s termination of any Service as set forth in the applicable PSA.
- 1.12 “Cell Line”** means the cell bank vials supplied to, in possession of, or otherwise made available to SBL to perform the Development and/or Manufacturing Services.
- 1.13 “Certificate of Analysis”**, if not defined in the applicable QAG, means a document prepared by SBL with respect to a particular Batch listing tests performed by SBL or an External Laboratory and the results of such tests.
- 1.14 “Certificate of Compliance”** means a document prepared by SBL with respect to a particular Batch that verifies completion of all operations in accordance with the Batch Record and Applicable Laws (including cGMP, if applicable).
- 1.15 “Change”** means any modification, alteration, adjustment, or correction to the Manufacturing Process, Services, or Specifications.
- 1.16 “Client”** is defined in the preamble.
- 1.17 “Client Invention”** means any Invention solely derived from Client Technology or Client Confidential Information, including any improvement, modifications, extensions, and expansions thereof.
- 1.18 “Client Materials”** means Client reagents and other materials supplied by Client or its third party supplier to be used in the Service hereunder. In the case of a Drug Product PSA, Client Materials include Drug Substance or other active pharmaceutical ingredients, which may or may not have been Manufactured by SBL.

**1.19 “Client Technology”** means know-how, technology, or research owned by Client relating to the Product, Services, Manufacturing Process, analytical methods, quality control analysis, specifications, transportation and storage requirements and provided by Client to SBL in connection with this MDSA and applicable PSA.

**1.20 “Clinical Product”** means a Drug Substance or Drug Product which is Manufactured by SBL pursuant to a PSA and which is to be used by Client in a research study or studies that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

**1.21 “Commercially Reasonable Efforts”** means with respect to an activity to be carried out by a Party pursuant to this MDSA, the carrying out of such activity in a diligent manner, and using efforts and resources comparable to the efforts and resources commonly used in the contract manufacturing of biologics (in the case of SBL) or in the biopharmaceutical industry (in the case of Client) by companies with resources and expertise similar to those of such Party. “Commercially Reasonable Efforts” requires prompt assignment of responsibility for such task or activity to specific qualified employee(s) and allocation of resources designed to advance progress with respect to such task or activity but does not require the taking of actions (a) which would require or is likely to require a material adverse change in such Party’s business strategy, existence or solvency, or significant assets, (b) disproportionate to the benefits received under this MDSA, or (c) would require either Party to violate Applicable Laws or break any existing contractual commitments with third parties which were entered into by prior to the Effective Date.

**1.22 “Confidential Information”** means any and all scientific, business, financial, contractual, marketing and technical information of or about a party or a Product which has been or may be disclosed, or to which access is provided, by such party (“**Disclosing Party**”) or any of its representatives to the other Party (“**Receiving Party**”) or any of its representatives, which (a) if in writing, is marked “confidential”, “proprietary” or other similar marking at the time of disclosure, or (b) if provided orally or visually, is identified as confidential at the time of disclosure and confirmed in writing to Receiving Party within fifteen (15) days of such disclosure, or (c) Receiving Party knows or has reason to know is confidential, trade secret or proprietary information of the Disclosing Party at the time of disclosure. For clarity, the existence and terms of this MDSA shall be deemed to be the Confidential Information of both Parties; provided however that in the event the Parties engage in a Cell Line Development Service using CHOZN cell line, SBL is obligated to disclose the existence of the contractual relationship to [\*\*\*], and thus shall be allowed to disclose a summary of the relevant intellectual property related terms of this MDSA or any applicable PSA to [\*\*\*], which summary shall under no circumstances include any Confidential Information related to the Client Background IP.

**1.23 “Core Team”** means a committee composed of an equal number of representatives from each of SBL and Client to oversee, review, and coordinate the day-to-day performance of the Services with the goal of ensuring effective communication between the Parties.

**1.24 “Critical Raw Material”** means Protein A resin and any other Raw Materials with similar financial value and importance, as reasonably agreed between the Parties.

**1.25 “Current Good Manufacturing Practices” or “cGMP”** means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Regulatory Authority, including as promulgated under and in accordance with (i) the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Parts 210, 211, 600, 601 and 610, (ii) relevant EU legislation, including European Directive 2003/94/EC or national implementations of that Directive, (iii) relevant guidelines, including the EU Guidelines for Good Manufacturing Practices for Medicinal Products (Eudralex Vol. 4 and Annexes thereto), (iv) International Conference on Harmonisation Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients and (v) and any analogous set of regulations, guidelines or standards as defined, from time to time, by any relevant Regulatory Authority having jurisdiction over the development, manufacture or commercialization of the Product, as applicable, in each case as in effect as of the date such manufacturing for the Product are or were conducted.

**1.26 “Customized or Dedicated Raw Materials”** means (1) media, resin (other than ProA Resin), UFDF membrane, and virus/depth filters, and (2) any other Raw Materials that (a) require customization or specific testing for Client or (b) are dedicated, under Section 4.3 of this MDSA, just for Client and not intended to be used across multiple product or customers.

**1.27 “Damages”** means any direct damages, costs, expenses, fines, penalties (including reasonable attorneys’ fees and costs), losses and liabilities.

**1.28 “Decision Memo”** means a binding memorandum summarizing and memorializing the Parties’ discussion, understanding, and agreement as to any aspect of the Manufacture that are not directly or specifically elaborated in the MDSA, PSA, Project Plan, or any previous Decision Memo, that is executed by authorized representatives of both Parties.

**1.29 “Deliverables”** means the “Deliverables” as defined in the applicable PSA.

**1.30 “Development”** means development services that SBL agrees to provide to Client pursuant to a separate PSA or Scope of Work, which may include cell line development, process development, optimizations studies, development of analytical methods, laboratory process scale-up, and generation of materials for toxicology studies.

**1.31 “Drug Product”** means a finished or intermediate dosage form that contains a Drug Substance, generally, but not necessarily, in association with one or more other ingredients.

**1.32 “Drug Substance”** means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

**1.33 “Effective Date”** is defined in the preamble.

**1.34 “EMA”** means the European Medicines Agency, or any successor agency.



**1.35 “External Laboratory”** means a third-party laboratory instructed by SBL, with Client’s prior consent, to conduct activities required to complete certain Services as discussed and agreed upon by the Parties including but not limited to vector construction, MCB manufacturing and characterization, mycoplasma testing, viral clearance studies, and adventitious virus screening.

**1.36 “Facility”** means one or more of the facilities of SBL or its Affiliate(s) where the Services shall be performed, as further specified in each PSA.

**1.37 “FDA”** means the United States Food and Drug Administration or any successor agency thereto.

**1.38 “Force Majeure Event”** means any event or occurrence which is beyond the non-performing Party’s reasonable control, including, to the extent beyond such Party’s reasonable control, fire, explosion, tsunami, earthquake, flood, landslide, pandemic, epidemics, or other acts of God; acts, regulations, export or import restrictions, embargos (including but not limited to those promulgated by any U.S. or E.U. Regulatory Authority), or laws of any government; terrorism, war; failure of public utilities; acts of decisions of duly constituted municipal, state, national or supra-national governmental authorities or of courts of law; or impossibility to obtain Raw Materials, equipment, supplies, fuel or other required materials or the occurrence of other supply or manufacture interruptions (at its or third-party facilities), in spite of having acted with Commercially Reasonable Efforts.

**1.39 “Handling Fees”** means the administrative or handling fees charged to Client on a cost-plus basis in a PSA with regards to Raw Materials, Client Materials, or External Laboratories as set forth in the applicable PSA.

**1.40 “Implementation Plan and Budget”** means an estimated plan and budget of the reasonable and necessary costs that would be incurred by SBL as a result of the implementation of any such Change(s), including but not limited to: (i) process and analytical development; (ii) equipment or the Facility modifications, qualification, validation, maintenance, and decommissioning/disposal; (iii) process and analytical validation; (iv) document revisions or changes, the Facility, equipment, and system modifications or changes; (v) additional stability testing; and (vi) preparing submissions to Regulatory Authorities.

**1.41 “Incoming Technology Transfer”** means the activities by the Parties necessary for SBL to perform the Services as further described in the applicable PSA which may include, among other things: (i) transfer of the Background IP and Client Material from Client to SBL; (ii) implementation of the Manufacturing Process at the Facility; (iii) Manufacturing Process fit activities, and (iv) tests and studies.

**1.42 “Indemnified Party”** means the Party claiming indemnification under SECTION 12.

**1.43 “Indemnifying Party”** means the Party subject to an indemnification claim from the other Party.

**1.44 “Intellectual Property”** means: (a) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, restorations, substitutions, renewals, registrations, revalidations,

reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (b) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), pictorial and graphic works; (c) trade secrets, technology, developments, discoveries and improvements, know-how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential economic value and are not available in the public domain; (d) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans, Internet domain names, and all goodwill associated therewith; and (e) all other intellectual property or proprietary rights, in each case whether or not subject to statutory registration or protection.

**1.45 “Invention”** means any Intellectual Property created by either Party which arises out of or results from the Service under the MDSA.

**1.46 “Joint Steering Committee”** or “JSC” means a committee composed of an equal number of representatives from each of SBL and Client, with the purpose of providing guidance to the Core Team and resolving any issues or disputes which in good-faith are not able to be resolved by the Core Team.

**1.47 “Manufacturing”** or to “**Manufacture**” means the manufacturing of the Batch(es) of Product, and any services relating to such manufacturing that are set forth in the applicable PSA, which shall commence from OOF date and includes applicable testing (including quality and stability), quality control, documentations, archiving, packaging, and labeling, and storing and up to and including release of the Product.

**1.48 “Manufacturing Documentation”** means with respect to a given Product, the data acquired and generated, documents and records describing or otherwise related to the Manufacturing Process including: documents and records consisting of or containing process descriptions, requirements and specifications; Client Materials and Specifications; analytical methods, process trend and variability data; validations protocols and reports; Batch Records; Batch Related Documents, and SOPs.

**1.49 “Manufacturing Process”** means, with respect to a given Product, the mutually agreed production process for the Manufacturing of the Product, which shall be deemed to commence at the OOF date for Drug Substance and the thawing date for Drug Product and end with SBL’s release of the Product.

**1.50 “Non-Affected Party”** means the Party other than the Affected Party under Section 16.3.

**1.51 “Non-Conforming Product”** means a Batch of Product that fails to conform to the Specifications, or other mutually agreed upon written express requirements for SBL to follow resulting in [\*\*\*].

**1.52** “**OOF**” or “**Out-of-Freeze**” means the thawing of the cell bank vials.

**1.53** “**Other Raw Material**” means any Raw Material other than Critical Raw Material and Customized or Dedicated Raw Material.

**1.54** “**Party**” and “**Parties**” is defined in the preamble.

**1.55** “**Product**” means Clinical Product to be Manufactured by SBL or its Affiliates pursuant to this MDSA and any applicable PSA.

**1.56** “**Product-in-process**” means any unfinished Product under the Manufacturing Process.

**1.57** “**Product Specific Agreement**” or “**PSA**” means a separate agreement specific to each Product (e.g., Cell Line Development, Process Development, Manufacture of Drug Substance or Drug Product, etc., for such Product), entered into and mutually agreed from time to time by duly authorized representatives of the Parties. Each PSA shall refer to and be integrated in this MDSA and may include, without limitation, details such as (i) a high level scope of work of the Services to be performed under such PSA which describes key activities and assumptions, (ii) the Product for which SBL will perform such Services for Client, (iii) fees to be paid to SBL by Client for the Services, and (iv) any other deliverables. Any Scope of Work, Project Plan, or Decision Memo attached to or executed under a PSA will be considered part of such PSA and will be deemed to be included in references herein to such PSA.

**1.58** “**Project Plan**” means a formal, approved document used to guide both project execution and project control and may, by mutual agreement, be substituted by or operate in conjunction with a Scope of Work to the PSA or a Decision Memo. The primary uses of the Project Plan are to document planning assumptions and decisions, facilitate communication among project stakeholders, and document approved scope, cost, and schedule baselines. The Project Plan will contain the description and overall objectives of the Services for Manufacturing a Product and may include, among other things: (a) JSC and Core Team membership rosters, (b) change request procedures, (c) details, intentions, and deliverables for Incoming Technology Transfer, (d) project schedule, (e) detailed procurement plan, as needed, and (f) project budgets and invoicing plans.

**1.59** “**PSA Effective Date**” means the effective date of any PSA entered into between the Parties.

**1.60** “**Purchase Order**” is a binding document issued by Client to SBL indicating, among other things, the quantity to be manufactured, the agreed prices for Product or Service, and the estimated delivery date to be later confirmed and fixed in accordance with Section 4.7.2(b).

**1.61** “**Quality Agreement**” or “**QAG**” means the quality agreement entered into by the Parties that governs the responsibilities related to quality systems and quality requirements for the Product(s) Manufactured hereunder, including quality control, testing and release of such Product(s) at the Facility entered into by the Parties.

**1.62** “**Quarter**” means each period of three (3) consecutive calendar months beginning on January 1, April 1, July 1, or October 1.

- 1.63 “Raw Materials”** means those materials procured by SBL that are used in the Services, including, but not limited to, chemicals, reagents, filters, excipients, disposable consumables, and secondary packaging materials. Raw Materials exclude the Client Materials.
- 1.64 “Regulatory Approval”** means all approvals, licenses, registrations or authorizations thereof of any national, regional, state or local regulatory agency, department, bureau or other governmental entity in any jurisdiction where the Product is marketed or intended to be marketed, necessary for the manufacture and sale of the Product manufactured by SBL at the Facility.
- 1.65 “Regulatory Authority”** means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, provincial, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction responsible for granting the Regulatory Approval.
- 1.66 “Reserved Capacity”** means the capacity for Development or Manufacturing the Product within SBL’s Facility reserved and dedicated solely to Client, the costs of which shall be calculated based on the Service Fees for such Development or Manufacturing Services that will be specified in the applicable PSA.
- 1.67 “SBL Assignable Error”** means: [\*\*\*].
- 1.68 “SBL Invention”** means any Invention other than Client Invention.
- 1.69 “Scope of Work”** means the document generally forming part of a PSA, specifying in detail the scope and schedule of the Services and the Service Fees as mutually agreed upon by the Parties.
- 1.70 “Service”** or **“Services”** means any service related to Development or Manufacturing for Client as specified in PSA and in accordance with the terms and conditions of this MDSA.
- 1.71 “Service Fee”** is the fee due and payable to SBL in consideration for SBL’s performance of Services and other obligations, but excluding the costs of Raw Materials, Handling Fees, and other expense or cost reimbursements authorized by the Parties in writing.
- 1.72 “Specification(s)”** means the criteria for the Products, Client Materials, or Raw Materials, as the case may be, which details are provided in documentation as reviewed and approved in good faith in writing by the Parties.
- 1.73 “Standard Operating Procedure(s)”** or **“SOP(s)”** means the standard operating procedures established by and mutually agreed upon by both Parties regarding the Manufacturing Process.
- 1.74 “Tax”** means all taxes, charges, customs duties, fees, levies, imposts, or withholding of whatever nature imposed by any law or regulations in any country in respect of the Services, importation or exportation of Raw Materials, Client Materials, Batches, and Product.
- 1.75 “Technology Transfer Out”** means [\*\*\*].

**1.76 “Term”** means the duration for which this MDSA stays in effect, which shall begin as of the Effective Date and will be in effect for as long as any PSA is in effect.

**1.77 “Warehouse”** means SBL’s warehouse for storage of the Product located at [\*\*\*].

## **SECTION 2 RELATED AGREEMENTS AND EXHIBITS**

**2.1 Product Specific Agreements.** SBL will perform Services for Client as specified in PSAs and in accordance with the terms and conditions of this MDSA. In the event of a conflict between any provision of this MDSA and the PSA, this MDSA shall control, except where the PSA specifically states otherwise and references this Section 2.1.

**2.2 Project Plan.** Concurrently with or, if mutually agreed, within a reasonable time after the PSA Effective Date, the Parties shall agree on a Project Plan and/or Scope of Work which will specify in detail the scope and schedule of the Services, including Incoming Technology Transfer, Development, and Manufacturing; provided however that the Parties acknowledge that the schedule set forth in the Project Plan or Scope of Work is an estimate only, as the biological processes involved in the Services are unpredictable by nature. The Project Plan or the Scope of Work may be updated as needed by mutual agreement of Client and SBL and is governed by and incorporated into the applicable PSA by reference. If Client request any change to a Project Plan or Scope of Work, SBL shall use reasonable efforts to accommodate such request. If there is a conflict between the Project Plan or Scope of Work and the applicable PSA, the PSA shall control. If the assumptions on which the Parties have agreed to the Project Plan are no longer valid or if additional activities are required, the Parties may change or update the Project Plan or the Scope of Work from time to time based on mutual agreement. SBL shall maintain capacity at the Facility for Client as per the Reserved Capacity set forth in the applicable PSA.

**2.3 Quality Agreement (QAG).** As required, the Parties shall agree upon a Quality Agreement applying to such Services, and such Quality Agreement shall be incorporated into this MDSA.

**2.4 Commercial Supply Agreement.** Upon Client’s request, the Parties shall use Commercially Reasonable Efforts to enter into a separate commercial supply agreement that are acceptable to both Parties for the commercial manufacture of Product at the Facility (“**Commercial Supply Agreement**”). Notwithstanding the foregoing, despite both Parties’ efforts, if the Parties cannot agree to mutually acceptable terms and conditions of the Commercial Supply Agreement within [\*\*\*] or such other timeframe as may be agreed in writing by the Parties, the Parties shall have no further obligations to proceed with such negotiations.

## **SECTION 3 MANAGEMENT OF SERVICE**

**3.1 General.** SBL shall adequately staff the Facility with personnel with necessary expertise to perform its obligations under the MDSA. Each Party will be responsible for its internal decision making process and for reasonably informing the other Party of decisions affecting the Service in a regular and timely manner. SBL and Client shall at all times make Commercially Reasonable Efforts to complete the Services in accordance with the estimated timelines set forth in the applicable PSA. Client shall supply

to SBL all information or materials that may be reasonably required by SBL to perform the Services. Client acknowledges that timely provision of information requested by SBL is critical to perform the Services and to meet the timeline set forth in the applicable PSA. SBL shall not be responsible in any way for any delays arising out of Client's failure to do so. In addition, Client shall be responsible for additional costs and expenses arising out of such delay including, if applicable, the costs of Reserved Capacity if such costs and expenses were incurred due to Client's failure to provide necessary information to provide the Services.

### **3.2 Core Team, and Joint Steering Committee.**

**3.2.1 Core Team and Joint Steering Committee.** The Parties shall establish the Core Team, which shall resolve any issues arising from the Services including those relating to changes to the project assumptions and timelines, Development activities, Specifications, or Manufacturing Process. The Parties shall also establish a Joint Steering Committee providing guidance to the Core Team and resolving any issues or disputes which in good-faith are not able to be resolved by the Core Team.

**3.2.2 Meetings and Decision Making.** The Core Team and JSC shall meet on schedules and in manners that are acceptable to their respective members. Each Party may appoint temporary or permanent substitutes for any of such Party's members on the Core Team or JSC and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend Core Team or JSC meetings. Each Party shall be responsible for its own expenses of traveling to and participating in any Core Team or JSC meeting. All decisions of the JSC and Core Team shall be made by the unanimous agreement of all of their members or their designated representatives, and shall be reflected in written meeting reports. Written reports of the JSC and Core Team shall be subject to approval by the authorized representatives of the Parties; provided, however, that the JSC and Core Team may not amend or waive any provision of the MDSA or applicable PSA except by the terms of this MDSA.

**3.2.3 Disputes.** In the event that the Core Team, is unable, despite the good faith efforts of the members, to resolve a disputed issue that is within the purview of the Core Team for a period of ten (10) days, one Party shall formally request referral of the issue to the JSC. If the dispute still cannot be resolved within an additional thirty (30) days after referral to the JSC, the matter may be handled in accordance with SECTION 15.

**3.3 Person in Plant.** Client may request up to two (2) of its personnel during normal business hours to be on-site at the Facility to observe and consult with SBL during the performance of Services under this MDSA and such additional personnel in such numbers as deemed necessary shall be accommodated upon mutual agreement. Any reasonable expenses associated with such on-site Client personnel incurred by SBL shall be passed through to Client by SBL. While at the Facility, all such Client personnel shall have reasonable access to all areas as are relevant to SBL's performance of the Service hereunder, provided that SBL may reasonably restrict Client personnel's access to the Facility as it deems necessary, and all such Client personnel shall agree to and comply with confidentiality obligations to third parties, SBL policies and procedures related to safety, confidentiality, and cGMP, and all instructions of SBL

employees at the Facility. Client shall remain responsible at all times as its own for the compliance with the terms of this MDSA and PSA by its employees and personnel.

**3.4 Subcontract.** SBL may subcontract any portion of the Services with prior approval from the Client. Each such subcontractors must be appropriately and fully qualified in all respects to perform the applicable Services. The appointment of any subcontractor shall not relieve SBL from any liability or obligation under this MDSA or any PSA and SBL shall be responsible for all acts and omissions of the subcontractor to the same extent as if they were its own acts or omissions. All costs associated with activities outsourced to subcontractors will be included as part of the Service fees set forth in each PSA, unless otherwise agreed to in each such PSA.

**3.5 External Laboratories.** Client and SBL agree to use External Laboratories for specific operations (e.g. vector construction, MCB manufacturing and characterization, viral clearance, Mycoplasma, adventitious virus screen, etc.) as set forth in the PSA or Project Plan. SBL shall not be responsible for [\*\*\*]. All fees paid by SBL to the External Laboratories for their services (including taxes, if any) will be passed through to Client with an additional Handling Fee set forth in the applicable PSA.

**3.6 Development and Manufacturing Site.** Unless otherwise agreed by Client and except for any Service performed by approved subcontracts or External Laboratories, SBL shall perform all Services at the Facility.

**3.7 Manufacturing Documentation.** SBL shall maintain Manufacturing Documentation to be true and accurate, and shall keep it in strict confidence and shall not use it for purposes other than providing or performing the Service or other obligations hereunder. SBL shall maintain all such Manufacturing Documentation for at least that period specified in the applicable QAG. Upon written request of Client and at mutually agreed times, Client shall have the right to review Manufacturing Documentation at the Facility, including as further defined in the applicable QAG. Client may also request scanned or printed copies of such Manufacturing Documentation, but shall be responsible for reasonable documented costs associated therewith. SBL shall record and maintain such records, data, documentation and other information in the language as so required in the applicable QAG or as so required by a Regulatory Authority and in compliance with Applicable Law. To the extent necessary, SBL may redact or withhold Manufacturing Documentation provided to Client pursuant to this MDSA or any applicable PSA to protect the confidential information of its other clients or third parties, but not when provided directly by SBL to any Regulatory Authority. The form and style of Batch documents, including but not limited to Batch production records, lot packaging records, equipment set up control, operating parameters, data printouts, raw material data and laboratory notebooks, are the exclusive property of SBL. Notwithstanding anything to the contrary, SBL's SOPs not specific to the Client's Products may be provided to Client for on-site review if reasonably necessary for the Development or Manufacture of the Product hereunder. Such SOPs cannot be removed from the SBL premises, copied, photographed or otherwise replicated, unless SBL is required by applicable Law or any Regulatory Authority to make such disclosure.

## **SECTION 4 SERVICE DESCRIPTIONS**

**4.1 Incoming Technology Transfer.** Client shall transfer to SBL copies of and grant to SBL the license set forth below in Section 10 in respect of the Client Technology, Client Materials, and Cell Line in accordance with the plan, timelines, and quantities agreed upon by the Parties. In the event that Client agrees to utilize SBL's [\*\*\*] portal for Incoming Technology Transfer, Client agrees that (a) in the event of any relevant change that affects a Client user's authorization to use such portal, Client shall immediately notify SBL so that SBL may disable their usernames and remove / change passwords in order to secure the SBL Portal and (b) Client shall ensure that all of Client users have up-to-date antivirus software installed on the computer devices used to access such portal.

**4.2 Additional Work.** Should the Parties mutually agree to any additional work to be added to the Project Plan or the Scope of Work, the Service Fees for such additional work shall be based on SBL's submitted proposal at the time of adding such additional work, and depending on the nature of such additional work, the Parties shall execute a Decision Memo or an amended Projected Plan or Scope of Work accordingly. In any event, SBL shall not be obligated to accept or perform any additional work requested by Client.

### **4.3 Raw Materials.**

**4.3.1 Management.** SBL shall procure and maintain a reasonable quantity of Raw Materials required for the Services in accordance with the MDSA and any applicable PSA. On a per-Product basis, SBL shall prepare the categorization of the Raw Materials into (i) Critical Raw Materials, (ii) Customized or Dedicated Raw Materials, and (iii) Other Raw Materials, and send the categorization to Client for approval as soon as practicable after the Effective Date. Client shall approve the categorization in accordance with this MDSA and any applicable PSA no later than [\*\*\*] after the receipt of such a categorization from SBL. SBL shall not be liable for [\*\*\*]. Client shall not be liable for [\*\*\*]. The list of Raw Materials may be amended from time to time, subject to the Parties' mutual agreement; provided however that, Client shall at all times be solely responsible for the costs of Raw Materials including those used in small scale runs during Technology Transfer In, which is not included in the Service Fees. During Technology Transfer In, the Core Team shall agree on estimates for Raw Materials anticipated to be consumed in the Services. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for [\*\*\*]; provided, however, that SBL shall be responsible for [\*\*\*]. Client acknowledges that SBL's safety stock strategy is based on the SBL's reasonable estimation of the necessary quantity needed for Manufacturing Reserved Capacity in accordance with applicable PSA. In the event SBL is not able to utilize any Reserved Capacity due to Client's failure to agree to such strategies, then Client shall be responsible for the costs of such Reserved Capacity regardless of whether it is utilized or not.

**4.3.2 Raw Material Specifications.** Client and SBL shall agree on the Specifications of Raw Materials, including analytical methods, supplier information including supplier site information, and other information concerning the stability, storage, and safety thereof that are required for the Services hereunder, as further described in the applicable QAG.



**4.3.3 Testing and Evaluation.** SBL or vendors qualified by SBL shall perform all testing and evaluation of Raw Materials as required by the Specifications for the Raw Materials and the cGMPs, as further described in the applicable QAG, if applicable.

**4.3.4 Storage.** SBL shall secure sufficient and suitable storage for the Raw Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise reasonable care to preserve and protect Raw Materials from destruction, theft, or loss after receipt by SBL and prior to Services and except [\*\*\*], Client shall be responsible for [\*\*\*]. At the end of each calendar year of the relevant PSA, Client shall be responsible for the loss of Raw Material to the extent purchased in reliance on a Purchase Order where such Raw Material expires or becomes obsolete because Client fails to honor such a Purchase Order and SBL cannot reasonably otherwise utilize such Raw Material.

**4.3.5 Handling Fee Related to Raw Material.** Raw Materials will be charged on a cost-plus basis to Client in accordance with Sections 8.1(ii) and 8.3.2, subject to any changes as agreed between the Parties.

#### **4.4 Client Materials.**

**4.4.1 Management.** Client shall provide, either by itself or through its third-party supplier(s), to SBL free of charge, Client Materials in amounts reasonably necessary to carry out the Services as agreed by the Parties. SBL shall make Commercially Reasonable Efforts to import the Client Materials to the Republic of Korea in a timely manner, and Client shall provide reasonable assistance necessary for such a timely importation. Delivery conditions for the Client Materials shall be [\*\*\*]. During Incoming Technology Transfer, the Core Team shall agree on estimates for Client Material anticipated to be consumed in the Services. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for [\*\*\*]; provided, however, that (a) SBL shall be responsible for [\*\*\*] and (b) notwithstanding anything to the contrary, SBL will not in any circumstance be responsible for [\*\*\*]. Client acknowledges that SBL's safety stock strategy is based on the SBL's reasonable estimation of the necessary quantity needed for Manufacturing Reserved Capacity in accordance with applicable PSA. In the event SBL is not able to utilize any Reserved Capacity due to Client's failure to agree to such strategies, then Client shall be responsible for [\*\*\*].

**4.4.2 Client Material Specifications.** Client shall provide SBL with the Specifications of the Client Materials, including without limitation analytical methods, supplier information, and other information concerning the stability, storage, and safety thereof that are required for the Services hereunder, as may be further described in the applicable QAG.

**4.4.3 Testing and Evaluation.** SBL shall perform testing of the Client Materials in accordance with the applicable QAG or Client's instruction prior to the performance of the Services hereunder in order to determine whether such Client Materials meet the Specification described in the applicable QAG (if applicable). SBL shall inform Client of (a) any damage to the Client Materials received that is visually obvious (e.g., damaged or punctured containers and temperature monitoring

results outside of predetermined Specifications) within [\*\*\*] after SBL's receipt of the Client Materials and (b) any non-conformance of the Client Materials to Specification either: (i) within [\*\*\*] after SBL's receipt of the Client Materials or (ii) if release testing of Client Materials is not performed until it is needed for Services, within [\*\*\*] after such release testing is performed; or (iii) as otherwise agreed between the Parties. If, prior to performing any Service on the Client Materials, SBL determines that such Client Materials are defective or damaged, SBL shall not perform the Service on such Client Materials and shall follow Client's written instructions regarding disposal or return of such Client materials to Client, such disposal or return to be at Client's discretion and cost.

**4.4.4 Storage.** SBL shall secure sufficient and suitable storage for the Client Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise reasonable care to preserve and protect the Client Materials from destruction, theft, and loss after receipt by SBL and prior to Services.

**4.4.5 Handling Fee Related to Client Material.** Handling fees relating to the Client Material will be charged to Client in accordance with Sections 8.1(iii) and 8.3.3.

**4.5 Purchase Orders.** For each Product and Service, Client shall issue a binding purchase order in the form and substance agreed to between the Parties sufficiently in advance, requesting SBL to perform certain Services as set forth in the PSA or Manufacture a specific amount of Product as detailed in the Purchase Order. The Parties acknowledge that, with or without a Purchase Order issued in advance, an invoice may be issued in accordance with this MDSA, PSA, or applicable Decision Memo for Services, Raw Materials, and Handling Fees, and such invoices shall be processed and paid in accordance with Section 8.3.

#### **4.6 Batch Failure during Manufacture.**

**4.6.1** If, during Manufacture of a Batch and prior to SBL's batch release, the Core Team reasonably determines that the Batch is Non-Conforming Product (a "**Batch Failure**"), SBL shall take Commercially Reasonable Efforts to promptly re-Manufacture and deliver to Client a replacement Batch on a date to be mutually agreed by the Parties, which Service Fees and associated costs/fees (as set forth in Section 8.1 below) shall be invoiced and paid for by the Client. Client shall provide SBL with adequate Client Materials to Manufacture such Batches. The remedies contained in Section 4.6 of this MDSA shall be the sole and exclusive remedies of Client regarding a Batch Failure and a Batch Failure shall not constitute a material breach of this MDSA or a PSA unless SBL fails to provide the remedies contained in this Section 4.6.

**4.6.2** SBL shall promptly conduct a root cause analysis of any Batch Failure, which shall be done through SBL's deviation process and which result will be reviewed and confirmed by the JSC. If either the members on the Core Team do not agree as to the occurrence of a Batch Failure or on the Batch Failure root cause, or the members on the JSC do not agree as to the occurrence of a Batch Failure or on the results of the Core Team's Batch Failure root cause analysis, the Parties shall refer to an independent mutually agreed-on laboratory or firm with international repute, acting as a neutral arbiter, to confirm if there has been a Batch Failure and, if so, to conduct a root cause analysis of

the Batch Failure. The costs of the independent laboratory will be shared by the Parties equally; provided, however, that the Party that is determined to be incorrect as to the Batch Failure will be responsible for those reasonable costs and must reimburse the correct Party for its share of the reasonable costs incurred. The decision of the independent laboratory must be in writing and will be binding on the Parties. SBL, the Core Team, and the JSC shall work as expeditiously as possible in reviewing suspected Batch Failures, as the Parties recognize that delays in making such determinations could be costly to Client.

**4.6.3** In the event of Batch Failure, SBL or Client shall be responsible for [\*\*\*]. To the extent the Batch Failure is caused [\*\*\*], SBL shall be responsible for (1)-(4) above, and in all other Batch Failure cases Client shall be responsible for (1)-(4) above. Any such cost responsibility shall be [\*\*\*]. Notwithstanding anything to the contrary, SBL shall not be responsible [\*\*\*].

#### **4.7 Storage, Packaging and Delivery.**

**4.7.1 Service Deliverables other than Products.** Storage, packaging, and delivery of the Service deliverables other than Products Manufactured and the Products Manufactured hereunder shall be made by SBL in accordance with the terms of this MDSA, applicable PSA, Project Plan, applicable QAG and the Applicable Laws.

#### **4.7.2 Products.**

##### **(a) Release by SBL and Acceptance by Client.**

- (i)** SBL shall perform all testing in accordance with the Specifications of the Product and release the Product in accordance with the terms of the applicable QAG. Upon such release, SBL shall deliver to Client the Batch Related Documents, including a Certificate of Analysis and Certificate of Compliance, in accordance with the applicable QAG;
- (ii) Acceptance of Product.** Client will complete the Acceptance Procedure and determine the acceptability of such Product in accordance with the applicable QAG and notify SBL of the result within [\*\*\*] of Client's receipt of the complete Batch Related Documents. Upon Client's acceptance ("**Acceptance**"), SBL will have no liability for such Product (provided that this will not relieve SBL of its obligations and liabilities set forth in [\*\*\*]). If Client does not reject such Product within the [\*\*\*] period, the Product will be deemed to have been irrevocably accepted by Client and SBL will have no liability for such Product.
- (iii) Non-Conforming.** If, during the Acceptance Procedure, any Product is claimed by Client as Non-Conforming Product, (A) both Parties shall discuss in good faith and determine the reason for Client's claim; (B) SBL shall conduct a root cause analysis as per the processes set forth in Section 4.6.2, and (C) if SBL confirms such non-conformity or such Non-Conforming Product is confirmed as per the

processes set forth in Section 4.6.2, such non-conformity shall be treated as a Batch Failure, and the remedy set forth in Section 4.6 above shall apply to the Non-Conforming Product, in each case, *mutatis mutandis*. The remedies contained in this Section 4.8.2 shall be the sole and exclusive remedy of Client in the event of Non-Conforming Product (provided that this will not relieve SBL of its obligations and liabilities set forth in [\*\*\*]).

**(b) Delivery.** Shipping conditions for the Product Manufactured hereunder shall be [\*\*\*], unless otherwise agreed to in the applicable PSA. The title to Product hereunder shall be transferred from SBL to Client when the following conditions are both satisfied: [\*\*\*]. The Parties further agree as follows:

- (i)** after SBL's release of the Product and prior to each pick-up by Client or Client's designated carrier, SBL shall propose to Client a delivery schedule of the Product, in order for the Parties to agree on it in advance for each pick-up. SBL shall schedule Delivery with the carrier selected and paid for by Client;
- (ii)** SBL shall not deliver the Product until it has been instructed to by Client in accordance with the applicable QAG. Client shall confirm specific delivery instructions with SBL prior to SBL's release. Upon SBL's release of Product, SBL shall store the Manufactured Product as described in Section 4.7.2(c) and Client shall compensate SBL for storage costs for the Manufactured Product as set forth in the applicable PSA;
- (iii)** SBL shall provide Client with invoice, packing lists, supporting export documents as specified by Client by separate delivery and shipment documentation instructions, together with each shipment of the Product (or such other deliverables); and
- (iv)** in cooperation with Client and subject to the delivery schedule agreed by the Parties, SBL shall adhere to the first-expire-first-out (FEFO) principle in shipping all released Product.

**(c) Storage, Packaging and Shipping Container.**

- (i)** Pursuant to the terms of this MDSA and any applicable PSA, SBL shall store the Products Manufactured hereunder.
- (ii)** SBL shall store, package, label and prepare shipment according to the Specifications for the Product Manufactured hereunder, the applicable QAG and the SOPs, and using storage and/or shipping containers determined in the applicable PSA.
- (iii)** If Client does not direct SBL to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up date within [\*\*\*] of Client's

receipt of the Batch Related Documents, SBL shall store the Product at the Warehouse, and Client shall pay to SBL storage fees tiered based on the duration of storage as set forth in Section 8.1 for the period of storage at the Warehouse until the actual delivery date; provided however that under no circumstances shall the period of storage in the Warehouse exceed [\*\*\*].

**SECTION 5 CHANGES TO THE SPECIFICATIONS, ANALYTICAL METHODS, MANUFACTURING PROCESS, FACILITY OR EQUIPMENT**

**5.1 Approval for Change.** Change shall be implemented only with mutual agreement between the Parties acting reasonably and in good faith and in accordance with the applicable QAG. For clarity, any Changes for any Services in process or subject to Reserved Capacity may only be made with Client's approval, not to be unreasonably withheld, conditioned, or delayed.

**5.2 Changes Required by cGMP, Regulatory Authorities or Requested by Client.** Except as otherwise expressly set forth to the contrary in the applicable QAG, in the event that cGMP, a Regulatory Authority, Applicable Law, or any other regulatory or legal authority requires, or Client requests, a Change, SBL shall accommodate such requirements or requests, subject to the following:

- (a) Client shall promptly notify SBL in writing of the required or requested Change(s) after Client becomes aware of them, and provide information in Client's possession reasonably necessary for SBL to evaluate the effect of such Change(s), and SBL shall promptly advise Client as to any: (i) additional equipment required, modifications to the Facility or equipment, and/or additional equipment and the Facility qualification and validation requirements; (ii) Manufacturing Process Development, transfer, scale-up, testing, qualification, or validation requirements; (iii) regulatory requirements pursuant to such Changes; (iv) changes to the Manufacturing scheduling and/or Product delivery schedule; and (v) other impacts on the Facility or SBL's ability to manufacture products (including the Products) in the Facility, if any, which may result from such Change(s). The notification and formal approval procedure of such Changes shall be in accordance with the applicable QAG (i.e., change control procedures) (if applicable). The Parties shall meet in a timely manner to identify and discuss such Changes as appropriate;
- (b) prior to implementation of any such Change(s), SBL shall provide Client with an Implementation Plan and Budget, which shall include costs and allocation of costs as per Section 5.2(d). Following review and approval by Client of such Implementation Plan and Budget, subject to the Core Team's approval and agreement followed by the Parties' written agreement pursuant to Section 16.11 (if applicable), SBL shall commence implementation of such Change(s);
- (c) during any such implementation, SBL shall provide Client with regular updates on the progress of implementation. Subject to any timeframe imposed by Applicable Law, SBL shall exercise Commercially Reasonable Efforts to implement the Change according to the Implementation Plan and Budget's target completion date. SBL shall provide written

notice to Client if SBL becomes aware of any cause which may create delay with the implementation of Changes. Following any such notice, both Parties shall discuss an amendment of Implementation Plan and Budget; and

(d) as part of the Implementation Plan and Budget for Change(s), both Parties shall negotiate in good faith to determine the allocation of the costs incurred by SBL for the implementation of any such Change(s) between the Parties, in accordance with the following principles:

(i) the costs for the general Facility Changes required by cGMP, any Regulatory Authority, or any Applicable Laws related to the maintaining the Manufacturing Facility by SBL as set forth in Section 6.2, shall be borne by SBL, provided that where the Change relates exclusively or partially and specifically to the Manufacture of Product (and not to manufacture of products generally) in which case the costs shall be borne by Client fully or proportionally, respectively;

(ii) the costs for the Changes other than (i) above, and requested by Client and required uniquely for the Development or Manufacture of the Product and beneficial solely to Client shall be borne by Client; and

(iii) the costs for the Changes other than (i) and (ii) above shall be discussed in good faith by the Parties to achieve equitable allocation of costs.

## **SECTION 6 REGULATORY APPROVALS AND INSPECTIONS.**

**6.1 Regulatory Approvals.** To the extent applicable, SBL shall provide reasonable assistance and cooperation in order for Client to obtain and maintain the Regulatory Approvals. The costs and fees associated with such assistance and cooperation shall be detailed in the MDSA or PSA. Any additional cost or fee associated with or in addition to such assistance and cooperation shall be agreed between the Parties in writing, such cost or fee of which shall be borne by Client. As specified in the applicable PSA, the Parties shall discuss and agree on which Regulatory Approvals are to be obtained.

**6.2 Regulatory Approvals for the Facility.** To the extent applicable, SBL shall obtain and maintain all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity (other than the Regulatory Approvals, which will be obtained or maintained by Client) that are required to Manufacture the Product at the Facility and perform the Services.

**6.3 Regulatory Support Activities.** Any regulatory support activities required and agreed to by Client to support Regulatory Approval of the Product from the Facility shall be performed and supported by SBL as reasonably requested by Client and shall be paid for by the Client at the price set out in the applicable PSA. Unless otherwise agreed by the Parties, Client will have the sole right to correspond with and submit regulatory applications and other filings to any Regulatory Authorities to obtain Regulatory Approvals or other approvals to import, export, conduct clinical trials with, or sell the Product, alone or

in combination with other products when and as Client may deem useful and/or necessary. Accordingly, except as otherwise required by Applicable Laws and Regulatory Authorities' requirements, SBL will not correspond directly with any Regulatory Authority with respect to the Product without, in each instance, first obtaining Client's prior written consent.

## **SECTION 7 QUALITY COMPLIANCE**

**7.1 Quality Agreement.** Both Parties shall adhere to the provisions of the applicable QAG and the Parties agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the applicable QAG. In the event of a conflict between a Quality Agreement and either any provision of this MDSA or any PSA, the MDSA or PSA shall control except with respect to matters directly and specifically related to Product quality or regulatory requirements, in which case, the Quality Agreement will control.

## **7.2 Records & Audit.**

**7.2.1 Audit by Client.** Upon Client's request, but no more than [\*\*\*] (except that additional for-cause audits may be conducted), SBL shall accept a formal audit of the Facility and, if necessary, the Warehouse, by Client and allow Client to inspect the Facility and, if necessary, the Warehouse, and Manufacture of the Product during provision of the Services solely to ascertain compliance by SBL with the terms of this MDSA or any applicable PSA; provided, however that in the event Client uses a designee, SBL must provide prior written consent. SBL shall be reimbursed for its reasonable costs for audits beyond the audits described in the first sentence of this Section 7.2.1. SBL will make Commercially Reasonable Efforts to require vendors or subcontractor to accept an audit of their facilities by Client upon similar notice as described in Section 7.2.2 below.

**7.2.2 Audit Notice.** Client shall provide SBL with a written notice at least [\*\*\*] prior to the initiation of the audit of the Facility and, if necessary the Warehouse, set forth in Section 7.2, which shall be conducted on a mutually agreeable date and time, and with a mutually agreed duration, agenda, and visitor list. Notwithstanding the foregoing, if the audit is required for cause (i) due to safety reasons that necessitate immediate audit of or visit to the Facility or (ii) Client asserts that a substantial violation of the Quality Agreement has occurred which cannot be resolved through the normal Core Team / JSC process, the foregoing sentence shall not apply and Client may conduct such audit or visit by providing SBL with a prior notice by email. Access to SBL's facilities shall be coordinated with SBL so as to minimize disruption to SBL's ability to perform services for its other clients. Client representatives must comply with all of SBL's cGMP, confidentiality and security procedures and protocols (either made available to the representatives in writing or considered by a reasonable person working in the biopharmaceutical industry as typical procedures and protocols to be complied with) during such observations, consultations, and inspections. SBL shall at all times cooperate and provide all the necessary documents reasonably required by Client during such audit; provided that, to the extent necessary, SBL may redact or withhold documents to protect the confidential information of its other clients. Client shall be solely responsible for any costs and liability caused by Client's or its representatives' failure to comply with SBL's security, safety or confidentiality procedures to the same extent as if they were its own failure to comply.

## **SECTION 8 CONSIDERATION AND PAYMENT TERMS**

**8.1 Consideration.** In consideration for SBL's performance of the Service and other obligations undertaken by SBL pursuant to a PSA, Client shall pay SBL (i) the Service Fees as set forth in the applicable PSA; (ii) a Handling Fee of a certain percentage or certain amount to be set forth in the applicable PSA of the costs of Raw Materials paid by SBL (including but not limited Taxes); (iii) a Handling Fees of a certain percentage or certain amount to be set forth in the applicable PSA related to the Client Materials (which shall be based on the actual costs of such materials as supported by reasonable documentary evidence as opposed to the market value thereof and including Taxes); and (iv) storage fees as set forth in the relevant PSA.

**8.2 Travel.** SBL will not undertake any travel or travel-related expenses reimbursable by Client without Client's prior written consent.

### **8.3 Invoices.**

**8.3.1 Service Fee of the Project Stages and Batches.** Services and Batches shall be invoiced as set forth in the applicable PSA, unless otherwise agreed in writing by the Parties. SBL's invoices pursuant to this MDSA shall be electronic, unless otherwise agreed by the Parties.

**8.3.2 Raw Materials.** With respect to the Raw Materials, SBL shall submit invoices to Client for the applicable Raw Materials cost (including any approved safety stock for Customized or Dedicated Raw Materials) as set forth according to Section 8.1 as follows. Unless otherwise expressly specified in each applicable PSA, SBL shall submit an invoice to Client (i) for the cost of Critical Raw Materials and Customized or Dedicated Raw Materials upon [\*\*\*]; and (ii) for the cost of Other Raw Materials used upon [\*\*\*]. In each case, for all Raw Materials, SBL shall prepare a billing summary detailing the Raw Materials used and send the same to Client in accordance with Section 8.4. Within [\*\*\*]of receiving the billing summary for Raw Materials from SBL, Client shall either (1) accept and issue a purchase order for the Raw Material in accordance with the billing summary or (2) reject the billing summary based on reasonable grounds, in which case SBL shall promptly re-issue the billing summary. Client's failure to accept or reject a billing summary within the [\*\*\*] period shall be deemed an acceptance of the billing summary, and SBL will issue the corresponding invoice with or without a previously issued purchase order from Client.

**8.3.3 Client Materials.** With respect Handling Fees for the Client Materials, which shall be supplied by Client to SBL at no cost during SBL's performance of the Service, SBL shall invoice as set forth in the applicable PSA, unless otherwise agreed in writing by the Parties.

**8.3.4 Disclosure of Original Invoices.** For any Raw Materials purchased from third-party vendors, Services outsourced to External Laboratories, or Services for which costs will be passed through to Client, Client agrees and acknowledges that SBL shall be under no obligation to disclose the original invoice or any confidential information therein from the vendors due to its confidentiality obligation with such vendors, and that not furnishing such documents shall not constitute a valid ground for rejecting SBL's billing summary or invoice. Client may, however, request a third-party audit at



Client's expense, and SBL will allow any such audit upon Client presenting reasonably objective and reliable market data or price quotation justifying such an audit, with the auditor confirming the sole issue of whether there is any discrepancy or inaccuracy between the vendor's invoices and SBL's billing summary or invoice (without the auditor disclosing any confidential information of the vendor to Client). Should a discrepancy or inaccuracy be found through such an audit, SBL shall be responsible for [\*\*\*].

#### **8.4 Payment.**

**8.4.1 Mode of Payment; Foreign Exchange.** All payments to SBL due under the MDSA or any applicable PSA shall be made in US\$ within [\*\*\*] from the receipt of SBL's invoice in US\$ by means of telegraphic transfer to the account with the bank designated by SBL in the applicable invoice without any deduction, deferment, set off, or lien. For the purpose of computing payment amounts incurred by SBL in a currency other than US\$, such currency shall be converted into US\$ using the Bank of Korea Standard Rate published by the Bank of Korea at the opening of business on such invoice date.

**8.4.2 Taxes.** All prices and charges are exclusive of any Taxes, which shall be paid by Client. For the avoidance of doubt, the foregoing shall not include any taxes imposed on the income or profit of SBL levied on any payment to be made by Client to SBL or taxes on SBL's properties or personnel, each of which shall be solely borne by SBL. Client shall pay or reimburse SBL for all Taxes in connection with the purchase, sale, storage, importation or exportation of any Raw Materials, Client Materials, Batches, or Product or the provision of Services, except to the extent such Taxes are recoverable by or refundable to SBL. If SBL is required to charge and remit any such Taxes, it shall itemize all such taxes on an applicable invoice sent Client. SBL agrees to use Commercially Reasonable Efforts to assist Client in claiming exemption under double taxation or similar agreement or treaty from time to time in force to obtain a refund of any customs duties, value added taxes, and other taxes payable by SBL.

**8.4.3 Price Adjustments.** Starting on [\*\*\*], and annually thereafter effective on each January 1, Service Fees as set forth in the applicable PSA shall be adjusted [\*\*\*]. The relevant date for price adjustment under this Section shall be the issue date of SBL's invoice. Notwithstanding the above, in the event the term of an individual PSA is less than two (2) years, the yearly price adjustment in this Section 8.4.3 shall not apply.

**8.4.4 Default Interest.** Any amount that is (i) not disputed based on reasonably justifiable grounds and (ii) not paid by a Party to the other when due under the MDSA or any PSA shall bear default interest at the rate of [\*\*\*]. In the event there are amounts which (i) have been invoiced by SBL and (ii) are not disputed in good faith, but not paid by Client for more than six (6) months after the due date, such event shall be considered a material breach of the relevant PSA.

**8.5 Own Costs.** Except as otherwise expressly set forth in this MDSA or the applicable PSA, each Party will be responsible for its own costs and expenses of performing its activities pursuant to this MDSA and all PSAs.

## **SECTION 9 CONFIDENTIALITY**

**9.1 Confidential Information.** Both Parties agree to maintain the Disclosing Party's Confidential Information in confidence and not to disclose the Disclosing Party's Confidential Information, in whole or in part, to any third party, and not use the Disclosing Party's Confidential Information for any purpose other than performing its obligations under the MDSA or applicable PSA. The Receiving Party recognizes the proprietary nature of the Disclosing Party's Confidential Information and agrees that no right, title, ownership, license, or interest of any character in the Disclosing Party's Confidential Information other than as specifically granted herein, is conveyed or transferred to the Receiving Party. Each Party shall guard such Confidential Information using the same degree of care as it normally uses to guard its own confidential or proprietary information of like importance, but in any event no less than reasonable care. The Receiving Party shall limit disclosure of the Disclosing Party's Confidential Information to its and its Affiliates' directors, officers, employees, consultants and agents ("**Representatives**") only on a need-to-know basis, provided that, the Receiving Party shall undertake procedures such that each of its Representatives to whom the Disclosing Party's Confidential Information is disclosed understands (i) the confidential nature of the Disclosing Party's Confidential Information and (ii) that he or she is under an obligation similar to those contained herein to not disclose the Disclosing Party's Confidential Information.

**9.2 Exceptions.** Notwithstanding Section 9.1 above, Confidential Information shall not include the information, which as evidenced by written records: (a) was at the time of disclosure by the Disclosing Party hereunder publicly known or available; (b) after disclosure by the Disclosing Party hereunder, became publicly known or available by publication or otherwise, other than by an unauthorized act or omission by the Receiving Party; (c) was in the possession of the Receiving Party without confidentiality restriction at the time of the disclosure by the Disclosing Party hereunder; (d) was lawfully received from any third party having the lawful right to make such disclosure, without obligation of confidentiality; or (e) was independently developed by the Receiving Party's directors, officers or employees without reference to the Confidential Information, as demonstrated by records contemporaneous with such development.

**9.3 Authorized Disclosures.** Disclosure is permitted in the event that (a) the Disclosing Party's Confidential Information is reasonably required to obtain or maintain any Regulatory Approvals for the Products in any or all jurisdictions or (b) the Disclosing Party needs to disclose such Confidential Information to comply with Applicable Law or orders issued by a Regulatory Authority or other regulatory agencies, including the FDA and the Securities and Exchange Commission, or any nationally recognized securities exchange; provided that such Receiving Party shall exercise its Commercially Reasonable Efforts to limit disclosure of the Disclosing Party's Confidential Information to that which is necessary for compliance and to otherwise maintain the confidentiality of the Confidential Information. In the event that such disclosure is required as aforesaid, the disclosing Party shall make reasonable efforts to provide the other Party with at least ten (10) business days' advance notice and to coordinate reasonably with the other Party with respect to the wording and timing of any such disclosure.

**9.4 Survival of Confidential Obligations.** The confidential, non-disclosure, and non-use obligations of the Receiving Party shall survive for a period of [\*\*\*] from the expiration or termination of this MDSA,

provided that such obligations will continue with respect to Confidential Information that is protectable as a trade secret for as long as such Confidential Information remains as a trade secret.

**9.5 Return of the Confidential Information.** All written, printed or other tangible Confidential Information of the Disclosing Party disclosed under the MDSA, and all copies thereof shall be returned to the Disclosing Party (or destroyed at the Disclosing Party's request) by the Receiving Party within thirty (30) days from the written request by the Disclosing Party. All Confidential Information disclosed electronically shall be completely deleted and destroyed by the Receiving Party within thirty (30) days from the written request by the Disclosing Party. Notwithstanding the foregoing, (i) digital backup files automatically generated by the Receiving Party's customary electronic data processing system may be retained and properly stored as confidential files for the sole purpose of backup and will be deleted in accordance with the Receiving Party's retention policy, (ii) a single copy of the Confidential Information may be retained in the secured files of the Receiving Party for the sole purpose of determining the scope of obligations incurred by it under the MDSA; and (iii) the Receiving Party may keep copies of Confidential Information for which the Receiving Party has a continuing right or license to access or use such Confidential Information; provided that the Receiving Party shall keep such Confidential Information in confidence and will use the Confidential Information solely in accordance with the terms of the MDSA as well as in accordance with all Applicable Laws.

## **SECTION 10 OWNERSHIP OF MATERIALS AND INTELLECTUAL PROPERTY**

**10.1 Background Intellectual Property.** It is acknowledged that each Party owns or controls Background IP and nothing in this MDSA shall affect such rights in Background IP. Except as otherwise provided herein, the Parties shall not acquire any right, title, or interest in any Background IP of the other Party.

**10.2 Deliverables.** Except for any Background IP or SBL Invention contained in or used to generate the Deliverables, the Deliverables shall be the sole and exclusive property of Client; provided, however, that SBL shall at all times have the right to retain and maintain (in SBL's discretion) an archival copy of the Deliverables solely for regulatory compliance purposes and SBL shall have the right to access such Deliverables at any time solely for such purposes.

**10.3 Invention.** Client Inventions shall be owned solely by Client, and SBL Inventions shall be owned solely by SBL. SBL hereby assigns to Client all rights, title to, and interest it owns in and to any Client Invention. Subject to Section 10.6, Client may use Client Invention for any purpose, including filing a patent application for any such Client Invention, in which event, SBL shall provide reasonable assistance and cooperation to Client in connection therewith; provided however that, SBL makes no warranty, express or implied, of any kind whatsoever as to the outcome of such patent application(s). Client hereby assigns to SBL all rights, title to, and interest it owns in any SBL Invention. Subject to Section 10.6, SBL may use SBL Invention for any purpose, including filing a patent application for any such SBL Invention, in which event, Client shall provide reasonable assistance and cooperation to SBL in connection therewith; provided however that, Client makes no warranty, express or implied, of any kind whatsoever as to the outcome of such patent application(s). Any costs and fees associated with such assistance and cooperation, to the extent not detailed in this MDSA or PSA, shall be borne solely by the requesting Party.

## **10.4 Grant of License.**

**10.4.1 By SBL.** SBL hereby grants to Client a worldwide, non-exclusive, irrevocable, sublicensable (subject however to SBL's prior written consent as set forth in Section 10.5.2 of this MDSA), royalty-free, and fully-paid-up license under SBL Background IP and SBL Inventions to the extent such SBL Background IP and SBL Inventions are incorporated into the Service deliverables to further develop, manufacture, make, use, sell, offer to sell, export, and import the Product and reasonable modifications, extensions, and expansions of the Product but for the avoidance of doubt, not to any product other than Product (but, for clarity, Product includes both intravenous and subcutaneous formulations of such Product).

**10.4.2 By Client.** Client hereby grants to SBL a royalty-free, irrevocable, sublicensable (only to the extent necessary to conduct the Services through third parties) and fully-paid-up license under Client Background IP and Client Inventions during the Term for the sole purposes of performing the Services hereunder for Client.

## **10.5 Technology Transfer Out and License and Sublicense on SBL Background IP and SBL Inventions.**

**10.5.1** [\*\*\*].

**10.5.2** License granted in Section 10.4.1 is sublicensable only with a prior written consent of SBL, and such sublicense shall be subject to a reasonable royalty and sublicensing terms to be agreed upon by the Parties at such time.

**10.6 Prior Notice Requirement.** In the event Client intends to file, lodge, or submit any applications for Inventions (e.g. patents) or publish or formally present any information or data (e.g. at a conference, in a white paper, etc.) related to this MDSA or PSA, Client shall share the final draft of the patent application or the publication, as the case may be, with SBL at least ninety (90) days before such filing, lodging, submission, publication, or presentation in order for SBL to verify that the patent application or the publication is limited to Client Inventions and to remove any references to SBL's Inventions or SBL's Confidential Information; provided that SBL shall use Commercially Reasonable Efforts to shorten such review period upon Client's request if necessary to avoid missing any filing deadline or losing rights due to delay. Further, no Party shall use the name of the other Party or the names of the employees of the other Party nor disclose the terms of this MDSA or any PSA in any press releases, advertising or sales promotional material or in any publication without prior written consent of the other Party, which may be withheld in such Party's sole discretion, subject to the exceptions set forth Sections 9.2 and 9.3.

## **SECTION 11 WARRANTIES**

**11.1 The Parties General Warranties.** Each Party warrants and represents that: (i) it has the corporate power and authority to enter into this MDSA and has taken all necessary action on its part required to authorize the execution, delivery and performance of this Agreement; (ii) it is aware of no legal, contractual or other restriction, limitation or condition that might adversely affect its ability to enter into this MDSA and perform its obligations hereunder; (iii) it is duly organized, validly existing and in good standing

under the laws of the jurisdiction in which it is incorporated; (iv) this MDSA (a) has been duly executed and delivered by a duly authorized representative of it, and (b) is the legal, valid and binding obligation of it, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally; and (v) the execution, delivery and performance of this Agreement by it does not and will not (a) violate any Applicable Laws applicable to it, or (b) violate or conflict with any provision of its Articles of Incorporation or By-laws or other organizational documents.

**11.2 Client's Warranties.** Client represents and warrants to SBL that as of the Effective Date of the MDSA and during the Term: (a) the formulation, composition, use, distribution, marketing, or sale of the Product shall comply with all Applicable Laws and that, during the Term, Client will perform all obligations, and take other necessary actions in compliance with such requirements, Applicable Laws, rules and regulations, including applicable cGMPs; (b) Client will comply with all Applicable Laws, and that it will keep SBL informed of any information known to Client which would affect SBL's provision of the Service hereunder; and (c) to the best of its knowledge, SBL's use of the Client Materials, Client's Background IP, and Client Technology related to the Service as contemplated by the applicable PSA will not infringe any third party's Intellectual Property rights.

**11.3 SBL's Warranties.** SBL represents and warrants that:

**11.3.1** As of the Effective Date and during the Term, (i) SBL is the lawful owner, lessee, operator, or licensee of the Facility, equipment, machinery, as well as permissions, permits, approvals, and licenses required, to enable SBL to perform its obligations under this MDSA, and (ii) to the best of SBL's knowledge, none of the SBL Inventions, SBL Background IP, or the Services will infringe any third party's Intellectual Property rights.

**11.3.2** SBL personnel to be assigned to perform Services (i) have not been debarred and are not subject to a pending debarment pursuant to Section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a or equivalent in any jurisdiction; (ii) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)) in the United States) or equivalent in any jurisdiction; and (iii) are not disqualified by any government or Regulatory Authorities from performing specific services, and are not subject to a pending disqualification proceeding. If during the Term, SBL or any SBL personnel assigned to perform the Services becomes so debarred, suspended, excluded, sanctioned, or otherwise declared ineligible, SBL shall immediately notify Client, and such an event shall be a Material Breach by SBL, and SBL will immediately cease all activities relating to this MDSA unless and until directed otherwise by Client.

**11.3.3** All Product Batches, at the time of delivery to Client's designated carrier, shall (a) be Manufactured, packaged, handled and stored in compliance with the requirements of cGMPs, and all Applicable Laws; (b) comply with the Standard Operating Procedures and shall not be adulterated or misbranded under the Applicable Law; and (c) subject to Section 4.7.2(b), be transferred with good title free and clear of any liens, claims or encumbrances of any kind.

**11.4 No Other Warranties.** THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS SECTION ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND THE PARTIES HEREBY EXPRESSLY DISCLAIM AND NEGATE, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED (ARISING BY OPERATION OF LAW OR OTHERWISE), INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, EVEN IF THAT PURPOSE IS KNOWN.

## **SECTION 12 INDEMNIFICATION**

**12.1 Indemnification by SBL.** SBL shall indemnify and hold harmless Client, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude Client Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands, or actions based upon: (i) any SBL Assignable Error; or (ii) claim that SBL's Background IP, SBL Invention, SBL's Manufacturing processes, or its other performance of Services infringes, misappropriates or otherwise violates any third party's Intellectual Property rights; in each case (i) and (ii) except to the extent that such Damages are caused by the causes as set forth in Section 12.2 for which Client is obliged to indemnify.

**12.2 Indemnification by Client.** Client shall indemnify and hold harmless SBL, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude SBL Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands or actions based upon (i) gross negligence or willful misconduct of Client or its officers, directors, employees or agents, (ii) any product liability claims related to manufacture, sale, or distribution of Products that have been accepted by Client under Section 4.7.2, or (iii) any claim that any SBL's use of the Client Materials, Client Background IP, and Client Technology infringes, misappropriates, or otherwise violates any third party's Intellectual Property rights; in each case (i), (ii) and (iii) except to the extent that such Damages are caused by the causes as set forth in Section 12.1 for which SBL is obliged to indemnify.

**12.3 Indemnification Procedure.** The foregoing indemnification by SBL or Client shall be conditioned, if and to the extent Damages are based on or related to a third-party claim, upon a Party who intends to claim indemnification under 12.1 and 12.2 (the "**Indemnified Party**") (i) providing written notice to the other Party ("**Indemnifying Party**") within twenty (20) days after the Indemnified Party have been given written notice of such third-party claim, provided that absence or delay of such prior written notice will not relieve the Indemnifying Party of its obligation to indemnify except to the extent such absence or delay materially prejudices the Indemnifying Party's ability to defend the third party claim; (ii) permitting the Indemnifying Party, upon timely notice by the Indemnified Party, the opportunity to assume full responsibility (at the Indemnifying Party's cost and expense) for the investigation and defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, provided, however, that the Indemnifying Party shall keep the Indemnified Party informed as to the progress of the defense of any claim and that, at the Indemnifying Party's expense, the Indemnified Party shall cooperate in such defense and shall make available all records, materials and witness reasonably requested by the Indemnifying Party in connection therewith; and (iii) not settling or compromising any such claim

without the Indemnifying Party's prior written consent. Indemnifying Party shall not settle such action without the prior written consent of the Indemnified Party, which consent shall not be unreasonably denied, withheld, or conditioned; provided, however, that an Indemnified Party shall not be required to consent to any settlement that (a) does not include as an unconditional term thereof the giving by the claimant or the plaintiff of an unconditional release of the Indemnified Party from all liability with respect to such action or (b) involves the imposition of equitable remedies or the imposition of any material obligations on such Indemnified Party other than financial obligations for which such indemnified Party will be indemnified hereunder. Notwithstanding the assumption by the Indemnifying Party of the defense of any action as provided herein, the Indemnified Party shall be permitted to participate in the defense of such action and to employ counsel at its own expense; provided, however, that if the defendants in any action shall include both an Indemnifying Party and any Indemnified Party and such Indemnified Party shall have reasonably concluded that counsel selected by Indemnifying Party has a potential conflict of interest because of the availability of different or additional defenses to such Indemnified Party, counsel selected by Indemnified Party shall be at the expense of the Indemnifying Party, with it being understood, however, that the Indemnifying Party shall not be liable for the reasonable fees and expenses of more than one separate firm of attorneys at any time for all Indemnified Parties (in addition to local counsel) in such action or group of related actions.

### **SECTION 13 DISCLAIMER OF CONSEQUENTIAL DAMAGES; LIMITATION OF LIABILITY**

**13.1 Disclaimer of Consequential Damages.** [\*\*\*] LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR OTHER INDIRECT DAMAGES OF ANY TYPE OR NATURE, WHETHER BASED IN CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUES.

**13.2 Limitation of Liability.** Each Party's aggregate total liability to the other Party in respect of any Damages arising under or in connection with a given PSA for a given calendar year during the Term (whether in contract, tort, negligence, or otherwise however arising) shall be capped at an amount equal to [\*\*\*]; provided however that each Party's aggregate total liability to the other Party in respect of any Damages arising from [\*\*\*].

**13.3 Insurance.** SBL shall maintain, during the Term, adequate occurrence-based insurance or self-insure, in each case, in a manner adequate to cover its liabilities under this MDSA to the extent such liabilities are insurable.

### **SECTION 14 TERM AND TERMINATION OF AGREEMENT**

**14.1 Term.** This MDSA will become effective as of the Effective Date and will have its own initial term of [\*\*\*] and shall automatically renew for successive terms of [\*\*\*] years each unless either Party gives written notice to the other Party of its intention to terminate the MDSA at least [\*\*\*] prior to the end of the then current MDSA term. Notwithstanding anything to the contrary, this MDSA will be in effect for as long as any PSA is in effect.

**14.2 Termination.** This MDSA or a PSA may be earlier terminated as set forth in this Section 14.2.

**14.2.1 Material Breach.** A Party may terminate any PSA for a material breach by the other Party; provided, however, that the non-breaching Party shall give the breaching Party written notice of such breach and if the breaching Party fails to cure that breach within [\*\*\*] days after receipt of such written notice, then the non-breaching Party may terminate this Agreement on [\*\*\*] days written notice after expiration of such [\*\*\*] period. This MDSA shall terminate if all effective PSAs are terminated.

**14.2.2 Insolvency.** This MDSA may be terminated by either Party upon written notice at any time during the MDSA if the other Party: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such Party, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; or (d) makes an assignment for the benefit of its creditors. The Party affected shall immediately notify the other Party in writing of the occurrence of any of the foregoing events.

**14.2.3 Force Majeure.** Either Party may terminate a PSA if a Party is unable to perform its obligations pursuant to a PSA in the event of a Force Majeure Event in accordance with Section 16.3.

**14.2.4 Other Specified Events.** The Parties may additionally terminate a PSA as set forth in the applicable PSA.

**14.3 Effect of Expiration or Termination.**

**14.3.1 Payment of Amounts Due.** Expiration or termination of the MDSA or PSA for any reason shall not exempt either Party from paying to the other Party any amounts owing at the time of such expiration or termination.

**14.3.2 Survival.** Any termination or expiration of this MDSA shall not affect any outstanding obligations due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this MDSA. For greater certainty, except as otherwise expressly provided, termination or expiration of this MDSA, irrespective of the cause, shall not affect any rights or obligations which, from the context thereof, are intended to survive termination or expiration of this MDSA, including SECTION 8, SECTION 9, SECTION 10, SECTION 11, SECTION 12, SECTION 13, SECTION 14, SECTION 15, and SECTION 16.

**14.3.3 Effect of Termination.** Upon termination of a PSA for any reason, SBL shall cease and refrain from the Services described in the applicable PSA (including the Development, Manufacturing and supplying the Product) for Client unless otherwise provided in this Section 14.3.3, and both Parties shall pursue relevant decommissioning activities as set forth hereunder:



**(a) Settlement of Payment.** SBL shall be compensated no later than [\*\*\*] days after a termination for:

- (i) all Service Fees incurred up to the date of termination, subject however to Section 14.3.3(b) below;
- (ii) all costs incurred through the date of termination, including the costs of procuring Raw Materials used or purchased for use in connection with Services and the costs for External Laboratories plus applicable Handling Fees;
- (iii) any unreimbursed procurement fee of additional equipment that SBL has purchased on behalf of Client (if any); and
- (iv) any Cancellation Fees and other fees, costs, and expenses that are owed under this MDSA or applicable PSA, provided that no Cancellation Fees will be payable earlier than the date fees for the terminated Service would have been paid absent termination of such Service or the applicable PSA.

**(b) Delivery; Disposition of Raw Materials and Client Materials.**

- (i) SBL shall continue manufacturing Product-in-process as of the date of termination, Client shall pay for such completed Product, and SBL shall deliver the fully manufactured Product to Client in accordance with the schedule then agreed upon by the Parties or, without such an agreement, the terms of this MDSA and the PSA (including release and acceptance).
- (ii) As soon as practically possible after the termination and provided that Client has paid the invoice for such Raw Materials, SBL shall deliver to Client or its designee(s) and they shall accept (1) any Raw Material purchased for use in connection with Services, and (2) any Client Material then in possession of SBL; provided however that the Parties may mutually agree instead to destroy or discard such Raw Material or Client Material, in which case SBL shall promptly destroy or dispose of the same without making any further use of such materials.
- (iii) Any costs incurred in connection with any delivery or destruction of Raw Materials or Client Materials pursuant to this Section 14.3.3(b), as the case may be, shall be borne by the Party responsible for termination in accordance with 14.3.3(c) and 14.3.3(d) below; provided that, for all other cases, the Parties shall negotiate in good faith the allocation of all such costs and expenses.

**(c) Termination by SBL pursuant to Section 14.2.1 or 14.2.2.** In the event of termination by SBL pursuant to Section 14.2.1 or Section 14.2.2, the outstanding binding obligations related to or arising from Reserved Capacity shall survive termination of such PSA, and the Client shall be responsible for the costs incurred in connection with delivery or

disposal of Raw Materials, Client Material, or equipment during decommissioning activities.

**(d) Termination by Client pursuant to Section 14.2.1 or 14.2.2.** In the event of termination by Client pursuant to Section 14.2.1 or Section 14.2.2, Client shall be released from any outstanding binding obligations related to or arising from Reserved Capacity, except the decommissioning activities set forth in this Section 14.3.3 of the MDSA which shall be binding on both Parties.

**(e) Termination by either Party based on Section 14.2.3.** Both Parties shall negotiate in good faith and based on industry standards for the handling and delivery of the fully Manufactured Product, Product-in-process, Client Materials, and Raw Materials and the allocation of costs and expenses between the Parties.

**14.3.4 Effect of Expiration.** Upon expiration of a PSA at the end of the Term or any renewed Term, SBL shall cease and refrain from the Services described in any applicable PSA (including the Development, Manufacturing and supplying the Product), and Section 14.3.3 above shall apply *mutatis mutandis*, and both Parties shall negotiate in good faith the allocation of related costs and expenses for such decommissioning activities.

## **SECTION 15 ARBITRATION**

**15.1 Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this MDSA, or the rights or obligations of the Parties hereunder, the Parties shall first try to settle their differences amicably between themselves through the Core Team and then JSC level. Thereafter, either Party may initiate informal dispute resolution on the Executive level by sending written notice of the dispute to the other Party, and within fifteen (15) days after such notice appropriate Executives of the Parties shall attempt resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said fifteen (15) days, either Party may refer the matter by written notice to the Chief Executive Officer of the other Party, or his/her designee, and the Chief Executive Officer of such Party, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within thirty (30) days of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of this SECTION 15.

**15.2 Arbitration.** If the Parties do not fully settle a dispute pursuant to Section 15.1, and a Party wishes to pursue the matter, each such dispute, controversy or claim shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the International Chamber of Commerce (“ICC”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof to enforce the arbitration award. The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business, and within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The

place of arbitration shall be New York, New York, United States and all proceedings and communications shall be in English. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's direct compensatory damages, and in all cases, any decision or determination by the arbitrators shall comply with SECTION 14, as applicable. The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this MDSA until final resolution of the dispute through arbitration or other judicial determination.

**15.3 Costs and Fees.** Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators. Absent the filing of an application to correct or vacate the arbitration award as permitted by Applicable Law, each Party shall fully perform and satisfy the arbitration award within fifteen (15) days after the service of the award on such Party.

## **SECTION 16 MISCELLANEOUS**

**16.1 Notices.** Any notice required or permitted under the MDSA shall be in writing with duly authorized signature and made to the following addresses:

If to Client:

[\*\*\*]

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

[\*\*\*]

If to SBL:

[\*\*\*]

Either Party may change its designated address by notice to the other Party in the manner provided in this Section 16.1.

Any notice shall be deemed to have been delivered on the date of delivery if delivered personally, or on the date of receipt if delivered via email (if receipt is confirmed via email), or on the third day after being delivered by a national or internationally recognized overnight or two-day courier service, or on the fifth day of posting if sent by registered or certified mail with return receipt requested and postage prepaid.

**16.2 Governing Law.** This MDSA shall be construed and interpreted in accordance with the laws of State of New York, United States and all rights and remedies shall be governed by such laws without regard

to principles of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by the MDSA.

**16.3 Effect of Force Majeure Event.** The Affected Party shall not be liable to the other Party for failure or delay to perform its obligation under the MDSA or any applicable PSA when such failure or delay is due to Force Majeure Event. For clarity, this includes that Client will not be liable for payment of any Services that SBL is not able to perform due to any Force Majeure Event.

Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under the MDSA. If a condition constituting Force Majeure Event as defined herein exists for [\*\*\*], the Parties shall negotiate a mutually satisfactory solution to the problem, if practicable, including termination of this MDSA upon [\*\*\*] days written notice from the failure of reaching a mutually satisfactory solution to the Force Majeure Event, or the use of a third party to fulfill the obligations hereunder of the party invoking Force Majeure Event, at the expense of the party invoking Force Majeure Event.

#### **16.4 Assignment.**

**16.4.1** Neither Party shall assign, in whole or in part, this MDSA or any applicable PSA without a prior written consent of the other Party; provided, however, that a Party may, without such consent, assign this MDSA and its rights and obligations hereunder to (a) its Affiliate, or (b) any purchaser of the Party's rights relating to the Product or all or substantially all of the assets of the Party resulting from any merger or consolidation of such Party with or into another corporation or entity. Notwithstanding the above and anything else to the contrary, (i) the assigning Party shall require any such assignee or successor to expressly assume and agree in writing to perform the Party's obligations under this MDSA or any applicable PSA in the same manner and to the same extent that the assigning Party would be required to perform had there been no such an assignment; and (ii) in the event the assignee or successor refuses or fails to assume the terms of this MDSA or any applicable PSA, the assigning Party shall remain responsible for the terms and conditions of this MDSA or any applicable PSA as if there had been no assignment.

**16.4.2** In the event of an assignment, the Party assigning this Agreement or all rights and obligations hereunder shall be responsible for any and all additional costs and expenses incurred as a result of such an assignment, including any additional Services that need to be performed by SBL.

**16.5 No Grant of License.** Nothing in the MDSA shall affect, or grant any right to, patents, know-how or other Intellectual Property owned by either Party prior to the commencement of the MDSA unless otherwise expressly provided in the MDSA.

**16.6 No Right to Use Names.** Except as expressly provided herein, no right, expressed or implied, is granted by the MDSA to use in any manner the name of either of the Parties or any other trade name, symbol, logo or trademark of the other Party in connection with the performance of the MDSA, without the prior written consent of the other Party (which consent will be in the sole discretion of such Party).

**16.7 Non-Exclusive.** This MDSA is non-exclusive in nature and nothing herein will prevent Client from engaging other third parties to perform services that are the same or similar to those being performed by SBL, including for the Products that are subject to any PSA, subject in all instances to sublicensing terms and restrictions in Section 10.4.

**16.8 FCPA and Anti-Bribery Laws Compliance.** Each Party, as of the Effective Date and during the Term, shall not promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, any non-U.S. government official, in each case, in violation of the U.S. Foreign Corrupt Practices Act (“FCPA”) or any other applicable anti-bribery or anti-corruption law in connection with the Services, Manufacturing, sales, marketing, or distribution of the Product. Each Party shall cease all of its activities, as well as remediate any actions taken by such Party in violation of the FCPA or any other applicable anti-bribery or anti-corruption law in connection with the Services and Manufacturing of the Product. Each Party shall maintain systems or internal controls (including accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA or any other applicable anti-bribery or anti-corruption law in connection with the Services and Manufacturing of the Product.

**16.9 Independent Contractors.** The Parties hereto are independent contractors and nothing contained in the MDSA shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

**16.10 Integration.** This MDSA constitutes the entire agreement between the Parties relating to the subject matter of the MDSA and supersedes all previous oral and written communications between the Parties with respect to the subject matter of the MDSA.

**16.11 Decision Memo; Amendment; Waiver.** A Decision Memo may be entered into by the Core Teams or JSC with a binding effect, with it being understood that, in the event of a conflict between a Project Plan, Scope of Work, or Decision Memo and a later executed Decision Memo, the later executed Decision Memo shall prevail. Except as otherwise expressly provided herein, no alteration of or modification to the MDSA shall be effective unless made in writing and executed by an authorized representative of both Parties. No course of dealing or failing of either Party to strictly enforce any term, right or condition of the MDSA in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. The observance of any provision of the MDSA may be waived (either generally or any given instance and either retroactively or prospectively) only with the written consent of the Party granting such waiver (which consent will be in the sole discretion of such Party).

**16.12 Severability.** The Parties do not intend to violate any applicable law. However, if any sentence, paragraph, clause or combination of the MDSA is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination of the same shall be deleted and the remainder of the MDSA shall remain binding, provided that such deletion does not alter the basic purpose and structure of the MDSA.

**16.13 Construction.** The Parties mutually acknowledge that they have participated in the negotiation and preparation of the MDSA. Ambiguities, if any, in the MDSA shall not be construed against any Party,

irrespective of which Party may be deemed to have drafted the MDSA or authored the ambiguous provision.

**16.14 Interpretation.** The captions and headings to the MDSA are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of the MDSA. Unless context otherwise clearly requires, whenever used in the MDSA: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”; (b) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to the MDSA; (c) the word “or” has the same meaning as “and/or”; and (d) all references to the word “will” are interchangeable with the word “shall” and shall be understood to be imperative or mandatory in nature. All references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters, or calendar years. Whenever any matter hereunder requires consent or approval, such consent or approval shall not be unreasonably withheld or delayed unless otherwise expressly indicated.

**16.15 Counterparts.** This MDSA may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this MDSA as of the Effective Date above written.

**ALLAKOS INC.**

[\*\*\*]

**SAMSUNG BIOLOGICS CO., LTD.**

[\*\*\*]

## ALLAKOS INC.

## OUTSIDE DIRECTOR COMPENSATION POLICY

(Effective April 14, 2022)

Allakos Inc. (the “**Company**”) believes that the granting of equity and cash compensation to its members of the Board of Directors (the “**Board**,” and members of the Board, the “**Directors**”) represents an effective tool to attract, retain and reward Directors who are not employees of the Company (the “**Outside Directors**”). This Outside Director Compensation Policy (the “**Policy**”) is intended to formalize the Company’s policy regarding cash compensation and grants of equity to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given such term in the Company’s 2018 Equity Incentive Plan (the “**Plan**”). Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of any equity or cash payments such Outside Director receives under this Policy.

This Policy was adopted, approved and became effective on April 14, 2022 (the “**Effective Date**”).

**1. CASH COMPENSATION***Annual Cash Retainer*

Each Outside Director will be paid an annual cash retainer of \$47,500. There are no per-meeting attendance fees for attending Board meetings. This cash compensation will be paid quarterly in arrears on a prorated basis.

*Committee Annual Cash Retainer*

As of the Effective Date, each Outside Director who serves as the chairman of the Board or the chairman or a member of a committee of the Board will be eligible to earn additional annual fees (paid quarterly in arrears on a prorated basis) as follows:

Chair of the Board: \$45,000

Chair of Audit Committee: \$20,000

Member of Audit Committee: \$10,000

Chair of Compensation Committee: \$15,000

Member of Compensation Committee: \$7,500

Chair of Nominating and Governance Committee: \$10,000

Member of Nominating and Governance Committee: \$5,000

For clarity, each Outside Director who serves as the chairman of a committee will not receive the additional annual fee as a member of the committee. All cash payments to nonemployee Directors will be paid quarterly in arrears on a prorated basis.

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## 2. EQUITY COMPENSATION

Outside Directors will be entitled to receive all types of Awards (except Incentive Stock Options) under the Plan (or the applicable equity plan in place at the time of grant), including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to this Section 2 will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(a) Initial Option. Each person who first becomes an Outside Director on or following the Effective Date will be granted Nonstatutory Stock Options equal to \$509,600 of fair value based on the 30-day moving average prior to the grant date with any fractional award from such fair value rounded down to the nearest whole option (the “**Initial Option**”), provided, however, that a Director who is an Employee (an “**Inside Director**”) who ceases to be an Inside Director, but who remains a Director, will not receive an Initial Option. The Initial Option will be granted no later than the date of the first Board or Compensation Committee of the Board (the “**Compensation Committee**”) meeting occurring on or after the date on which such individual first becomes an Outside Director, whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy.

(b) Annual Option. On the date of each annual meeting of the Company’s stockholders (the “**Annual Meeting**”), each Outside Director will be automatically granted Nonstatutory Stock Options equal to \$243,100 of fair value based on the 30-day moving average prior to the grant date with any fractional award from such fair value rounded down to the nearest whole option (an “**Annual Option**”).

(c) No Discretion. No person will have any discretion to select which Outside Directors will be granted an Initial Option or Annual Option under this Policy or to determine the number of Shares to be covered by such Initial Option or Annual Option, as applicable (except as provided in Sections 5 and 7 below).

(d) Terms. The terms and conditions of each Initial Option or Annual Option will be as follows:

(i) Subject to Section 14 of the Plan and Section 2(e) of this Policy, each Initial Option will vest as to 1/36<sup>th</sup> of the Shares subject to the Initial Option each month following the commencement of the applicable Outside Director’s service as an Outside Director (the “**Vesting Commencement Date**”) on the same day of the month as the Vesting Commencement Date (or if there is no corresponding day on the last day of the month), in each case subject to the Outside Director remaining a Service Provider through such date.

(ii) Subject to Section 14 of the Plan and Section 2(e) of this Policy, each Annual Option will become fully vested on the earlier of (i) the one-year anniversary of the date of grant of such Annual Option or (ii) the date of the next Annual Meeting that occurs following the grant of such Annual Option, in each case subject to the Outside Director remaining a Service Provider through such date.

(iii) The term of each Initial Option and Annual Option granted under the Policy will be ten years, subject to earlier termination as provided in the Plan.

(iv) Each Initial Option and Annual Option granted under the Policy will have an exercise price per Share equal to 100% of the Fair Market Value per Share on the grant date.

(e) Change in Control. In the event of a Change in Control, all of an Outside Director’s outstanding Awards (including his or her Initial Option and his or her Annual Options, as applicable) will become fully vested and exercisable (if applicable) immediately prior to such Change in Control.

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3. **TRAVEL EXPENSES**

Each Outside Director's reasonable, customary, and documented travel expenses to Board meetings will be reimbursed by the Company.

4. **ADDITIONAL PROVISIONS**

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors.

5. **ADJUSTMENTS**

In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number of Shares issuable pursuant to Awards granted under this Policy.

6. **SECTION 409A**

In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (i) the 15th day of the 3rd month following the end of the Company's fiscal year in which the compensation is earned or expenses are incurred, as applicable, or (ii) the 15th day of the 3rd month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations and guidance thereunder, as may be amended from time to time (together, "**Section 409A**"). It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company reimburse an Outside Director for any taxes imposed or other costs incurred as a result of Section 409A.

7. **REVISIONS**

The Board may amend, alter, suspend or terminate this Policy at any time and for any reason. No amendment, alteration, suspension or termination of this Policy will materially impair the rights of an Outside Director with respect to compensation that already has been paid or awarded, unless otherwise mutually agreed between the Outside Director and the Company. Termination of this Policy will not affect the Board's or the Compensation Committee's ability to exercise the powers granted to it under the Plan with respect to Awards granted under the Plan pursuant to this Policy prior to the date of such termination.

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

I, Robert Alexander, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Allakos 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, 2022

By: \_\_\_\_\_  
**Robert Alexander, Ph.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

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

I, H. Baird Radford, III, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Allakos 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, 2022

By: \_\_\_\_\_  
**H. Baird Radford, III**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 6, 2022

By: \_\_\_\_\_ /s/ Robert Alexander  
**Robert Alexander, Ph.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 6, 2022

By: \_\_\_\_\_  
**/s/ H. Baird Radford, III**  
**H. Baird Radford, III**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

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