UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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	**45-4798831**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
825 Industrial Road, Suite 500 San Carlos, California	**94070**
(Address of principal executive offices)	**(Zip Code)**

(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 August 1, 2022, the registrant had 54,844,080 shares of common stock outstanding.

ALLAKOS INC.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

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

	June 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 82,452	$ 152,822
Investments	129,987	271,416
Prepaid expenses and other current assets	9,427	27,343
Total current assets	221,866	451,581
Property and equipment, net	41,300	43,100
Operating lease right-of-use assets	31,962	31,707
Other long-term assets	11,781	8,436
Total assets	$ 306,909	$ 534,824
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,865	$ 13,692
Accrued expenses and other current liabilities	26,638	26,557
Total current liabilities	36,503	40,249
Operating lease liabilities, net of current portion	47,597	49,099
Total liabilities	84,100	89,348
Contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 20,000 shares authorized as of June 30, 2022 and December 31, 2021; no shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value per share; 200,000 shares authorized as of June 30, 2022 and December 31, 2021; 54,844 and 54,622 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	54	54
Additional paid-in capital	1,081,965	1,058,399
Accumulated other comprehensive loss	(260)	(153)
Accumulated deficit	(858,950)	(612,824)
Total stockholders' equity	222,809	445,476
Total liabilities and stockholders' equity	$ 306,909	$ 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 34,448	$ 40,985	$ 211,255	$ 79,900
General and administrative	14,669	16,210	33,513	32,880
Total operating expenses	49,117	57,195	244,768	112,780
Loss from operations	(49,117)	(57,195)	(244,768)	(112,780)
Interest income	104	103	187	233
Other expense, net	(90)	(117)	(1,545)	(220)
Net loss	(49,103)	(57,209)	(246,126)	(112,767)
Unrealized gain (loss) on investments	209	(56)	(107)	24
Comprehensive loss	$ (48,894)	$ (57,265)	$ (246,233)	$ (112,743)
Net loss per common share:				
Basic and diluted	$ (0.90)	$ (1.07)	$ (4.50)	$ (2.11)
Weighted-average number of common shares outstanding:				
Basic and diluted	54,798	53,669	54,742	53,429

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				
Balance at December 31, 2021	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 investments	—	—	—	(316)	—	(316)
Net loss	—	—	—	—	(197,023)	(197,023)
Balance at March 31, 2022	54,761	$ 54	$ 1,070,138	$ (469)	$ (809,847)	$ 259,876
Stock-based compensation expense	—	—	11,761	—	—	11,761
Issuance of common stock upon exercise of stock options	25	—	66	—	—	66
Issuance of common stock upon vesting of restricted stock units	58	—	—	—	—	—
Unrealized gain on investments	—	—	—	209	—	209
Net loss	—	—	—	—	(49,103)	(49,103)
Balance at June 30, 2022	54,844	$ 54	$ 1,081,965	$ (260)	$ (858,950)	$ 222,809

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	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 investments	—	—	—	80	—	80
Net loss	—	—	—	—	(55,558)	(55,558)
Balance at March 31, 2021	53,457	$ 53	$ 1,014,435	$ 88	$ (398,522)	$ 616,054
Stock-based compensation expense	—	—	11,397	—	—	11,397
Issuance of common stock upon exercise of stock options	443	—	800	—	—	800
Issuance of common stock upon vesting of restricted stock units	36	—	—	—	—	—
Unrealized loss on investments	—	—	—	(56)	—	(56)
Net loss	—	—	—	—	(57,209)	(57,209)
Balance at June 30, 2021	53,936	53	1,026,632	32	(455,731)	570,986

See accompanying notes to unaudited interim financial statements

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

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (246,126)	$ (112,767)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,064	747
Stock-based compensation	23,153	23,751
Net amortization of premiums and discounts on investments	1,616	1,211
Noncash lease expense	961	1,541
Loss on disposal of property and equipment	28	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	17,621	(4,072)
Other long-term assets	(4,148)	(13,844)
Accounts payable	(3,645)	(2,034)
Accrued expenses and other current liabilities	1,969	7,952
Operating lease liabilities, net of current portion	(2,550)	1,474
Net cash used in operating activities	(207,057)	(96,041)
Cash flows from investing activities		
Purchases of investments	(19,988)	(215,461)
Proceeds from sales of investments	19,989	—
Proceeds from maturities of investments	140,000	310,000
Proceeds from sale of property and equipment	1,169	—
Purchases of property and equipment	(5,699)	(7,302)
Net cash provided by investing activities	135,471	87,237
Cash flows from financing activities		
Proceeds from exercise of stock options	170	4,588
Proceeds from issuance of common stock under the 2018 ESPP	243	995
Net cash provided by financing activities	413	5,583
Net increase (decrease) in cash, cash equivalents and restricted cash	(71,173)	(3,221)
Cash, cash equivalents and restricted cash, beginning of period	155,097	209,452
Cash, cash equivalents and restricted cash, end of period	$ 83,924	$ 206,231
Supplemental disclosures		
Noncash investing and financing items:		
Lessor-funded lease incentives included in property and equipment	$ —	$ 5,348
Increase (decrease) in payables related to purchase of property and equipment	$ (2,238)	$ 4,786

See accompanying 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 lirentelimab (AK002) and AK006 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.

Since inception, the Company has incurred net losses and negative cash flows from operations. During the six months ended June 30, 2022, the Company incurred a net loss of $246.1 million and used $207.1 million of cash in operations. At June 30, 2022, the Company had an accumulated deficit of $859.0 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 AG") regarding all outstanding manufacturing service agreements in February 2022.

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 June 30, 2022, the statements of operations and comprehensive loss, statements of stockholders' equity and statements of cash flows for the six months ended June 30, 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 June 30, 2022 and its results of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021 and its cash flows for the six months ended June 30, 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 June 30, 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 investments. 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):

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 82,452	$ 152,822
Restricted cash in other long-term assets	1,472	2,275
Total	$ 83,924	$ 155,097

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 203,956	$ 207,177
Restricted cash in other long-term assets	2,275	2,275
Total	$ 206,231	$ 209,452

Restricted cash at June 30, 2022 represents $1.5 million in security deposits for the lease of the Company's facility in San Carlos, California. The security deposit is in the form of a letter of credit secured by restricted cash.

Investments

The Company invests in marketable securities, primarily securities issued by the United States government and its agencies. The Company's investments 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.

Going Concern

Cash, cash equivalents and investments, excluding restricted cash, at June 30, 2022 totaled $212.4 million, compared to $424.2 million at December 31, 2021. Management believes that existing cash, cash equivalents and investments will be sufficient for the Company to continue as a going concern for at least 12 months from the issuance date of these unaudited interim financial statements. Management's view regarding sufficiency of cash and liquidity is primarily based on the Company's operating plans and financial forecast. Management's estimates as to how long it expects the Company's cash, cash equivalents and investments to continue to fund operations is based on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects.

Factors that may affect the Company's capital needs include, but are not limited to:

- the number, scope, and timing of clinical indications and clinical trials the Company decides to pursue;
- the scope and costs of manufacturing activities;
- the extent to which the Company acquires or in-licenses other product candidates and technologies, if any;
- the cost, timing and outcome of regulatory review of the Company's product candidates;

- the cost and timing of establishing sales and marketing capabilities for product candidates receiving marketing approval, if any;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the Company's efforts to enhance operational systems and ability to attract, hire and retain qualified personnel, including personnel to support the development of the Company's product candidates; and
- the costs associated with being a public company.

The Company intends to raise additional capital to support its ongoing and future clinical development and business operations. To the extent the Company raises additional funds through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to stockholders. There can be no assurance that sufficient funding will be available on favorable terms, or at all. The Company's ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions and volatility of financial markets in the United States and worldwide. If adequate funds are not available, the Company may be required to obtain funds by entering into collaboration, licensing or debt agreements on potentially unfavorable terms. If the Company is unable to raise funds on favorable terms, or at all, it may have to reduce its operating expenses and potentially delay, reduce or terminate some or all of its clinical development efforts, which would have a material adverse effect on the Company's business, financial condition and results of operations.

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 and six months ended June 30, 2022 and 2021 are a result of unrealized gains and losses on the Company's investments 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (49,103)	$ (57,209)	$ (246,126)	$ (112,767)
Denominator:				
Weighted-average shares of common stock outstanding, basic and diluted	54,798	53,669	54,742	53,429
Net loss per share, basic and diluted	$ (0.90)	$ (1.07)	$ (4.50)	$ (2.11)

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):

	Six Months Ended June 30,	
	2022	2021
Options to purchase common stock	5,543	5,826
Unvested restricted stock units	4,839	1,021
Unvested performance stock units	3,809	—
Shares issuable under employee stock purchase plans	67	8
Total	14,258	6,855

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):

	June 30, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 80,736	$ —	$ —	$ 80,736
Total cash equivalents	80,736	—	—	80,736
Investments:				
U.S. treasuries	129,987	—	—	129,987
Total investments	129,987	—	—	129,987
Total cash equivalents and investments	$ 210,723	$ —	$ —	$ 210,723

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 150,781	$ —	$ —	$ 150,781
Total cash equivalents	150,781	—	—	150,781
Investments:				
U.S. treasuries	271,416	—	—	271,416
Total investments	271,416	—	—	271,416
Total cash equivalents and investments	$ 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 and six months ended June 30, 2022 and 2021.

4. Investments

All investments were considered available-for-sale at June 30, 2022. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's investments by major security type at June 30, 2022 and December 31, 2021 are summarized in the table below (in thousands):

	June 30, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities:				
U.S. treasuries classified as investments	$ 130,247	$ —	$ (260)	$ 129,987
Total available-for-sale securities	$ 130,247	$ —	$ (260)	$ 129,987

	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	$ 271,570	$ 2	$ (156)	$ 271,416

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. As of June 30, 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 $130.0 million and $241.4 million, respectively. 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 June 30, 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 and six months ended June 30, 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):

	June 30, 2022	December 31, 2021
Laboratory equipment	$ 6,092	$ 4,676
Furniture and office equipment	3,947	1,947
Capitalized software	4,062	—
Leasehold improvements	32,458	4,581
Construction-in-progress	—	37,704
	46,559	48,908
Less accumulated depreciation	(5,259)	(5,808)
Property and equipment, net	$ 41,300	$ 43,100

Depreciation and amortization expense for the three months ended June 30, 2022 and 2021 was $1.9 million and $0.4 million, respectively. Depreciation and amortization expense for the six months ended June 30, 2022 and 2021 was $4.1 million and $0.7 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 $11.8 million and $8.4 million as of June 30, 2022 and December 31, 2021, respectively. Other long-term assets at June 30, 2022 and December 31, 2021 included $8.6 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):

	June 30, 2022	December 31, 2021
Accrued contract research and development expense	$ 16,411	$ 16,215
Accrued compensation and benefits expense	4,643	3,172
Current portion of operating lease liabilities	4,145	2,316
Other current liabilities	1,439	4,854
Total	$ 26,638	$ 26,557

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 December 31, 2021.

In November 2021 the Company entered into a lease termination agreement (the "Lease Termination Agreement") with respect to the 2018 Redwood City Lease. Pursuant to the Lease 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.

During the second quarter of 2022, the landlord paid $1.1 million in connection with the early termination and upon satisfaction of all remaining conditions including the delivery of certain equipment and other assets related to the building.

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. During the second quarter of 2022 and in accordance with the lease termination, the restrictions associated with the $0.8 million security deposit for the 2018 Redwood City Lease was released and such funds were recorded as cash and cash equivalents as of June 30, 2022.

Classification of the Company's operating lease liabilities included on the Company's balance sheets at June 30, 2022 and December 31, 2021 was as follows (in thousands):

	June 30, 2022	December 31, 2021
Operating lease liabilities		
Current portion included in accrued expenses and other current liabilities	$ 4,145	$ 2,316
Operating lease liabilities, net of current portion	47,597	49,099
Total operating lease liabilities	$ 51,742	$ 51,415

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 June 30,		Six Months Ended June 30, June 30,	
	2022	2021	2022	2021
Operating lease costs	$ 1,471	$ 1,675	$ 2,925	$ 3,409
Variable costs	1,005	152	1,688	239
Total lease costs	$ 2,476	$ 1,827	$ 4,613	$ 3,648

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 $3.4 million and $0.6 million for the six months ended June 30, 2022 and 2021, respectively.

Cash received for amounts related to tenant improvement allowances from lessors was $1.0 million and $5.1 million for the six months ended June 30, 2022 and 2021, respectively.

Operating Lease Obligations

Future lease payments required under operating leases included on the Company's balance sheet at June 30, 2022 are as follows (in thousands):

Fiscal Year Ending December 31,		
2022 (remaining 6 months)	$	4,687
2023		7,061
2024		7,273
2025		7,492
2026		7,716
Thereafter		40,679
Total future lease payments		74,908
Less:		
Present value adjustment		23,166
Present value of future lease incentives		—
Operating lease liabilities	$	51,742

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 June 30, 2022, the weighted-average remaining lease term of the Company's leases was 9.2 years and the weighted-average discount rate used to determine the operating lease liabilities included on the balance sheet was 8.5%.

As of June 30, 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 and six months ended June 30, 2022 and 2021. As of June 30, 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 lirentelimab, 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 June 30, 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 Sales"), 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 Sales. Under the terms of the agreement, the Company has made milestone payments of $3.4 million through June 30, 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 Sales. 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, except for the litigation described in the Legal Contingencies section below, 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 June 30, 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 lirentelimab. 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. On June 13, 2022, the defendants filed a motion to dismiss the second amended complaint. 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.

8. Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 4,870	$ 4,246	$ 9,305	$ 9,309
General and administrative	6,891	7,151	13,848	14,442
Total	$ 11,761	$ 11,397	$ 23,153	$ 23,751

No income tax benefits for stock-based compensation expense have been recognized for the three and six months ended June 30, 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 units and performance shares. 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 or (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 June 30, 2022, the maximum number of shares that may be added to the 2018 Plan pursuant to the preceding sentence is 3,248,256 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.76%	1.01%	2.61%	0.91%
Expected volatility	73.61%	70.03%	73.48%	69.84%
Expected dividend yield	—	—	—	—
Expected term (in years)	5.66	6.08	5.73	6.07

The Company's stock option activity during the six months ended June 30, 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	826	$ 3.53
Exercised	(59)	$ 2.89
Expired	(511)	$ 22.48
Forfeited	(243)	$ 64.47
Balance at June 30, 2022	5,543	$ 17.06
Options exercisable	4,379	$ 14.77
Options vested and expected to vest	5,519	$ 17.02

During the three and six months ended June 30, 2022 and 2021, the Company did not grant any stock options with performance-based or market-based vesting conditions.

As of June 30, 2022, total unrecognized stock-based compensation expense relating to unvested stock options was $16.4 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 six months ended June 30, 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	4,391	$ 5.53
Vested	(121)	$ 102.95
Forfeited	(937)	$ 52.23
Balance at June 30, 2022	4,839	$ 21.32

The weighted-average fair value of RSUs granted during the six months ended June 30, 2022 and 2021 was $5.53 and $107.32, respectively.

As of June 30, 2022, total unrecognized stock-based compensation expense relating to unvested RSUs was $91.5 million and the weighted-average remaining vesting period was 3.0 years.

Performance-based Restricted Stock Units ("PSUs")

PSU activity under the 2018 Plan during the six months ended June 30, 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	4,124	$ 5.57
Forfeited	(428)	$ 5.58
Balance at June 30, 2022	3,809	$ 7.77

As of June 30, 2022, total unrecognized stock-based compensation expense relating to unvested PSUs was $29.6 million and the weighted-average remaining vesting period was 1.5 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"). At inception, the 2018 ESPP had a maximum number of 500,000 shares of common stock available. 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 three and six months ended June 30, 2022, stock-based compensation expense related to the 2018 ESPP was $0.3 million and $0.5 million, respectively. During the three and six months ended June 30, 2021, stock-based compensation expense related to the 2018 ESPP was $0.3 million and $0.5 million, respectively.

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 and six months ended June 30, 2022, the Company made contributions to the 401(k) plan of $0.2 million and $0.7 million, respectively. During the three and six months ended June 30, 2021, the Company made contributions to the 401(k) plan of $0.2 million and $0.5 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 investments to fund our future operating expenses and capital expenditure requirements; and*
- *our anticipated uses of our existing cash, cash equivalents and investments.*

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, we have completed a randomized, double-blind, placebo-controlled Phase 2 study (ENIGMA 1) and Phase 3 study (ENIGMA 2) of lirentelimab 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, and pending agreement with the FDA on trial design and our ability to appropriately fund these studies, we plan to conduct additional studies with lirentelimab.

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. We also announced plans to initiate a randomized, double-blind, placebo-controlled trials of SC lirentelimab in patients with chronic spontaneous urticaria in the third quarter 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 $246.1 million and $112.8 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $859.0 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 a termination agreement (the "Termination Agreement") with Lonza AG, Lonza Sales Ltd and Lonza Sales AG (collectively, "Lonza AG") regarding all outstanding manufacturing service agreements 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 June 30, 2022, we had cash, cash equivalents and investments of $212.4 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"), we entered into the Termination Agreement with Lonza AG regarding all outstanding MSAs. Lonza AG 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 we shall pay 126 million Swiss Francs, approximately $137 million (the "Termination Amount") to Lonza AG, 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.

As the agreement was terminated on February 14, 2022, we 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 AG and therefore to be expensed in future periods as the services are performed.

In addition, Lonza AG held or had placed orders for raw materials to be used in the course of services Lonza AG was providing us. Pursuant to the Termination Agreement, the cost of such raw materials was included in the Termination Amount. We have been working on repurposing those items by using at alternative locations, reselling or otherwise returning to the extent possible. The raw materials were expensed as they were intended for research and development purposes. Any proceeds from any refund or sale of raw materials will be recognized as a benefit to Research and Development Expenses in the quarter in which the sale or refund occurs.

Reorganization Plan

Under the Reorganization Plan, we reduced our workforce by approximately 35%. Impacted employees received notice that their positions will be eliminated on February 16, 2022. At the time of departure, impacted employees were eligible to receive severance benefits and we 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 us.

In connection with the Reorganization Plan, we recognized restructuring charges of approximately $5.2 million during the first quarter of 2022, related to severance payments and other employee-related separation costs. We 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 us and our stockholders to put in place arrangements designed to provide that we 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 remaining which 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 we achieve 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 prior to December 31, 2023. As a result, these cash retention bonuses are being amortized over the requisite service period, with $0.4 million and $0.5 million in expense recorded during the three and six months ended June 30, 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 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, including raw material costs. 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 investments 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 our 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 and six months ended June 30, 2022 and 2021. As of June 30, 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 June 30, 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 Sales 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 Sales. Under the terms of the agreement, we have made milestone payments of $3.4 million through June 30, 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 Sales. 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 and six months ended June 30, 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 June 30, 2022 and 2021

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

	Three Months Ended June 30,	
	2022	2021
Operating expenses		
Research and development	$ 34,448	$ 40,985
General and administrative	14,669	16,210
Total operating expenses	49,117	57,195
Loss from operations	(49,117)	(57,195)
Interest income	104	103
Other expense, net	(90)	(117)
Net loss	(49,103)	(57,209)
Unrealized gain (loss) on investments	209	(56)
Comprehensive loss	$ (48,894)	$ (57,265)

Research and Development Expenses

Research and development expenses were $34.4 million for the three months ended June 30, 2022 compared to $41.0 million for the three months ended June 30, 2021, a decrease of $6.6 million. The period-over-period decrease in research and development expenses was primarily due to a $9.9 million decrease in contract research and development and clinical costs primarily relating to lirentelimab (AK002). This was offset by increases of $3.1 million of equipment and overhead related costs primarily due to the new corporate facility and $0.2 million in professional services and other research and development expenses.

General and Administrative Expenses

General and administrative expenses were $14.7 million for the three months ended June 30, 2022 compared to $16.2 million for the three months ended June 30, 2021, an decrease of $1.5 million. The period-over-period decrease in general and administrative expenses was primarily due to decreases of $0.6 million in equipment and overhead related costs, $0.4 million in personnel-related costs and $0.5 million in other general and administrative expenses.

Interest Income

Interest income was $0.1 million for each of the three months ended June 30, 2022 and 2021.

Other Expense, Net

Other expense, net was $0.1 million for each of the three months ended June 30, 2022 and 2021.

Net Loss

Net loss was $49.1 million for the three months ended June 30, 2022 compared to net loss of $57.2 million for the three months ended June 30, 2021. Total stock-based compensation, depreciation and amortization expense for the three months ended June 30, 2022 and 2021 was $13.7 million and $11.8 million, respectively.

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

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

	Six Months Ended June 30,	
	2022	2021
Operating expenses		
Research and development	$ 211,255	$ 79,900
General and administrative	33,513	32,880
Total operating expenses	244,768	112,780
Loss from operations	(244,768)	(112,780)
Interest income	187	233
Other expense, net	(1,545)	(220)
Net loss	(246,126)	(112,767)
Unrealized gain (loss) on investments	(107)	24
Comprehensive loss	$ (246,233)	$ (112,743)

Research and Development Expenses

Research and development expenses were $211.3 million for the six months ended June 30, 2022 compared to $79.9 million for the six months ended June 30, 2021, an increase of $131.4 million. The first quarter of 2022 includes $4.6 million of costs as a result of the Reorganization Plan. Additionally, the period-over-period increase in research and development expenses included $133.9 million related to the Lonza AG Termination Agreement and an additional $6.2 million in overhead and lab related costs primarily due to the new corporate facility. This was offset by a decrease of $11.0 million of contract research and development and clinical costs primarily relating to lirentelimab (AK002) after excluding the costs associated with the Lonza AG Termination Agreement, a decrease of $0.4 million in personnel-related costs after excluding the costs relating to the Reorganization Plan and a decrease of $1.9 million in professional services and other research and development expenses.

General and Administrative Expenses

General and administrative expenses were $33.5 million for the six months ended June 30, 2022 compared to $32.9 million for the six months ended June 30, 2021, an increase of $0.6 million. The period-over-period increase in general and administrative expenses was primarily due to $4.3 million related to costs as a result of the Reorganization Plan incurred in the first quarter of 2022. This was offset by decreases of $1.5 million in other personnel-related costs, $1.1 million in equipment and overhead expenses and $1.1 million in marketing and other general and administrative expenses.

Interest Income

Interest income was $0.2 million for each of the six months ended June 30, 2022 and 2021.

Other Expense, Net

Other expense, net was $1.5 million for the six months ended June 30, 2022 compared to other expense, net of $0.2 million for the six months ended June 30, 2021. The fluctuation was primarily attributed to foreign currency charges associated with payments made under the Termination Agreement with Lonza AG was recognized during the six months ended June 30, 2022.

Net Loss

Net loss was $246.1 million for the six months ended June 30, 2022 compared to net loss of $112.8 million for the six months ended June 30, 2021. Total stock-based compensation, depreciation and amortization expense for the six months ended June 30, 2022 and 2021 was $27.2 million and $24.5 million, respectively.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2022, we had cash, cash equivalents and investments of $212.4 million. Based on our existing business plan, we believe that our current cash, cash equivalents and investments 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.

Summary Cash Flows

Comparison of the six months ended June 30, 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):

	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	$ (207,057)	$ (96,041)
Net cash provided by investing activities	135,471	87,237
Net cash provided by financing activities	413	5,583
Net increase in cash, cash equivalents and restricted cash	$ (71,173)	$ (3,221)

Cash Used in Operating Activities

Net cash used in operating activities was $207.1 million for the six months ended June 30, 2022, which was primarily attributable to our net loss of $246.1 million adjusted for net noncash charges of $29.8 million and net changes in operating assets and liabilities of $9.2 million. Noncash charges included approximately $23.2 million in stock-based compensation expense, $4.1 million in depreciation and amortization expense, $1.6 million in amortization of premiums and discounts on investments and $1.0 million in noncash lease expense.

Net cash used in operating activities was $96.0 million for the six months ended June 30, 2021, which was primarily attributable to our net loss of $112.8 million adjusted for net noncash charges of $27.3 million and net changes in operating assets and liabilities of $10.5 million. Noncash charges included approximately $23.8 million in stock-based compensation expense, $1.5 million in noncash lease expense, $1.2 million in amortization of premiums and discounts on investments and $0.8 million in depreciation and amortization expense.

Cash Provided by Investing Activities

Net cash provided by investing activities was $135.5 million for the six months ended June 30, 2022, which consisted of $140.0 million in proceeds from maturities of investments, $20.0 million in proceeds from sales of investments and $1.2 million in proceeds

from the sale of property and equipment, partially offset by $20.0 million for the purchases of investments and $5.7 million for the purchases of property and equipment.

Net cash provided by investing activities was $87.2 million for the six months ended June 30, 2021, which consisted of $310.0 million in proceeds from maturities of investments, partially offset by $215.5 million for the purchases of investments and $7.3 million for the purchases of property and equipment.

Cash Provided by Financing Activities

Net cash provided by financing activities was $0.4 million for the six months ended June 30, 2022 primarily related to proceeds received from employees for the exercise of stock options and the purchase of common stock through the 2018 ESPP.

Net cash provided by financing activities was $5.6 million for the six months ended June 30, 2021 primarily related to proceeds of $4.6 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

As of June 30, 2022, we had cash, cash equivalents and investments, excluding restricted cash, of $212.4 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance date of our unaudited interim financial statements included elsewhere in this Quarterly Report on Form 10-Q. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We intend to seek to raise funding from time to time 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, scope, and timing 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. We expect 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 investments.

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 six months ended June 30, 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 June 30, 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 June 30, 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, our 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 $246.1 million for the six months ended June 30, 2022. As of June 30, 2022, we had an accumulated deficit of $859.0 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 significant 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 need to reevaluate our operating plan and 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 June 30, 2022, we had $212.4 million in cash, cash equivalents and investments. We believe that our existing cash, cash equivalents and investments 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 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 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 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. Additionally, our ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions and volatility of financial

markets in the United States and worldwide. 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 our Phase 3 ENIGMA clinical trial. On June 13, 2022, the defendants filed a motion to dismiss the second amended complaint. 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	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38582	3.1	7/24/2018
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38582	3.2	7/24/2018
10.1*#	Master Services Agreement, dated November 1, 2020, by and among Fujifilm Diosynth Biotechnologies UK Limited, Fujifilm Diosynth Biotechnologies Texas, LLC, Fujifilm Diosynth Biotechnologies U.S.A., Inc. and Biogen (Denmark) Manufacturing APS – a Fujifilm Diosynth Biotechnologies Group Company.				
10.2	Separation Agreement, dated April 17, 2022, by and between Mark Asbury and Allakos Inc.	8-K	001-38582	10.1	4/20/2022
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document - the instance document does not appear in 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 June 30, 2022, has been formatted in Inline XBRL.				

* Filed herewith.
** Furnished herewith.
# Portions of the exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. A copy of any omitted portions will be furnished to the SEC upon request.

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: August 4, 2022

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

Date: August 4, 2022

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

Exhibit 10.1

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.

(1) FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED

(2) FUJIFILM DIOSYNTH BIOTECHNOLOGIES TEXAS, LLC

(3) FUJIFILM DIOSYNTH BIOTECHNOLOGIES U.S.A., INC

(4) BIOGEN (DENMARK) MANUFACTURING APS

AND

(6) ALLAKOS, INC.

MASTER SERVICES AGREEMENT

EFFECTIVE DATE: 01 November 2020

CONTENTS

THIS AGREEMENT is made on the date it is signed by the last signing party.

BETWEEN

(1) **FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED** incorporated and registered in England and Wales with company number 05803359 whose registered office is at Belasis Avenue, Billingham, TS23 1LH, England ("**FDBK**");

(2) **FUJIFILM DIOSYNTH BIOTECHNOLOGIES TEXAS, LLC** incorporated and registered in Texas whose principal place of business is at 100 Discovery Drive, Suite 200 College Station, Texas 77845 United States of America ("**FDBT**");

(3) **FUJIFILM DIOSYNTH BIOTECHNOLOGIES U.S.A., INC** incorporated and registered in Delaware whose principal place of business is at 101 J Morris Commons Lane, Morrisville, North Carolina 27560, United States of America ("**FDBU**");

(4) **BIOGEN (DENMARK) MANUFACTURING APS – A FUJIFILM DIOSYNTH BIOTECHNOLOGIES GROUP COMPANY** incorporated and registered in Denmark with company number 26060702 whose registered office is at Biogen Alle 1, 3400 Hillerød, Denmark ("**FDBD**"); and

(5) **ALLAKOS, INC.** incorporated and registered in Delaware, USA whose registered office is at 975 Island Drive, Suite 201, Redwood City, CA 94065, USA (the "**Customer**").

BACKGROUND

(A) Fujifilm (as defined below) is a biopharmaceutical contract development and manufacturing organization. The Customer wishes to appoint Fujifilm to carry out non-exclusive development and manufacturing services in relation to certain of the Customer's products.

(B) Fujifilm and the Customer have agreed to work together on the terms and conditions contained in this Agreement.

AGREED TERMS

1. **DEFINITIONS AND INTERPRETATION**

1.1 In this Agreement the following words have the following meanings unless inconsistent with the context:

"Affiliate"	means in relation to an entity, each or any other entity who for the time being directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such entity. For purposes hereof, "control" shall mean: (a) holding the majority of the voting rights or share capital of such entity; (b) any power (whether direct or indirect and whether by the ownership of share capital, the possession of voting power, contract, or otherwise) to appoint or remove all or such of the members of the board or other governing body of a body corporate as are able to cast the majority of the votes capable of being cast by members of that board or body on all, or substantially all, matters, or (c) otherwise to control or have the power to control the policies, management and affairs of that body corporate;
"Alternate Manufacturer"	has the meaning given to it in clause 11.8.1;
"Ancillary Services"	has the meaning given to it in Schedule 1 (Charges);

"Applicable Laws"	applicable law, regulations and binding guidance which applies in the jurisdiction in which the Program is being performed;
"Authorized Third Parties"	has the meaning given to it in clause 13.1.3;
"Background IP"	all Intellectual Property Rights controlled, owned or jointly owned by any party (or a third party on its behalf) prior to the Effective Date or developed independently from the Program. Fujifilm's proprietary manufacturing, expression, or purification technologies, including: (a) an expression system within the scope of international patent application PCT/GB2007/000351 (the "pAVEway™ Expression System"); (b) expression technology within the scope of international patent application PCT/GB2014/000165 (the "Apollo™ Expression Technology"); and (c) Fujifilm's proprietary alcohol oxidase yeast Pichia pastoris expression system (the "Yeast Expression System"), ((a), (b), and (c), each the "**Fujifilm Expression Technology**") is Fujifilm's Background IP;
"Batch"	a quantity of Product that is produced from a run of the Process at the Facility;
"Batch Cancellation Fee"	the Batch Cancellation Fee described in Schedule 1;
"Batch Fee"	the Batch Fee as set forth in the applicable SoW;
"Business Day"	(a) in relation to notices given under this Agreement rather than a specific Scope of Work, a day other than a Saturday, Sunday or public holiday in England, the US, Denmark or the country in which the Customer's head office is located; and (b) in relation to notices given under a specific Scope of Work a day other than a Saturday, Sunday or public holiday in England if FDBK is a contracting party, the US if FDBT or FDBU is a contracting party, Denmark if FDBD is a contracting party or the country in which the Customer's head office is located;
"cGMP"	Current Good Manufacturing Practice as defined in (i) the Federal Register volume 66 No 186 and those sections applicable within the FDA Regulations 21 CFR Part 210, 211, Part 11, Parts 600-610 and (ii) the rules governing medicinal products in the European Union and the United Kingdom. Eudralex Volume 4 – Guidelines for good manufacturing practices for medicinal products for human and veterinary use. Part I – Basic Requirements for Medicinal Products. Part II – Basic Requirements for Active Substances used as Starting Materials, ICHQ7 and ICHQ10, and the European Commission (EC) Directives 2001/83/EC;
"cGMP Batch"	a Batch identified in a Scope of Work which is intended to be manufactured during a Manufacturing Stage and subject to Disposition in each case in accordance with cGMP;

"**Cancellation Fees**"	has the meaning given to it in clause 15.8.1;
"Change"	has the meaning given to it in clause 14;
"Charges"	has the meaning given to it in clause 8.2;
"CMC Section"	has the meaning given to it in clause 5.2.1;
"Commercially Reasonable Efforts"	with respect to the activities pursuant to a Program, the reasonable efforts and resources used by a reputable biopharmaceutical contract manufacturing organization for products of similar nature, complexity and developmental stage in the same or similar circumstances as the applicable Product;
"Competitor"	a contract development or contract manufacturing organization in the biopharmaceutical industry listed on Schedule 3 hereto;
"Confidential Information"	the fact and terms of this Agreement and/or any Scope of Work, and all information (in whatever form) in respect of the business of each of the parties and each of its Affiliates which is (in each case) provided or obtained by one party to or for the other, including any ideas; business methods; finance information; prices, business, financial marketing or development plans; products or services, know-how or other matters connected with products or services manufactured or marketed; customer lists or details; computer systems and software;
"Conforming Batch"	a cGMP Batch which has been produced in accordance with cGMP and which meets the Product Specification;
"Consumable"	a consumable item used or intended for use in a Program, including PEG, reagents (including analytical reagents), raw materials, packaging components, chromatography resins, filters, filtration membranes, media, buffer bags, refold bags, tubing, hoses, disposable analytical test kits, in-process measurement probes, columns (including analytical columns) and disposable containers;
"Customer Foreground IP"	all Foreground IP that constitutes an improvement, modification, or derivative which is specific to or requires the use of the Customer's Background IP, Customer's Materials or Customer's Confidential Information, in each case, obtained or developed by any party hereto (or any of its subcontractors), alone or jointly with any other party;
"Customer Indemnitee"	has the meaning given to it in clause 12.1;
"Delay"	has the meaning given to it in clause 15.1.1;
"Delivery Date"	has the meaning given to it in clause 7.2;
"Demonstration Batch"	a Batch which is manufactured in a non cGMP R&D facility for demonstration purposes and which is not intended for human use;
"Deviation"	a cGMP deviation as detailed in the Quality Agreement;
"Disclosing Party"	has the meaning given to it in clause 13.1;

“Disposition”	the Stage during which (a) the Product is tested for compliance versus the Product Specification; (b) all production instruction and analytical records relating to cGMP manufacture of each cGMP Batch prepared by Fujifilm are reviewed by Fujifilm; and (c) a Fujifilm recommendation for Product release or reject is made; in each case as applicable;
“Drug Product”	the final dosage form of product which contains Product in association with other active or inactive ingredients;
“Drug Substance”	Any substance or mixture of substances intended to be used in the manufacture of a Drug Product and that, when used in the production of a drug, becomes an active ingredient of the Drug Product. Such substances are intended to furnish pharmacological activity or other direct effect on the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
“Effective Date”	01 November 2020;
“Engineering Batch”	a Batch that is manufactured in a cGMP Facility at scale using the Process but which is not intended for human use;
“Facility”	any of Fujifilm’s manufacturing facilities in which a Program will be performed;
“Force Majeure Event”	any event or circumstances outside the reasonable control of a party affecting its ability to perform any of its obligations under this Agreement, including act of God, fire, flood, severe weather, epidemic or pandemic, war, revolution, acts of terrorism, riot or civil commotion, acts of government, trade embargo, labor disputes (excluding labor disputes involving the party in question), interruption of utility service, restraints or delays affecting shipping or carriers, inability or delay in obtaining supplies of adequate or suitable materials, inability or delay in obtaining third party services, breakdown or failure in equipment or machinery (other than due to failure to perform appropriate maintenance) or cyber-attack, but shall not include the failure of the Product in clinical trials or failure of the Product to gain regulatory approval;
“Foreground IP”	all Intellectual Property Rights that arise or are obtained or developed by or on behalf of any party in the course of the performance of a Program;
“Fujifilm”	FDBK, FDBT, FDBU or FDBD as the context requires in accordance with clause 1.3;
“Fujifilm Foreground IP”	all Foreground IP obtained or developed by Fujifilm (or any of its subcontractors), alone or jointly with any other party, other than Customer Foreground IP;
“Fujifilm Regulatory Responsibility”	has the meaning given to it in clause 5.2.4;
“Fujifilm Services”	the research and development services to be provided by Fujifilm for the Customer during a Program as the same are described in the relevant Scope of Work, excluding the Ancillary Services;
“Gross Negligence”	a conscious and voluntary or reckless disregard of the need to use reasonable care, which is likely to cause foreseeable grave injury or harm to persons or property;

"Historic Documents"	any historic contractual documentation which cover the same subject matter as a Program as identified in the relevant SoW;
"Indemnified Party"	has the meaning given to it in clause 10.12;
"Indemnify"	on demand to indemnify and keep indemnified, and hold harmless, the party to be indemnified on an after-tax basis;
"Indemnifying Party"	has the meaning given to it in clause 10.12;
"Indemnity Claim"	has the meaning given to it in clause 10.12;
"Intellectual Property Right"	any current and future intellectual property rights and interests including patents, utility models, designs, design rights, copyright (including rights in software), works of authorship, technical materials, decryption rights, database rights, trade marks, rights pursuant to passing off, service marks, business and trade names, domain names, know-how, results, data, databases, formulations, compounds, rights in biological or chemical materials, rights under data exclusivity laws, rights under unfair competition laws, topography rights, inventions, rights in confidential information (including technical and commercial trade secrets), supplementary protection certificates and image rights, and rights of a similar or corresponding character in any part of the world, in each case whether registered or not and including any application for registration and renewals or extensions of such rights in any country in the world and whether subsisting now or in the future;
"Joint Steering Committee"	has the meaning given to it in clause 4.3;
"Latent Defect"	has the meaning given to it in clause 6.7;
"Liabilities"	any (a) liabilities of any nature, whether accrued, absolute, contingent or otherwise and whether in contract, tort (including negligence) or otherwise; (b) losses, costs (including internal costs/overheads), damages, fines or expenses including reasonable legal fees; and (c) claim, demand, proceeding, action or cause of action including those by third parties; in each case howsoever arising. "**Liability**" shall be construed accordingly;
"New Opportunity"	has the meaning given to it in clause 13.1.2;
"Manufacturing Stage"	a Stage of a Program during which production, testing and Disposition (if applicable) of Engineering Batches or cGMP Batches are intended to take place, including pre and post manufacturing activities; Facility change–over, setup and cleaning before, between and after Batch manufacturing;
"Materials"	has the meaning given to it in clause 7.1;
"Mitigation Application"	any cost savings achieved by virtue of the Mitigation Efforts (for example reuse of Consumables) and any fees received by Fujifilm from third parties for its services (but not in relation to Ancillary Services provided for that third party) as a result of selling un-utilized slots to a third party customer shall be set off against the Batch Cancellation Fee or Program Cancellation Fee;

"**Mitigation Efforts**"	[***];
"Modifications"	a modification to a Facility; or equipment (including Process specific qualification and installation of existing equipment at the Facility), required in order to perform a Process at the Facility and detailed in the applicable Scope of Work*;*
"**MRB**"	has the meaning given to it in clause 6.8.1;
"Non-Conforming Batch"	a cGMP Batch which has not been produced in accordance with cGMP or does not meet the Product Specification;
"Non-Manufacturing Stage"	a Stage of a Program, which is not a Manufacturing Stage, during which the non-manufacturing activities described in the relevant SoW are undertaken, including the production and testing of Demonstration Batches;
"Pandemic"	has the meaning given to it in clause 16.1;
"Process"	a particular process used, or to be used, for manufacture of a Product;
"Process Specification"	the Process operating parameters and specifications as documented in the regulatory submission or a QA Document (including Deviations) which has been agreed by the parties for cGMP Batch production;
"Process-Specific Consumable"	a Consumable which is required to operate the Process and which is specific to the Process or a Consumable which is required in such large volumes as would not be possible for Fujifilm to consume during other manufactures or within the shelf life of such Consumable;
"Process-Specific Equipment"	an item of equipment which is required by Fujifilm to operate the Process and which is specific to the Process in addition to that equipment which Fujifilm uses in its Facilities as at the SoW Effective Date (which existing equipment is not already dedicated to other customer(s) of Fujifilm);
"Product"	the particular product or substance (compound or molecule) created during and as a result of performing the Process, the name of the relevant Product being identified in the applicable Scope of Work;
"Product Specification"	the Product specification which is documented in a QA Document;
"Program"	a program of work implemented through one or more SoWs, as each may be amended from time to time by agreement of the Customer and Fujifilm, to be carried out by Fujifilm in accordance with the terms of this Agreement;
"Program Cancellation Fee"	the Program Cancellation Fee described in Schedule 1;
"Program Manager"	the Program manager appointed by each of Fujifilm and the Customer under the applicable Scope of Work;

"Program Plan"	the Program plan controlled by Fujifilm's Program Manager and communicated to the Customer from time to time, which plan is for planning purposes only;
"Quality Agreement"	the document agreed by the parties which sets out the mutually agreed quality standards applicable for any cGMP activity under the Program;
"QA Documents"	the Quality Agreement and the documents produced and approved in accordance with the Quality Agreement;
"Receiving Party"	has the meaning given to it in clause 13.1;
"Regulatory Authority"	the U.S. Food and Drug Administration, the European Medicines Agency, the Medicines & Healthcare products Regulatory Agency, the Danish Medicines Agency and any successor to any such entities and any other similar regulatory authorities as may be agreed upon in writing by Fujifilm and the Customer;
"Replacement Batch"	has the meaning given to it in clause 6.5.1;
"Scope of Work" or "SoW"	the document setting out the detail of the work to be undertaken by Fujifilm for the Customer as part of the Program;
"Services"	all or any part of the services to be performed by Fujifilm under this Agreement, including the Fujifilm Services and Ancillary Services;
"SoW Effective Date"	for each Scope of Work, the date that the Scope of Work is fully signed by all relevant parties;
"Special Waste"	waste or effluent which requires special handling including waste or effluent which is required to be collected in a special container (for example by tanker) for external disposal or which requires incineration;
"Stage"	a stage of the Program as described in the SoW;
"Subcontracted Work"	work subcontracted by Fujifilm under clause 22.3 but excluding any work subcontracted between FDBK, FDBT, FDBU or FDBD;
"Tax"	value added tax, sales tax, or any other similar type of turnover tax;
"Term"	has the meaning given to it in clause 3.1;
"third party claim"	any claim, action, or proceeding brought against a party hereto by any third party not affiliated with the other party, including any claims, actions, or proceedings brought by any governmental or administrative body (including fines and penalties issued thereby); and
"Willful Misconduct"	a knowing violation of: (a) a reasonable and uniformly enforced rule or policy; or (b) Applicable Law. It means intentionally doing that which should not be done or intentionally failing to do that which should be done, knowing that injury will probably result or recklessly disregarding the possibility that injury may result.

1.2 In this Agreement (except where the context otherwise requires) : (a) any words following the terms "**including**", "**include**", "**for example**" or any similar expression are by way of illustration and emphasis only and shall not limit the generality or extent of any other words or expressions; and (b) the term "**or**" will be non-exclusive and have the same meaning as "and/or."

1.3 Each Scope of Work will be entered into by FDBK, FDBT, FDBU or FDBD or a combination of FDBK, FDBT, FDBU or FDBD and, subject to clause 19.3, each reference to Fujifilm or a "party" in this Agreement shall apply only to such of FDBK, FDBT, FDBU or FDBD as is carrying out the Program under the relevant Scope of Work. Whichever of FDBK, FDBT, FDBU or FDBD has entered into the Scope of Work in respect of that Program shall be fully and solely responsible for the obligations and liabilities of that party under the Scope of Work.

1.4 Insofar as this Agreement obliges any party to this Agreement to negotiate, take action or to do something, that party shall conduct such negotiations, take such action or do such thing in good faith. There shall be a general obligation on the parties to act in good faith in relation to the matters contemplated in this Agreement.

1.5 In the case of conflict or ambiguity between terms of the main body of this Agreement, any Schedule to this Agreement or any other terms in any Scope of Work, the order of priority shall be as follows: (a) the main body of the Agreement; (b) the Schedules to the Agreement; (c) the main body of the Scope of Work unless a Scope of Work specifically varies a provision of the Agreement or a Schedule to the Agreement by reference to the provision it is amending, in which case the Scope of Work shall take precedence in that instance.

1.6 In the case of conflict or ambiguity between the terms of this Agreement or any specific Scope of Work and the terms of the QA Documents, the terms of the QA Documents shall prevail solely in relation to cGMP quality matters subject to clause 10.9.

1.7 Where a defined term is used in clause 10 (Liability) it shall retain its meaning even when the entire word that is a defined term is in capitals.

2. APPOINTMENT OF FUJIFILM

2.1 This Agreement establishes the general terms and conditions applicable to Fujifilm's performance of each Program for the Customer and is structured so that a separate, numbered Scope of Work (or in some cases multiple Scopes of Work thereunder) shall be entered into by the parties for the provision of each Program.

2.2 The provisions of this Agreement shall apply to each Scope of Work and no Scope of Work shall be effective or binding on any party until it has been signed by an authorized representative of each contracting party.

2.3 Nothing in this Agreement or any Scope of Work shall oblige any party to enter into any Scope of Work, and each Scope of Work constitutes a separate contract.

2.4 This Agreement is non-exclusive in nature and nothing herein will prevent the Customer from engaging other third parties to perform services that are the same or similar to those being performed by Fujifilm, including for the Products that are subject to any Program.

3. TERM

3.1 This Agreement shall come into force on the Effective Date and shall continue until terminated by a party in accordance with the terms of this Agreement (the "**Term**").

3.2 A party may terminate this Agreement upon giving 3 (three) months' written notice to the others, provided that there are no uncompleted Programs existing at the date such notice is given.

3.3 Each Scope of Work will take effect from the SoW Effective Date and shall continue until the earlier of:

3.3.1 the date specified in the Scope of Work, or if no such date is specified, the date the Program, or part of the Program referred to in the Scope of Work is completed; or

3.3.2 termination of this Agreement or the relevant Scope of Work in accordance with the terms of this Agreement.

4. **PERFORMANCE OF PROGRAMS**

4.1 The Customer and Fujifilm shall agree upon one or more written Scope(s) of Work for each Program. If a given Program is intended to be implemented through more than one Scope of Work, the first Scope of Work for such Program will provide a high-level summary of the overall Program.

4.2 Each party shall appoint a Program Manager for each Program. The Program Managers will be responsible for overseeing the Program. The Program Managers shall have regular teleconferences to discuss the progress of the Services, the expectation of the parties being that these will usually take place on a weekly basis or as otherwise agreed by the parties. Each party may change its Program Manager from time to time upon written notice to the other party. In the event that any dispute cannot be resolved by the Program Managers, such dispute shall be escalated to the Joint Steering Committee as set forth in clause 17.2.

4.3 Promptly following the Effective Date, the parties shall establish a ("**Joint Steering Committee**") consisting of 4 members from each party. The Joint Steering Committee shall meet once per calendar quarter, or at such other frequency as may be necessary and is mutually agreed by the parties. Decisions of the Joint Steering Committee shall be made by consensus of both parties (and not by a majority of individual committee members). In the event that a Joint Steering Committee cannot reach consensus with respect to a particular matter within its authority, such dispute shall be escalated as set forth in clause 17.2.

The function of the Joint Steering Committee is to provide oversight of all Programs, ensure the ongoing communication between the parties, and discuss any issues arising under this Agreement. In addition to the function described above, the Joint Steering Committee shall also take on the following responsibilities:

4.3.1 discuss and seek resolution of issues around management of all Programs;

4.3.2 monitor the progress of each Program against the current applicable Program Plan and the SoWs;

4.3.3 discuss and recommend any Changes (although such Changes will not take effect until they have been approved in writing by the parties as set forth in clause 14); and

4.3.4 discuss and seek resolution for any dispute regarding the terms of this Agreement.

4.4 Fujifilm shall:

4.4.1 carry out each Program, or parts of a Program, in a diligent, professional, and workmanlike manner using Commercially Reasonable Efforts, and in accordance with:

(a) the terms of this Agreement and the applicable Scope of Work;

(b) Applicable Laws;

(c) the Quality Agreement and cGMP (in both cases when applicable);

(d) the Process Specification for the applicable cGMP Batch (if any); and

4.4.2 retain appropriately qualified and trained personnel with the requisite knowledge and experience to undertake the Program in accordance with this Agreement.

4.5 Fujifilm shall use Commercially Reasonable Efforts to provide all assistance, information and advice and to do all acts which the Customer may reasonably request to enable the Customer

to comply with its obligations and responsibilities under this Agreement, any Scope of Work, and the Quality Agreement.

4.6 The parties agree that it shall not be considered a breach of this Agreement by Fujifilm if an objective of a Program is not achieved, provided that Fujifilm has complied with its obligations set out in clause 4.4. The parties acknowledge and agree that the services to be performed during the Programs are by their nature developmental and Fujifilm cannot (and consequently does not) guarantee to the Customer the achievement of a successful outcome for a Program, production of Conforming Batches, or production of a specified volume of Product. The foregoing does not limit Fujifilm's express obligations in this Agreement, including as set forth in Clause 6.

4.7 Each Scope of Work contains assumptions on which Fujifilm's ability to perform the Program depends. If an assumption set out in the Scope of Work proves to be incorrect or actual circumstances differ from an assumption (including if such assumption cannot be met at such time as Fujifilm reasonably requires to enable it to perform its obligations) then Fujifilm shall promptly provide the Customer with notice of the same and the parties shall agree upon a reasonable Change to account for the change in assumption.

4.8 The Customer shall:

4.8.1 meet all its obligations and responsibilities under this Agreement, any Scopes of Work (including, in particular, any Customer dependencies set out in a Scope of Work) and the Quality Agreement;

4.8.2 comply with Applicable Laws; and

4.8.3 promptly provide all assistance, information, and advice and do all acts which Fujifilm may reasonably request to enable Fujifilm to comply with its obligations and responsibilities under this Agreement any Scope of Work, and the Quality Agreement.

5. QUALITY AND REGULATORY MATTERS

5.1 Quality Agreement

5.1.1 As soon as reasonably practicable following the Effective Date the parties shall execute the Quality Agreement (unless the Quality Agreement has already been executed prior to the Effective Date).

5.1.2 The Customer acknowledges that Fujifilm shall not commence any cGMP activity until the Quality Agreement is executed by both parties.

5.2 Regulatory Assistance

5.2.1 The Customer shall provide Fujifilm with a copy of the Customer's Chemistry, Manufacturing and Controls section of any submission to a Regulatory Authority supporting the Customer's regulatory filing activities for the applicable Product or Process at the Facility which relates to or contains information about: the Process as conducted at the Facility; the Facility (including Fujifilm equipment); the Fujifilm Services; or the Ancillary Services ("CMC Section") in accordance with the Quality Agreement. The Customer shall provide CMC Sections to Fujifilm with reasonable time to review and comment and Customer shall (a) implement Fujifilm's comments to the extent relating specifically to the Facility or Fujifilm's equipment or Fujifilm's ability to complete Disposition, and (b) in good faith consider all other Fujifilm comments.

5.2.2 During each Program, the Customer may request assistance from Fujifilm in respect of the CMC Section, subject to payment by the Customer of a reasonable commercial rate for such assistance and Fujifilm's reasonable expenses, unless otherwise set forth in the applicable Scope of Work. However, no advice or assistance given by Fujifilm shall

be deemed to be or construed as a guarantee that a Drug Product will receive regulatory approval.

5.2.3 Fujifilm will provide one electronic (PDF) copy of any documents which may be reasonably required by the Customer in support of its regulatory filing activities. If the Customer requires copies of the laboratory notebooks, provision of these will be subject to discussion and agreement by the parties and agreement of an additional fee associated with copying.

5.2.4 The Customer shall have the right and responsibility for determining regulatory strategy, decisions, and actions relating to each Program and any Product or Drug Product subject to clause 5.2.5 and provided that Fujifilm shall have the right and responsibility for determining regulatory strategy, decisions and actions to the extent relating to:

(a) the Facility (including, in particular, utilities and equipment);

(b) Fujifilm's quality systems, policies and internal procedures; or

(c) any requirement imposed on Fujifilm by a Regulatory Authority

(d) any other commitments made by Fujifilm prior to the relevant SoW Effective Date of the applicable Program,

(each a "**Fujifilm Regulatory Responsibility**"), provided further that Fujifilm will not, except to the extent required by Applicable Law, initiate correspondence directly with any governmental authority regarding the Product without, in each instance, providing the Customer with as much prior notice as possible.

5.2.5 The Customer acknowledges that Fujifilm Quality Assurance team reserves the right to Disposition Product to the Customer in accordance with the Quality Agreement.

5.2.6 The Customer shall not make any change to its regulatory filings, including its Investigational New Drug application, which would likely have an impact on any Fujifilm Regulatory Responsibility without prior agreement with Fujifilm.

5.3 Recalls. If the Customer recalls any Product (voluntarily or by order of a governmental authority) or is required to respond to inquiries of governmental authorities relating to the Products [***].

5.4 No Debarment.

5.4.1 Each party represents and warrants to the other that neither it nor any of its officers, directors, or its employees performing services under this Agreement has been debarred, or convicted of a crime which could lead to debarment, under the Generic Drug Enforcement Act of 1992, 21 United States Code §§335(a) and (b), sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. § 1320 a-7b(f)), including the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any federal agency or program.

5.4.2 If during the Term, any party or any of its officers, directors, or its employees performing services under this Agreement becomes so debarred, suspended, excluded, sanctioned, or otherwise declared ineligible, (i) if such party is Fujifilm, the Customer may terminate this Agreement and all SoWs, (ii) if such party is the Customer, Fujifilm may terminate this Agreement and all SoWs, and (ii) if it is another person, the applicable party will immediately notify the other party and remove such person from performing any services, and, unless the adverse consequences can be cured by removing such person from performing the services, the other party may terminate all affected SoWs.

6. **CONFORMING BATCHES AND NON-CONFORMING BATCHES**

6.1 Each cGMP Batch will be determined by Fujifilm to be a Conforming Batch or a Non-Conforming Batch before or in connection with the Disposition of the Batch.

6.2 Deviations will be handled in accordance with the Quality Agreement and, for the avoidance of doubt, the Customer acknowledges that the occurrence of a Deviation does not automatically mean that a Batch is a Non-Conforming Batch.

6.3 In respect of Conforming Batches, Fujifilm will complete Disposition, and issue a certificate of analysis, a cGMP compliant statement (i.e. a certificate of compliance), and such other documentation as required by the QA Documents for such Batch on the date of such Disposition. The Customer will have the right to inspect the Batches following Disposition to determine if they are Non-Conforming Batches in accordance with its own release process and the Quality Agreement. The provisions of clauses 6.4 to 6.6 shall apply to Non-Conforming Batches only.

6.4 If a Batch is a Non-Conforming Batch and the cause of that Batch being a Non-Conforming Batch is [***], then the Customer shall pay the Charges relating to the Non-Conforming Batch in full and the relevant Manufacturing Stage, Disposition and all related and ancillary activities shall be deemed to have been completed under the Scope of Work. Any further work in relation to such a Non-Conforming Batch (such as analysis of the Batch) or manufacture of a replacement cGMP Batch (if required by Customer) shall be carried out at a time and price to be agreed in writing by the parties in a Change.

6.5 If a Batch is a Non-Conforming Batch and the cause of the Batch being a Non-Conforming Batch is a failure by Fujifilm to comply with clause 4.4, then Fujifilm shall, [***]:

6.5.1 use Commercially Reasonable Efforts to manufacture a replacement cGMP Batch ("**Replacement Batch**") as soon as is reasonably practicable. In these circumstances the Customer shall pay for:

(a) all Charges in respect of the original Non-Conforming Batch in accordance with the SoW (save that any instalments of the Charges which are not due until after the date that the Non-Conforming Batch is determined to be a Non-Conforming Batch shall become due on completion of the Replacement Batch); and

(b) the Charges for the Ancillary Services provided in relation to the Replacement Batch but the Fujifilm Services provided in relation to the Replacement Batch shall be free of charge; or

6.5.2 [***].

6.6 If the Customer requests delivery of a Non-Conforming Batch, the parties shall agree in writing (in a Change) on fair consideration payable for that Non-Conforming Batch. Fujifilm agrees to deliver a Non-Conforming Batch to the Customer on the express condition that it (a) will not be used for human or clinical trials; (b) will be labeled as "Not for Human Use"; and (c) is subject to the Customer's indemnity given under clause 10.6.3.

6.7 [***].

6.8 If the parties cannot agree if a Batch is a Conforming Batch or a Non-Conforming Batch and/or if the cause of a Batch being a Non-Conforming Batch is not agreed by the parties following the exhaustion of the processes set out in the Quality Agreement, then this clause 6.8 shall apply:

6.8.1 the parties will first exhaust the investigation/resolution options set out in the Quality Agreement including reference to the Material Review Board ("**MRB**") under the Quality Agreement;

6.8.2 if the MRB is unable to resolve this matter then the documentation related to the applicable Batch will be reviewed by an independent GMP consultant acceptable to both parties. The result of such independent review will be binding for both parties solely for the purpose of determining whether the Batch is a Non-Conforming Batch or if the cause of a Batch being a Non-Conforming Batch is a Fujifilm failure to comply with clause 4.4;

6.8.3 if the independent GMP consultant finds that the Batch is not a Non-Conforming Batch or that the event that caused the Batch to be a Non-Conforming Batch was not caused by a Fujifilm failure to comply with clause 4.4, the Customer will pay Fujifilm for the Batch in question in accordance with clause 6.4;

6.8.4 if the independent GMP consultant finds that the Batch is a Non-Conforming Batch and that the event that caused the Batch to be a Non-Conforming Batch was caused by a Fujifilm failure to comply with clause 4.4, the remedial procedure set out in clause 6.5 will be applied; and

6.8.5 unless otherwise agreed by the parties, the costs associated with the independent GMP consultant will be paid by the party against whom the independent GMP consultant finds.

7. DELIVERY, TITLE AND RISK

7.1 Delivery by Fujifilm to the Customer, or the Customer's designee, of any material in connection with the Program including any quantity of Product manufactured during the Program, any Process-Specific Equipment, or Process-Specific Consumables and return of any samples and cell lines supplied by the Customer ("**Materials**") will be made Ex Works the Facility (Incoterms 2010) and clauses 7.2 to 7.5 shall apply to such Materials. Fujifilm shall package the relevant Material ready for shipment in accordance with the Customer's reasonable instructions.

7.2 Delivery of Materials will be deemed to be complete on the date which Fujifilm makes the Materials available for collection by the Customer (which is the point of delivery as set forth in Ex Works (Incoterms 2010)) following notification, of at least [***], by Fujifilm to the Customer that it will make those Materials available for collection (the "**Delivery Date**"). For the avoidance of doubt, Product subject to Disposition will not be made available for collection by the Customer until Disposition is complete.

7.3 [***], Fujifilm may, at Fujifilm's election, destroy or store the Materials at the Customer's risk and expense. For clarity, no storage fee is payable for the first [***] after the date of first notice, all notices pursuant to this clause must be provided in accordance with clause 19, and title and risk of loss for such stored Material passes to the Customer as set forth in clause 7.4.

7.4 Risk in Material shall pass to the Customer on the Delivery Date.

7.5 Title to the Product shall pass to the Customer on the Delivery Date.

7.6 From time to time Fujifilm may agree to store Materials (including intermediate Product for future processing) for Customer. If Fujifilm agree to store Materials the parties will enter into a storage agreement on Fujifilm's standard terms.

7.7 Delivery of any materials which the Customer is required to supply to Fujifilm pursuant to the SoW shall be delivered to Fujifilm DDP the Facility (Incoterms 2010). Risk in those materials remains with the Customer.

8. PRICE AND PAYMENT

8.1 Under this Agreement, and the relevant Scope of Work, the Customer appoints, on a non-exclusive basis, Fujifilm to carry out services concerning the research and development, testing, manufacture, and Disposition of the Product by Fujifilm under a Program. The

Charges relate specifically to those services and are not in consideration of the supply of any material (including Product) which Fujifilm may produce as a consequence of the performance of those services.

8.2 The Customer shall pay to Fujifilm for each Program:

8.2.1 the fees for the Fujifilm Services as set out in the relevant Scope of Work; and

8.2.2 the fees for Ancillary Services in accordance with Schedule 1,

together the "**Charges**".

8.3 Fujifilm may invoice the Customer for the Charges in respect of each Program in accordance with the terms set out in the Scope of Work and Schedule 1.

8.4 The Customer shall pay each invoice issued to it by Fujifilm within [***] of the invoice, in full and in cleared funds in the currency specified in the Scope of Work by electronic transfer to the financial institution specified in the relevant invoice.

8.5 The Charges are exclusive of any Tax which may apply and which shall be payable by the Customer to Fujifilm at the rate prescribed by law. For clarity, tax on Fujifilm's income, personnel, and assets will be the sole responsibility and liability of Fujifilm.

8.6 If there is a change in the rate of Tax payable or in the Tax treatment of some or all of the services provided by Fujifilm or the Product, a change of law or practice or interpretation of the existing legislation or revised determination by HMRC (Her Majesty's Revenue and Customs) or the IRS (Internal Revenue Service), then the Customer agrees that Fujifilm shall be entitled, where Tax is imposed on a supply by Fujifilm under or in connection with this Agreement, to invoice the Customer (in a valid Tax invoice) for a sum equal to the amount of the Tax which becomes due on that supply and any fees or interest which HMRC or the IRS levies on Fujifilm in relation to the outstanding sums or non-payment. The Customer shall pay those invoices in accordance with clause 8.4.

8.7 The Customer shall:

8.7.1 be responsible for the collection, remittance and payment of any or all taxes, charges, levies, assessments and other fees of any kind imposed by governmental or other authority in respect of the purchase, importation, exportation, sale or other distribution of any Materials delivered to it by Fujifilm in connection with the Program; and

8.7.2 make all payments under this Agreement without withholding or deduction of, or in respect of, any tax unless required by law. If withholding tax is deducted then the Customer will provide all documentation required to enable Fujifilm to recover the tax withheld.

8.8 Without prejudice to any other right or remedy that it may have, if the Customer fails to pay any undisputed sum to Fujifilm on the due date for payment:

8.8.1 the Customer shall pay interest on the overdue amount at the rate of [***]. Such interest shall be payable in respect of the period from the due date until actual payment of the overdue amount (whether before or after judgment) in accordance with clause 8.4; and

8.8.2 [***].

8.9 If the Customer disputes the payment of any Charges or a part of them, the Customer shall:

8.9.1 notify Fujifilm of the disputed amount within [***] of the invoice in which such disputed amount is included giving reasonable details of the dispute and must be made in good faith; and

8.9.2 pay the amount of Charges not in dispute in accordance with clause 8.4,

and the dispute shall be dealt with under the dispute resolution process set out in clause 17.

9. **FUJIFILM WARRANTIES.**

9.1 Fujifilm warrants that:

9.1.1 Fujifilm is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

9.1.2 the Fujifilm Services will be performed in accordance with clause 4.4;

9.1.3 the Services shall be performed in accordance with all Applicable Laws and this Agreement;

9.1.4 title to Product will pass to the Customer under this Agreement free and clear of any security interest, lien, or other encumbrance; and

9.1.5 to Fujifilm's knowledge, the use by Fujifilm or the Customer of Fujifilm's Background IP or Fujifilm's Confidential Information will not infringe, misappropriate, or violate any third party's Intellectual Property Rights.

10. **LIABILITY**

10.1 Nothing in this Agreement limits or excludes the liability of any party to the other for any liability that is not permitted to be limited or excluded by law or results from death or personal injury caused by its negligence (and clauses 10.2 to 10.7 are expressly agreed to be subject to this clause 10.1).

10.2 [***]:

10.2.1 TO THE EXTENT THERE HAS BEEN NO GROSS NEGLIGENCE OR WILLFUL MISCONDUCT BY [***]:

(a) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER ANY NON-MANUFACTURING STAGE UNDER A SOW, [***] LIABILITY SHALL BE LIMITED TO AN AMOUNT EQUAL TO [***]; AND

(b) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER A MANUFACTURING STAGE (INCLUDING LIABILITY RELATING TO THE MANUFACTURE OF, OR FAILURE TO MANUFACTURE, A BATCH), [***] LIABILITY SHALL BE LIMITED TO AN AMOUNT EQUAL TO [***]; OR

10.2.2 TO THE EXTENT THERE HAS BEEN GROSS NEGLIGENCE OR WILLFUL MISCONDUCT BY [***]

(a) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER A NON-MANUFACTURING STAGE UNDER A SOW, [***] LIABILITY SHALL BE LIMITED TO AN AMOUNT EQUAL TO [***]; AND

(b) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER A MANUFACTURING STAGE, (INCLUDING LIABILITY RELATING TO THE MANUFACTURE OF, OR FAILURE TO MANUFACTURE, A BATCH), [***] LIABILITY SHALL BE LIMITED TO AN AMOUNT EQUAL TO [***]; AND

10.2.3 IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER A SCOPE OF WORK, [***] LIABILITY SHALL BE LIMITED IN [***]; AND

10.2.4 IN RESPECT OF ANY OTHER LIABILITY RELATING TO THIS AGREEMENT FALLING OUTSIDE THE SCOPE OF CLAUSES 10.2.1, 10.2.2 AND 10.2.3, THE [***] TOTAL LIABILITY SHALL BE [***].

10.3 [***] WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), FOR BREACH OF STATUTORY DUTY OR OTHERWISE, ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR: LOSS OF PROFIT; LOSS OF BUSINESS; DEPLETION OF GOODWILL; LOSS OF ANTICIPATED SAVINGS; LOSS OR CORRUPTION OF DATA OR INFORMATION; OR ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR PURE ECONOMIC LOSS, COSTS, DAMAGES, CHARGES OR EXPENSES.

10.4 Liability for Product and Drug Product: the Customer shall Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of or resulting from the use or resale of the Product or the Drug Product or any other deliverable arising out of the Program [***].

10.5 Liability for the Process: the Customer shall Indemnify Fujifilm from and against all Liabilities arising from third party claims incurred by Fujifilm or its Affiliates arising out of or resulting from the use or operation of the Process (or any Part of the Process) [***].

10.6 Liability for Non-Conforming Batches:

10.6.1 THE PROVISIONS OF CLAUSE 6 SHALL APPLY TO NON-CONFORMING BATCHES AND FUJIFILM SHALL HAVE NO LIABILITY IN RESPECT OF NON-CONFORMING BATCHES EXCEPT TO COMPLY WITH CLAUSE 6.

10.6.2 FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TERMS WHATSOEVER (WHETHER AS TO COMPLIANCE WITH CGMP OR OTHERWISE) IN RESPECT OF THE USE BY THE CUSTOMER OF ANY BATCH IDENTIFIED BY FUJIFILM TO THE CUSTOMER AS A “NON-CONFORMING BATCH” EITHER PRIOR TO DELIVERY THEREOF TO THE CUSTOMER, OR PRIOR TO THE CUSTOMER’S USE OF SUCH NON-CONFORMING BATCH.

10.6.3 If the Non-Conforming Batch is delivered to the Customer pursuant to clause 6.6, the Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates in any third party claim arising out of or resulting from the use of that Non-Conforming Batch after such delivery.

10.6.4 The Customer uses any material produced in an identified Non-Conforming Batch at its own risk and shall undertake such tests as are necessary in order to satisfy itself that such materials are fit for the purposes for which the Customer proposes to use such materials.

10.7 Liability for Demonstration and Engineering Batches

10.7.1 FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TERMS WHATSOEVER (WHETHER AS TO COMPLIANCE WITH CGMP OR OTHERWISE) IN RESPECT OF THE DEMONSTRATION BATCHES OR ENGINEERING BATCHES OR THE USE BY THE CUSTOMER OF AN ENGINEERING BATCH OR DEMONSTRATION BATCH.

10.7.2 FUJIFILM SHALL HAVE NO LIABILITY TO THE CUSTOMER IN CONNECTION WITH THE USE BY THE CUSTOMER OF THE DEMONSTRATION BATCHES OR ENGINEERING BATCHES.

10.7.3 The Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates in any third party claim arising out of or resulting from the use of the Demonstration Batches or Engineering Batches after their delivery to the Customer.

10.7.4 The Customer uses any material produced in a Demonstration Batch or Engineering Batch at its own risk and shall undertake such tests as are necessary in order to satisfy

itself that such materials are fit for the purposes for which the Customer proposes to use such materials. Customer expressly agrees that Product produced pursuant to a Demonstration Batch or an Engineering Batch is not suitable, and will not be used, for human consumption or use or in clinic trials.

10.8 ALL WARRANTIES, CONDITIONS AND OTHER TERMS, EXPRESS (OTHER THAN THOSE SET OUT IN THIS AGREEMENT) OR IMPLIED, STATUTORY, CUSTOMARY OR OTHERWISE WHICH BUT FOR THIS CLAUSE 10 WOULD OR MIGHT SUBSIST IN FAVOR OF THE CUSTOMER, ARE (TO THE FULLEST EXTENT PERMITTED BY LAW) EXCLUDED FROM THIS AGREEMENT INCLUDING, IN PARTICULAR, ANY IMPLIED WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR USE AND NON-INFRINGEMENT.

10.9 No claim for Liabilities incurred pursuant to the Quality Agreement may be made under the Quality Agreement by any party. Accordingly, performance of the Quality Agreement shall be deemed to be performance under the SoW to which the Quality Agreement relates and, as such, any breach of the Quality Agreement shall be deemed to be a breach of the relevant SoW and all Liabilities shall be construed and limited in accordance with this clause 10.

10.10 If the parties enter into a Scope of Work for stability or analytical services subject to this Agreement, the parties agree that such services shall be incidental and it is therefore reasonable that such Scope of Work may contain lower limits on Fujifilm's Liability than are contained in this Agreement, in which case such limitation as set out in such Scope of Work shall apply to such Scope of Work.

10.11 Each party agrees to take all reasonable steps to mitigate any Liabilities that it may seek to claim from the other under or in connection with this Agreement including pursuant to any Indemnity.

10.12 If a party is entitled to benefit from an Indemnity (the "**Indemnified Party**") from another party (the "**Indemnifying Party**") in accordance with this Agreement (an "**Indemnity Claim**"), the Indemnified Party shall notify the Indemnifying Party in writing of the Indemnity Claim (providing all necessary details) and the Indemnifying Party shall at its own expense conduct all negotiations and any litigation arising in connection with the Indemnity Claim provided always that:

10.12.1 the Indemnifying Party shall consult the Indemnified Party on all substantive issues which arise during the conduct of such litigation and negotiations and shall take due and proper account of the interests of the Indemnified Party;

10.12.2 the Indemnifying Party shall not settle or compromise the Indemnity Claim without the Indemnified Party's prior written consent (not to be unreasonably withheld or delayed) and shall ensure that any settlement or compromise does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of the Indemnified Party;

10.12.3 the Indemnified Party shall not make any admissions or admit liability in relation to the Indemnity Claim or otherwise settle any Indemnity Claim without the written agreement of the Indemnifying Party;

10.12.4 the Indemnified Party shall fully cooperate and assist the Indemnifying Party, at the Indemnifying Party's cost and expense, in relation to the Indemnity Claim (without limiting the extent of the Indemnity);

10.12.5 the Indemnified Party may participate in the Indemnity Claim through counsel of its own choosing at its own expense; and

10.12.6 the failure to deliver prompt written notice to the Indemnifying Party of any Indemnity Claim, to the extent prejudicial to its ability to defend such Indemnity Claim, shall relieve

the Indemnifying Party of its obligation to the Indemnified Party to Indemnify only to the extent of such prejudice.

10.13 Each party shall maintain, [***] adequate insurance (which may be through self-insurance) to enable it to satisfy its Liabilities under this Agreement as they arise.

11. **INTELLECTUAL PROPERTY**

11.1 Subject to clauses 11.2 and 11.8.2, no party shall acquire any right, title or interest in another party's Background IP.

11.2 The Customer grants to Fujifilm a royalty-free, non-transferable, non-exclusive, revocable licence to use Customer's Background IP for the exclusive purpose of performance of the Program for the Customer. Except as express set forth in the prior sentence, Fujifilm receives no license, right, title or interest in or to the Product, Customer Confidential Information, Customer's Background IP or Customer Foreground IP and all such rights are reserved by Customer. To the extent any of Customer's Background IP is licensed from any third-party, Fujifilm will comply with all restrictions and limitations related to such Background IP and its use as set forth in the applicable SoW(s). Customer warrants that to Customer's knowledge, the use by Fujifilm of Product, Customer's Background IP or Customer's Confidential Information will not infringe any third party's Intellectual Property Rights.

11.3 Unless separately agreed by the parties in a SoW, the parties shall not enter into any SoW for delivery of materials (including any cell bank or cell paste) comprising Fujifilm Expression Technology unless and until a licence is granted in writing on terms to be agreed under the relevant Background IP.

11.4 All title to and all rights and interest in any Customer Foreground IP shall vest in Customer. Fujifilm hereby assigns to the Customer all title to and all rights and interest it owns in any Customer Foreground IP.

11.5 All title to and all rights and interest in any Fujifilm Foreground IP shall vest in Fujifilm. The Customer hereby assigns to Fujifilm all title to and all rights and interest it owns in any Fujifilm Foreground IP.

11.6 If requested to do so by another party, each party shall at the expense of the requesting party execute all documents and do all such further acts as the requesting party may reasonably require to perfect the assignment under clause 11.4 or 11.5.

11.7 Fujifilm grants to Customer a royalty free, non-exclusive, perpetual, irrevocable, worldwide licence to use the Fujifilm Foreground IP for the exclusive purpose of researching, developing, manufacturing, having manufactured, selling, and importing the Product and reasonable modifications, extensions, and expansions of the Product.

11.8 Technology Transfer to the Customer or Alternative Manufacturers.

11.8.1 Subject, if and to the extent applicable, to the grant of a written licence to Fujifilm Expression Technology employed in a Program, upon the written request of the Customer and provided that the Customer is not in material breach of this Agreement (which material breach is incurable or has not timely been cured by the Customer, as the case may be), the Customer shall be permitted to transfer the Process to itself or another manufacturer (an "**Alternate Manufacturer**") for the manufacture of the Product and reasonable modifications, extensions, and expansions of the Product. Upon receipt of such request, Fujifilm shall provide reasonably requested documents (including the Product batch records and release reports, technology transfer guidance and summary report and Process protocols) to complete such technology transfer at Customer's cost. If the Customer requires or reasonably requests technical support in relation to the Process transfer, then Fujifilm shall make such reasonable technical support available to the Customer, with the scheduling of such technical support to be mutually agreed upon by the parties. The Customer shall reimburse Fujifilm for any

costs and expenses incurred by Fujifilm in connection with producing the documents and providing the support set forth in this clause, with costs for Fujifilm's internal resources charged on a man day rate based upon Fujifilm's then-prevailing standard charge for technical support;. Fujifilm shall allow the Customer rights to cross-reference Fujifilm's drug master files and other regulatory submissions and approvals to the extent necessary or used for the production of Product by Fujifilm using some or all of the Process and to the extent such information is not included in the materials transferred to the Customer pursuant to this Clause 11.8.1.

11.8.2 [***].

12. INTELLECTUAL PROPERTY INDEMNITY

12.1 Fujifilm shall fully Indemnify the Customer and its Affiliates ("**Customer Indemnitees**") from and against all Liabilities incurred by a Customer Indemnitee arising out of any third party claim that the use of Fujifilm's Background IP or Fujifilm's Confidential Information in performing a Program infringes, misappropriates, or violates a third party's Intellectual Property Rights.

12.2 The Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of any third party claim that Fujifilm's use of materials, Product, Customer's Confidential Information, or Customer's Intellectual Property Rights, in each case provided by the Customer and used in accordance with this Agreement, infringes, misappropriates, or violates a third party's Intellectual Property Rights.

12.3 If a third party claim is made in accordance with clause 12.1 or 12.2 then the Indemnified Party may require the Indemnifying Party to provide proof that it has adequate financial means to pay out under the indemnity provisions provided for in those clauses (for example by way of set aside capital or insurance). If the Indemnifying Party cannot provide reasonable evidence that has the financial standing to meet its obligations with respect to the Indemnities under the applicable clause then the Indemnified Party has the option to terminate this Agreement on written notice. If a Party exercises its option to terminate under this clause 12.3 then (without prejudice to the survival of the relevant Indemnity obligations) such termination shall be treated as a termination under clause 15.2.2 (and, for clarity, if the termination is by Fujifilm, clause 15.5.2 shall apply).

13. CONFIDENTIALITY

13.1 Each party (the "**Receiving Party**") agrees with the other (the "**Disclosing Party**"):

13.1.1 to keep the Disclosing Party's Confidential Information confidential;

13.1.2 not to access or use the Disclosing Party's Confidential Information save for the purposes of:

(c) complying with its obligations under this Agreement and each Scope of Work;

(d) complying with, or exercising its rights under, any confidentiality disclosure agreement then in force between the parties; or

(e) undertaking activity by and between the parties to enable the parties to explore a new business opportunity involving the Customer and one or more of the other parties ("**New Opportunity**");

13.1.3 not to disclose the Disclosing Party's Confidential Information to a third party other than to the Receiving Party's:

(a) Affiliates;

(b) officers and employees and those of its Affiliates that need to know the Confidential Information for the purpose of performing its obligations under this Agreement or in relation to a New Opportunity;

(c) contractors and sub-contractors, professional advisers, consultants and agents and those of its Affiliates who are engaged to advise that party in connection with the Program or this Agreement or in relation to a New Opportunity; and

(d) any other person to whom the Disclosing Party agrees in writing that Confidential Information may be disclosed in connection with the Program,

the "**Authorized Third Parties**".

13.2 The Receiving Party shall procure that each of the Authorized Third Parties keeps the Disclosing Party's Confidential Information confidential in accordance with this clause 13 and shall remain primarily liable to the Disclosing Party for any act or omission of any of the Authorized Third Parties.

13.3 The Receiving Party shall within [***] days of receipt of the Disclosing Party's written request (including after termination of this Agreement and any Scope of Work):

13.3.1 deliver up to the Disclosing Party all items and copies of all or any Confidential Information of the Disclosing Party;

13.3.2 expunge or make irretrievable all Confidential Information of the Disclosing Party from any computer or other similar device in which it is stored and, if further requested, certify in writing signed by an authorized representative that it has done the same (provided that this clause 13.3.2 shall not apply to automatically archived electronic files or electronic back-ups made in the ordinary course of business, on secured central servers, which cannot reasonably be deleted and such electronic files shall be retained subject to the obligations of confidence set out in this clause 13); and

13.3.3 destroy all hard copies of notes, analyses or memoranda containing the Disclosing Party's Confidential Information (and, if further requested, certify in writing signed by an authorized representative that it has done the same)

provided that the Receiving Party shall be entitled to retain copies of the Confidential Information to enable it to monitor its obligations under this Agreement or which is required to be maintained by applicable laws or a governmental authority for which it has a continuing license to use such Confidential Information, in each case, subject always to the obligations of confidence under this Agreement.

13.4 Confidential Information shall not include information which:

13.4.1 is, or becomes, generally available to the public other than as a direct or indirect result of the information being disclosed by the Receiving Party or its Authorized Third Parties in breach of this Agreement (except that any compilation of otherwise public information in a form not publicly known shall still be treated as Confidential Information);

13.4.2 was available to the Receiving Party on a non-confidential basis prior to disclosure by the Disclosing Party;

13.4.3 was, is, or becomes available to the Receiving Party on a non-confidential basis from a person who, to the Receiving Party's knowledge, is not under any confidentiality obligation in respect of that information;

13.4.4 is developed by or for the Receiving Party independently of and without use or reference to the information disclosed by the Disclosing Party;

13.4.5 is necessarily disclosed by the Receiving Party pursuant to a statutory or regulatory obligation, but then only to the extent of such required disclosure and save that the Receiving Party shall, to the extent it is lawful to do so, give prompt notice to the Disclosing Party of any such potential disclosure and allow the Disclosing Party a reasonable opportunity to limit such disclosure; or

13.4.6 the Disclosing Party and the Receiving Party agree in writing is not confidential.

13.5 The Customer may use and disclose Confidential Information of Fujifilm solely to the extent necessary in communications with existing or prospective investors, sub-licensees or commercial partners of the Customer provided that: (a) such recipients are under obligations of confidentiality obligations at least as restrictive as the terms of this clause 13; (b) none of the financial terms or other commercially sensitive terms of the Agreement are disclosed to any such investor, sublicensee or commercial partner without the prior written consent of Fujifilm; and (d) such recipients are treated as Authorized Third Parties for the purposes of clause 13.2.

14. **CHANGE**

14.1 If a party wishes to change ("**Change**") any aspect of this Agreement or any Scope of Work (including if additional or different work is requested or required such as the production of a different number of Batches or if such work is required to be carried out at a different time or if actual circumstances differ from the assumptions set out in the Scope of Work (including if such assumptions cannot be met at all or in a timely fashion)), then Fujifilm shall draft a Change document using its standard format for that Change and the Change shall not be effective until the applicable Change document is signed by each party.

14.2 If the parties are unable to agree the terms of a Change and the dispute resolution process set out in clause 17 has been unsuccessfully exhausted, then [***].

15. **DELAY, CANCELLATION, TERMINATION AND CONSEQUENCES**

15.1 Delay:

15.1.1 If the Customer either causes or requests a delay to any Stage, Stages, or the Program as a whole and that delay prevents, or will prevent, Fujifilm from performing a Manufacturing Stage or the Program as a whole in accordance with the Scope of Work (a "**Delay**") and the parties cannot agree a Change to accommodate that Delay:

(a) then either the Batch Cancellation Fee(s) or the Program Cancellation Fee (as applicable) shall be payable; and

(b) the Batch Cancellation Fee or Program Cancellation Fee (as applicable) shall be calculated by reference to the date on which notice was given by the Customer in relation to the Delay if such notice is given, or the date on which the Delay becomes apparent to Fujifilm.

15.1.2 If the parties agree to a Change to accommodate the Delay and that results in the Delayed Stage(s) or Program (as applicable) being performed partially within the original period reserved for the Delayed Stage(s) or Program as a whole, then the Batch Cancellation Fee(s) or the Program Cancellation Fee (as applicable) shall be reduced proportionally to reflect the period of time that the program was Delayed (as determined by Fujifilm acting reasonably).

15.2 Termination of this Agreement as a Whole. Fujifilm collectively or the Customer shall be entitled to terminate this Agreement (and all Scope of Works made under it) immediately upon giving notice to the other if:

15.2.1 the other party commits a material breach of this Agreement and such breach:

(a) is not capable of cure (a breach shall be considered capable of cure if the party in breach can comply with the provision in question in all respects other than as to time of performance); or

(b) is capable of cure, and the breaching party fails to cure the breach within a reasonable period (not to exceed 60 days) after receipt of notice giving full particulars of the breach and requiring it to be cured, provided, however, that such cure period shall be suspended during any time that a party seeks resolution of a dispute as to whether an alleged material breach occurred pursuant to clause 17;

15.2.2 the other party takes any step or action in connection with its entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction; or

15.2.3 [***].

15.3 Termination of a Stage/Scope of Work by the Customer for Convenience

15.3.1 The Customer may cancel a Non-Manufacturing Stage or Non-Manufacturing Program for convenience by giving written notice to Fujifilm, in which case:

(a) the SoW shall terminate in respect of that Stage if a Stage is being terminated but in all other respects the SoW shall continue in full force;

(b) the SoW(s) in respect of that Program shall terminate if a Program as a whole is being terminated; and

(c) the Customer shall pay Fujifilm the Charges that are due for the Fujifilm Services that have been performed and [***] of the Charges for the Fujifilm Services (other than those associated with any Manufacturing Stage) scheduled to be performed [***] plus any Charges owed in respect of Ancillary Services.

15.3.2 The Customer may cancel any Manufacturing Stage for convenience by giving written notice to Fujifilm, in which case:

(a) the SoW shall terminate in respect of that Stage;

(b) in all other respects the SoW shall continue in full force; and

(c) the Customer shall pay the Charges that are due for the Fujifilm Services that have been performed, the relevant Batch Cancellation Fee plus any Charges owed in respect of Ancillary Services.

15.3.3 The Customer may cancel a Scope of Work which includes Manufacturing for convenience by giving written notice to Fujifilm in which case:

(a) the SoW(s) in respect of that Program shall terminate; and

(a) the Customer shall pay the Charges that are due for the Fujifilm Services that have been performed, the Program Cancellation Fee plus any Charges owed in respect of Ancillary Services.

15.3.4 If a critical Stage, or more than one Stage, under a Program which includes Manufacturing is cancelled and that has the effect of cancelling that Program as a whole, then clause 15.3.3 shall apply instead of clauses 15.3.1 or 15.3.2.

15.4 Termination of a Program Due to Technical Issues.

15.4.1 Fujifilm may terminate a Program at any time up to completion of the Non-Manufacturing Stages by giving written notice to the Customer if it reasonably believes that Fujifilm will be unable to carry out and complete such Program in accordance with the Scope of Work(s) due to discovery of a factor (other than an breach by Fujifilm of this Agreement) which:

(a) materially adversely affects the development of the Process at the Facility; or

(b) materially adversely affects, or is likely to materially adversely affect, production of Product in the Facility when conducted in accordance with Fujifilm's standard operating procedures; or

(c) is likely to have a material adverse effect on a customer's Product licence (being the licence authorising marketing of a medicinal product granted by a Regulatory Authority (also known as a "Marketing Authorisation" in Europe)) or Manufacturing Licence (being the licence to manufacture biotechnology-derived Drug Substances issued to Fujifilm by the applicable Regulatory Authority) as a result of the Product being introduced into the Facility and that customer was a customer of Fujifilm prior to the Program commencement,

provided that, in each case, the factor was not known and could not reasonably have been known at the commencement of the applicable Program, and provided further that Fujifilm has used Commercially Reasonable Efforts in its attempts to address the factor prior to such termination. [***].

15.4.2 If a party terminates a Program under clause 15.4.1 then the Customer shall pay the Charges that are due for the Fujifilm Services that have been performed and [***] of the Program Cancellation Fees plus any Charges owed in respect of Ancillary Services.

15.5 Termination of a Scope of Work for Breach

15.5.1 If any party commits a material breach of a Scope of Work, the non-breaching party may give written notice to the other party, specifying the nature of the material breach and, if such material breach is not remedied within a reasonable period (not to exceed 60 days) after receipt of such notice (provided, however, that the cure period shall be suspended during any time that a party seeks resolution of a dispute as to whether an alleged material breach occurred pursuant to clause 17), then the non-breaching party shall have the right, in its sole discretion, to immediately terminate that Scope of Work.

15.5.2 If Fujifilm terminates a Scope of Work under this clause 15.5 or all Scopes of Work under clause 15.2, then, without prejudice to Fujifilm's other rights and remedies, the Program Cancellation Fee shall be payable by the Customer to Fujifilm plus any Charges owed in respect of Ancillary Services.

15.5.3 If the Customer terminates a Scope of Work under this clause 15.5 or all Scopes of Work under clause 15.2 then, for clarity, no Program Cancellation Fee or Batch Cancellation Fee, will be due by the Customer and such termination will be without prejudice to the Customer's other rights and remedies.

15.6 If a party exercises any of its rights of termination in respect of only one or more SoWs then:

15.6.1 this Agreement shall terminate in respect of those SoWs and the provisions of this Agreement relating to termination of this Agreement shall apply in relation to those SoWs; and

15.6.2 in all other respects this Agreement shall continue in full force and those SoWs in respect of which the party has terminated this Agreement will be deemed to be removed from the definition of the SoWs.

15.7 Additional Consequences of Termination

15.7.1 The termination of this Agreement, any Scope of Work shall be without prejudice to the rights and remedies of any party which may have accrued up to the date of termination.

15.7.2 On termination of this Agreement or any SoW (as applicable) for any reason whatsoever:

(a) save as set out in clause 11, the relationship of the parties shall cease and any rights or licenses granted under or pursuant to this Agreement shall cease to have effect save as (and to the extent) expressly provided for in this clause 15;

(b) the provisions of the following clauses together with any provision which expressly or by implication is intended to come into or remain in force on or after termination shall continue in full force and effect clauses 1, 5.3, 8, 9, 10, 11, 12, 13, 15.7.2, 17, 18.2, 19, 23, and 24; and

(c) the Customer shall immediately pay to Fujifilm all of Fujifilm's outstanding unpaid invoices and, in respect of Fujifilm Services and Ancillary Services supplied but for which no invoice has been submitted, Fujifilm may submit an invoice, which shall be payable immediately on receipt.

15.8 [***].

15.8.1 [***].

15.8.2 [***].

16. **FORCE MAJEURE**

16.1 Based on conditions as of the Effective Date, Fujifilm has the capacity to undertake the anticipated services under this Agreement. However, each party is unable to predict how the global COVID-19 pandemic (the "**Pandemic**") may affect its ability to perform its obligations set forth in this Agreement or a Scope of Work. Effects of the Pandemic, including staff shortages (either as a result of government recommended/mandated physical isolation or distancing or illness of workers) and the inability to obtain required supplies or services, may require Fujifilm to alter the way its facilities operate after the Effective Date. As of the Effective Date, Fujifilm has a process to fairly address the needs of its various customers. However, each party acknowledges and accepts that factors arising from the Pandemic may impact a party's ability to perform its obligations under this Agreement or a Scope of Work for an indeterminate period of time, and as a result, the expected timing of performance of a party's obligation under a Scope of Work (except for payment of money) may need to be deferred to the extent affected by such unforeseen factors.

16.2 Subject to clause 16.3, no party shall be liable to the other(s) for any delay or non-performance of its obligations under any Scope of Work (except for the payment of money) arising from a Force Majeure Event.

16.3 If a party is delayed or prevented from performing its obligations due to a Force Majeure Event such party shall:

16.3.1 give notice of such delay or prevention due to the Force Majeure Event to the non-affected parties as soon as reasonably practical stating the commencement date and extent of such delay or prevention, the cause thereof and its estimated duration;

16.3.2 use reasonable endeavors to mitigate the effects of such Force Majeure Event, provided that such party shall not be required to procure materials or services at unreasonable prices or under unreasonable terms; and

16.3.3 resume performance of its obligations as soon as reasonably practicable.

16.4 If a party's delay or prevention due to the Force Majeure Event in question continues for more than [***], the Customer may terminate the affected Scope of Work by giving notice to Fujifilm. The notice to terminate must specify the termination date, which must not be less than 5 (five) Business Days after the date on which the notice is given, and once such notice has been validly given, that Scope of Work will terminate on that termination date.

17. **DISPUTE RESOLUTION**

17.1 Quality Disputes. If there is a dispute in relation to or in connection with the QA Documents, such dispute shall be dealt with in accordance with the procedures set out in the Quality Agreement.

17.2 Business Escalation.

17.2.1 In respect of any dispute concerning this Agreement (other than a dispute in connection with the QA Documents) the parties shall seek to resolve the matter as follows:

(a) by referral in writing summarizing the nature of the dispute by a party in the first instance to the decision of each party's Program Manager;

(b) if the dispute is not resolved within 10 (ten) Business Days of its referral to the Program Managers it shall be referred to the decision of the Joint Steering Committee;

(c) if the dispute is not resolved within 10 (ten) Business Days of its referral to the Joint Steering Committee it shall be referred to the decision of each party's Chief Business Officer; and

(d) if the dispute is not resolved within 10 (ten) Business Days of its referral to each party's Chief Business Officer it shall be referred to the decision of each party's President or Chief Executive Officer (as applicable/appropriate).

17.3 Arbitration. Except as otherwise set forth in clause 6.8, any dispute, claim or controversy arising out of or relating to this Agreement or the breach, termination, enforcement, interpretation or validity thereof (including all issues or disputes regarding the existence, validity, scope or applicability of this agreement to arbitrate, the arbitrability of any claims, and the proper parties to the arbitration) shall be determined by arbitration in New York, New York and the arbitration shall be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures, in each case before three arbitrators. The arbitration shall be conducted and the award shall be rendered in the English language. The arbitrators will have no authority to award any damages prohibited by this Agreement or any remedy that could not have been awarded by a state or federal court located in Delaware, USA. The arbitrators' decisions and awards shall be provided in writing and shall include the basis on which they are made. The award rendered by the arbitrators shall be final, non-appealable and binding on the parties. Judgment on the award may be entered in any court having jurisdiction. During any such dispute, each party agrees to continue to perform its obligations under this Agreement if and until such performance is excused pursuant to the resolution of such dispute. In addition, each party hereby submits to the non-exclusive jurisdiction of the state and federal courts located in Delaware, USA for purposes of determining the arbitrability of any dispute, causing such party to appear for and participate in such arbitration, and enforcing any award granted by the arbitrators, and each party hereby submits to such jurisdiction.

17.4 General. Notwithstanding the provisions of this clause 17 any party may commence or take proceedings or seek remedies before the courts or any other competent authority for interim, interlocutory or injunctive remedies in relation to this Agreement.

18. **AUDIT**

18.1 Quality Audit:

18.1.1 The Customer may carry out quality audits at the times, and in accordance with the terms, set out in the Quality Agreement, provided that access by the Customer or its representatives to records, information, and systems shall be on a supervised basis, subject to the Customer complying with the security and confidentiality requirements of Fujifilm to protect information which relates to anything other than the Programs.

18.1.2 Audit access shall not be extended to Fujifilm's confidential records, including details of financial transactions and contracts with third parties that relate to this Agreement.

18.1.3 If Fujifilm is in material breach of clause 4.4 of this Agreement or if the Customer reasonably believes that Fujifilm is in material breach of clause 4.4 of this Agreement, the Customer may upon giving reasonable written notice to Fujifilm carry out an audit on the same basis as in clause 18.1.1.

18.2 Books and Records.

18.2.1 Together with each invoice issued by Fujifilm to the Customer hereunder, Fujifilm shall provide reasonably detailed documentation to validate the amounts included on each invoice which are subject to the true-up mechanism contemplated in Schedule 1. The Customer may request reasonable additional validating information provided that (i) the Customer shall not request evidence validating a given amount more than once and (ii) it is acknowledged that Fujifilm may not provide copies of vendor invoices because Fujifilm may be prevented from doing so by law (including by vendor confidentiality obligations) and/or those invoices may not accurately represent the amounts invoiced to the Customer because of Fujfilm's use of SAP weighted average "actual cost".

18.2.2 Fujifilm will provide reasonable support to the Customer in the event that the Customer is audited by a third party and requires information to demonstrate proper payment of Fujifilm invoices under a SoW.

19. **NOTICES**

19.1 Subject to clause 19.2 the parties may communicate with each other in any way that is normal in the course of their business.

19.2 Any notice required or permitted to be given under this Agreement shall only be effective if it is in writing, sent to a party at its address or email address and for the attention of the individual, as set out in Schedule 2 (or such other address, email address or individual as that party may notify the other in accordance with this clause 19) and is given in accordance with clauses 19.3 to 19.5 below.

19.3 Where a notice must be given to Fujifilm under clauses 3.2, 15 or 22.2 such notice must be given to FDBK, FDBT, FDBU and FDBD.

19.4 Notice may be given by hand or sent by email, recorded delivery, registered post or airmail and will be deemed to have been duly served:

19.4.1 if delivered by hand, at the time and date of delivery;

19.4.2 if sent by email, at the time and date of sending;

19.4.3 if sent by recorded delivery or registered post, 48 (forty-eight) hours from the date of posting (such date as evidenced by postal receipt); and

19.4.4 if sent by registered airmail, five days from the date of posting,

provided that, where in the case of delivery by hand or transmission by email, such delivery or transmission occurs either after 4.00pm on a Business Day, or on a day other than a Business Day, service will be deemed to occur at 9.00am on the next Business Day.

19.5 In proving service of a notice it will be sufficient to prove that delivery was made or that the envelope containing the notice or document was properly addressed and posted (either by prepaid first class recorded delivery post or by prepaid airmail, as the case may be) or that no failed delivery message was received, as the case may be.

20. EXPORT/IMPORT CONTROLS AND SANCTIONS COMPLIANCE

20.1 The Customer shall at all times during the term of this Agreement comply with applicable Sanctions or Export/Import Laws and ensure that it has in place appropriate controls and safeguards to prevent any action being taken by it that would amount to or result in a violation of or non-compliance with any Sanctions or Export/Import Laws.

20.2 The Customer shall provide all information that Fujifilm may reasonably require from time to time in order for Fujifilm to assess or manage its compliance with Sanctions and Export/Import Laws (including provision of end-user statements or applicable Authorizations and notifying Fujifilm of any restrictions or export compliance obligations prior to providing Fujifilm access to controlled information/technology).

20.3 The Customer will not directly or indirectly use, sell, dispose of, (re)export, transship or otherwise transfer any Product, software, technology or Confidential Information: (a) unlawfully to any country in respect of which a Sanctions Authority maintains Sanctions or a Sanctioned Person; (b) in a manner that would expose Fujifilm to the risk of negative consequences under Sanctions; or (c) in violation of Export/Import Laws.

20.4 If any Authorization is required so that the performance of a Program does not contravene any Sanctions or Export/Import Laws, the Customer will at its own cost and expense obtain that Authorization and Fujifilm shall provide any commercially reasonable assistance (including reasonable information) that the Customer may require for the purposes of obtaining that Authorization. The Customer's rights and Fujifilm's obligations under this Agreement, any Scope of Work in relation to that Program shall immediately be suspended if any required Authorization is not obtained. In the event that the Customer's rights and Fujifilm's obligations are suspended for more than thirty (30) calendar days, a Program may be terminated immediately by Fujifilm giving written notice to the Customer. If Fujifilm terminates a Program under this clause 20.4 then the Customer shall pay the Charges that are due for the Fujifilm Services that have been performed during that Program and [***].

20.5 The Customer shall Indemnify Fujifilm against any and all Liabilities incurred by Fujifilm in any third party claim as a result of the Customer's non-compliance with the terms of this clause 20.

20.6 In this clause 20 the following terms have the following meanings:

"Authorization"	all consents, licences, authorisations, approvals, permissions, registrations, certificates and clearances and any precondition in any relevant jurisdiction;
"Export/Import Laws"	(a) any laws of the United States of America, the United Kingdom, the European Union or of any of its Member States or Japan that relate to the control of (re)export, transfer or import of Products, software or technology and technical data; or (b) any other (re)export, transfer or import controls or restrictions imposed or adopted by any government, state or regulatory authority in a country in which obligations under this Agreement are to be performed;
"Sanctions"	any economic, financial, trade or other sanction, embargo, import or export ban, prohibition on transfer of funds or assets or on performing services or equivalent measure imposed by any Sanctions Authority or by the laws of any state or any union of states from time to time;
"Sanctions Authority"	means (a) the Security Council of the United Nations, (b) the Organization for Security and Co-operation in Europe, (c) the United Kingdom, (d) the European Union, (e) any Member State of the European Union, (f) the United States of America, (g) Japan (h) the governments and official institutions or agencies of any of paragraphs (a) to (h) above and (i) any other regulatory body imposing or enforcing sanctions legislation in any country or territory from which or into which the Customer is exporting or importing; and
"Sanctioned Person"	any person who appears on or is owned, operated or controlled by any person who appears on any list issued or maintained by any Sanctions Authority or is referred to in any list or public announcement issued by any Sanctions Authority, in each case as amended, supplemented or substituted from time to time.

21. **MODERN SLAVERY AND CORRUPTION**

21.1 Each party shall endeavour to hold itself and its suppliers to the highest performance, ethical and compliance standards, including basic human rights, not engaging in any activity, practice or conduct which would constitute an offence under anti-slavery legislation in the United Kingdom, the USA or Denmark, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. In performing its duties under this Agreement, each party acknowledges the value and importance of performance and ethical behaviour in its performance under this Agreement.

21.2 Each party warrants that on the Effective Date and each SoW Effective Date, it, its directors, officers or employees have not offered, promised, given, authorized, solicited or accepted any undue pecuniary or other advantage of any kind (or implied that they will or might do any such thing at any time in the future) in any way connected with this Agreement or a SoW and that it has taken reasonable measures to prevent subcontractors, agents or other third parties, subject to its control or determining influence, from doing so.

21.3 The parties agree that, at all times in connection with and throughout the term of this Agreement, they will comply with and that they will take reasonable measures to ensure that their subcontractors, agents or other third parties will comply with all applicable anti-corruption

legislation including the Bribery Act 2010, the Foreign Corrupt Practices Act 1977 and the Danish Criminal Code.

21.4 Each party shall not do, or omit to do, any act that would cause one of the other parties to be in breach of any anti-corruption legislation including the Bribery Act 2010, the Foreign Corrupt Practices Act 1977 and the Danish Criminal Code.

22. **ASSIGNMENT AND SUB-CONTRACTING**

22.1 A party may assign or transfer all of its rights and responsibilities under this Agreement to:

22.1.1 an Affiliate, provided that such Affiliate has reasonable financial creditworthiness; or

22.1.2 a purchaser of all or substantially all of the equity of the assigning party, provided that such third party has reasonable financial creditworthiness and is not a Competitor; or

22.1.3 a purchaser of all or substantially all of assets to which this Agreement relates, provided that such third party has reasonable financial creditworthiness and is not a Competitor; or

22.1.4 an exclusive licensee of the Product, provided that such third party has reasonable financial creditworthiness and is not a Competitor,

but not otherwise without written consent of the other parties (such consent not to be unreasonably withheld or delayed) and provided that (a) the assignee agrees in writing to assume all obligations undertaken by its assignor in this Agreement and (b) in relation to assignment in part no such assignment shall relieve the assigning party of responsibility for the performance of any of its obligations under this Agreement.

22.2 If a party assigns or transfers all or any of its rights and responsibilities under clause 22.1 it shall immediately notify the other parties in writing.

22.3 Fujifilm may sub-contract all or any of its obligations under this Agreement provided that in relation to any subcontract manufacture, processing or handling of Product, Fujifilm must first obtain the Customer's written consent (which may be by signature of the relevant SoW(s) which specify that an obligation will be sub-contracted) and such subcontractors must be appropriately and fully qualified in all respects to perform the applicable Services.

22.4 The appointment of any subcontractor shall not relieve the party sub-contracting from any liability or obligation under this Agreement and the party sub-contracting shall be responsible for all acts and omissions of the subcontractor, and its compliance or non-compliance with the terms of this Agreement, to the same extent as if they were its own acts or omissions.

23. **GENERAL**

23.1 Entire agreement: This Agreement contain all the terms which the parties have agreed with respect to their subject matter and supersede all previous agreements and understandings between the parties (whether oral or in writing) relating to such subject matter, including the Historic Documents. Each party acknowledges and agrees that it has not been induced to enter into this Agreement by a statement or promise which it does not contain. Each party confirms that save as otherwise expressly set out in this Agreement, the other party gives no warranties either in this Agreement or elsewhere in connection with the provision of the Programs. Nothing in this clause 23.1 shall exclude or limit a party's liability for fraud, including fraudulent misrepresentation.

23.2 Third party rights: Save as expressly set out in this Agreement, the parties do not intend that any person who is not a party to this Agreement shall have any right to enjoy the benefit or enforce any of the terms of this Agreement.

23.3 Variations: With the exception of Changes, which shall be subject to clause 14, no variation of this Agreement shall be valid unless in writing and signed by a duly authorized representative of each of the parties. A party is entitled assume that a representative of another party is authorized to act on that party's behalf if that individual is apparently or seemingly acting in the normal course of the business relationship. An exchange of emails shall not be capable of constituting an agreement to vary this Agreement.

23.4 Waiver: No failure or delay by a party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. The single or partial exercise by any party of any right, power or remedy under this Agreement shall not in any circumstances preclude any other or further exercise of it, or the exercise of any right, power or remedy. A waiver by any party of a breach of any provision of this Agreement shall not be considered as a waiver of a subsequent breach of the same or any other provision of this Agreement.

23.5 Severability: If any provision of this Agreement or a SoW is found by any court or administrative body of competent jurisdiction to be invalid, illegal or unenforceable in any jurisdiction then it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible that provision shall be deemed to be omitted from this Agreement or the SoW in so far as this Agreement or that SoW relates to that jurisdiction and the validity and enforceability of that provision in other jurisdictions and the other provisions of this Agreement or SoW shall not be affected or impaired.

23.6 Counterparts:

23.6.1 This Agreement may be executed in any number of counterparts. Any party may enter into this Agreement by executing a counterpart and all the counterparts taken together will constitute one and the same agreement. This Agreement shall not be effective until each party has signed one counterpart.

23.6.2 Transmission of an executed counterpart of this Agreement (but for the avoidance of doubt not just a signature page) by email (in PDF, JPEG or other agreed format) shall take effect as delivery of an executed counterpart of this Agreement. If this method of delivery is adopted, without prejudice to the validity of the Agreement so made, each party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter.

23.7 Publicity: The parties anticipate that there may be opportunities for joint or independent press releases or other announcements relating to the activities contemplated hereby. Notwithstanding the foregoing, no party shall use the name of the other party(ies) or the names of the employees of the other party(ies) nor disclose the terms of this Agreement or any Scope of Work in any press releases, advertising or sales promotional material or in any publication without prior written permission of such party(ies), which may be withheld in such party(ies) sole discretion. This provision shall not restrict a party's ability to use the other parties names and to disclose the terms of this Agreement or a Scope of Work to the extent, in the reasonable opinion of such party's legal counsel, required by law or by the requirements of any nationally recognized securities exchange, quotation system, or over-the-counter market on which such party has its securities listed or traded. In the event that such disclosure is required as aforesaid, the disclosing party shall make reasonable efforts to provide the other parties with at least ten (10) Business Days' advance notice and to coordinate reasonably with the other parties with respect to the wording and timing of any such disclosure, subject to the requirements of such securities laws.

23.8 Non-Exclusive Nature of Remedies: Unless otherwise expressly set forth in this Agreement, no remedies set forth herein shall be considered an exclusive remedy. Pursuit or receipt of any remedies by a party for breach of this Agreement by the other party does not constitute an election of remedies by such party to the exclusion of other remedies potentially available.

24. **GOVERNING LAW**

The formation, existence, construction, performance, validity and all aspects whatsoever of this Agreement or any term of it and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature) shall be governed by, and construed in accordance with, the laws of the State of Delaware, USA and the USA.

IN WITNESS of the above the parties have signed this Agreement on the dates set out next to their signature.

Schedule 1 Charges

The Customer will pay to Fujifilm the Charges for the Fujifilm Services in accordance with the Scope of Work and clause 8 of the Agreement (the Fujifilm Services being the services to be performed by Fujifilm that are described in the relevant Scope of Work which are not Ancillary Services).

The Customer will also pay Charges to Fujifilm in consideration of the research and development and technical consultancy services in relation to the procurement, testing and management of Consumables; Subcontracted Work (including delivery of material to and from such subcontractors); Process-Specific Equipment (including installation and qualification thereof); Modifications; and Special Waste (the "**Ancillary Services**") as calculated in accordance with this Schedule 1.

1. **Charges for Consumables in Non-Manufacturing Stage and Manufacturing Stage**

1.1 On the date(s) set out in the Scope of Work or otherwise mutually agreed in writing by the parties, the Customer shall pay to Fujifilm an amount in advance in consideration of the Ancillary Services relating to the purchase of Consumables intended to be used during the applicable Non-Manufacturing Stages and Manufacturing Stages. These amounts will be based upon an estimation of the sums required to purchase Consumables based upon Fujifilm's historical data from previous manufactures at the applicable scale of production plus [***] (the "**Consumables Advance Payment**").

1.2 On completion of each applicable Non-Manufacturing Stage or Manufacturing Stage, Fujifilm shall calculate the expenditure incurred in respect of Consumables procured for use during such Non-Manufacturing Stage or Manufacturing Stage and shall add a sum equivalent to [***], the aggregate amount being referred to as "**Actual Production Expenditure**".

1.3 If the Actual Production Expenditure is greater than the Consumables Advance Payment plus any other amounts paid under paragraph 1.4, Fujifilm shall issue a further invoice for the Ancillary Services in relation to the Consumables for a sum equivalent to the difference. If the Actual Production Expenditure is less than the Consumables Advance Payment, Fujifilm shall issue a credit note (or refund if requested by the Customer) against the earlier invoice for a sum equivalent to the difference.

1.4 Each month, Fujifilm may issue an invoice to the Customer in relation to the Ancillary Services regarding any Consumables used during or procured for use in any Stage during the previous month (or if longer, since the last invoice under this paragraph 1.4 was issued) in amounts which are not covered by the Consumables Advance Payment equivalent to the expenditure on such additional Consumables during the previous month plus [***].

2. **Additional Charges in Respect of Subcontracted Work, Process-Specific Equipment, Modifications and Special Waste**

2.1 Fujifilm shall invoice the Customer for the Ancillary Services relating to the Subcontracted Work, Process-Specific Equipment, Modifications and disposal of Special Waste as the case may be in the same amount as the expenditure which Fujifilm incurs in respect of such Ancillary Services plus [***].

2.2 Fujifilm shall issue invoices for such Ancillary Services either at the time Fujifilm incurs expenditure in respect of the Subcontracted Work, Process-Specific Equipment, Modifications or disposal of Special Waste or as set out in the relevant SoW as the case may be.

3. **Product Samples, Cell Banks and other materials on completion or termination**

3.1 Prior to completion of each Program, the Customer shall notify Fujifilm what (if any) samples or cell banks used during the Program the Customer wishes Fujifilm to deliver to the Customer and delivery of those samples/cell banks shall take place in accordance with clause 7. If the Customer does not give any such notification to Fujifilm prior to completion of the Program, Fujifilm shall destroy such samples or cell banks at the Customer's cost (provided that Fujifilm

gives the Customer at least [***] prior notice of such destruction and the opportunity to take possession thereof during such [***] period).

3.2 Fujifilm shall, in a manner of its choosing, destroy any Product, samples, cell banks or other property of the Customer which remains in the possession of Fujifilm in excess of [***] following the effective date of termination (provided that Fujifilm gives the Customer at least [***] prior notice of such destruction and the opportunity to take possession thereof during such [***] period).

4. **Batch Cancellation Fees**

4.1 The Batch Cancellation Fee shall be:

4.1.1 the applicable percentage of the Batch Fee (in each case as detailed in the SoW) set out in the table below, which will reflect the period of time between:

(a) notice of cancellation of such Batch(es); and

(b) the then current scheduled date for commencement of the relevant Batch;

4.1.2 less any sums already received under the SoW for the Fujifilm Services in relation to the cancelled Batch(es) that have not been performed at the time the Batch Cancellation Fee is calculated.

4.2 Percentage of Batch Fee payable in respect of Batches to be manufactured by FDBK, FDBT or FDBU:

[***]

4.3 Percentage of Batch Fee payable in respect of Batches to be manufactured by FDBD:

[***]

5. **Program Cancellation Fees**

5.1 The Program Cancellation Fee shall be:

5.1.1 the Batch Cancellation Fee for each cancelled Batch in the Program determined in accordance with Section 4 of this Schedule 1,

5.1.2 plus [***] for the Fujifilm Services (other than those associated with any Manufacturing Stage) scheduled to be performed [***],

5.1.3 less any sums already received under the SoW(s) for the Fujifilm Services in relation to the cancelled element of the Program that have not been performed at the time the Program Cancellation Fee is calculated.

5.2 For the avoidance of doubt, the Customer will not be expected to pay both Batch Cancellation Fees and Program Cancellation Fees, and the Program Cancellation Fee for Non-Manufacturing Program are solely the fees described in clause 15.3.1.

Schedule 2 Addresses for Notice

FDBK: [***]	**Copied to:** [***]
FDBT: [***]	**Copied to:** [***]
FDBU: [***]	**Copied to:** [***]
FDBD: [***]	**Copied to:** [***]
Customer: [***]	**Copied to:** [***]

Schedule 3 - Competitors

[***]

SIGNED for and on behalf of **FUJIFILM DIOSYNTH BIOTECHNOLOGIES TEXAS, LLC:**

Signature: /s/ Gerry Farrell

Title: Chief Operating Officer

Date: October 26, 2020

SIGNED for and on behalf of **FUJIFILM DIOSYNTH BIOTECHNOLOGIES U.S.A., INC:**

Signature: /s/ Chris Vannais

Title: Chief Operating Officer

Date: October 26, 2020

SIGNED for and on behalf of **FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED:**

Signature: /s/ Paul Found

Title: Chief Operating Officer

Date: October 26, 2020

SIGNED for and on behalf of BIOGEN (DENMARK) MANUFACTURING APS:

Signature: /s/ Lars Petersen

Title: Chief Operating Officer

Date: October 25, 2020

SIGNED for and on behalf of **ALLAKOS, INC.:**

Signature: /s/ Robert Alexander

Title: Chief Executive Officer

Date: October 23, 2020

Exhibit 31.1

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: August 4, 2022

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

Exhibit 31.2

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: August 4, 2022

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

Exhibit 32.1

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

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending June 30, 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: August 4, 2022

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

Exhibit 32.2

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

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending June 30, 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: August 4, 2022

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