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DELTA REPORT

10-Q

SVRA - SAVARA INC

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	1521
CHANGES	172
DELETIONS	224
ADDITIONS	1125

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

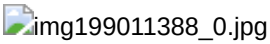
For the quarterly period ended September 30, March 31, 2023 2024

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 001-32157



Savara Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1717 Langhorne Newtown Road, Suite 300 Langhorne, Pennsylvania	**19047**
(Address of principal executive offices)	**(Zip Code)**

(512) 614-1848

(Registrant's telephone number, including area code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	SVRA	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, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act. ☐

Large accelerated filer	☐	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 ☐ ☒ No ☒

As of November 9, 2023 May 9, 2024, the registrant had 135,341,024 138,188,891 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

PART I – FINANCIAL INFORMATION

Item I. Financial Information

Savara Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	September 30, 2023 (Unaudited)	December 31, 2022	March 31, 2024 (Unaudited)	December 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	$ 27,690	$ 52,100	$ 16,785	$ 26,585

Short-term investments	140,561	73,776	126,258	135,734
Prepaid expenses and other current assets	1,845	3,078	3,144	3,628
Total current assets	170,096	128,954	146,187	165,947
Property and equipment, net	277	51	248	270
In-process R&D	10,497	10,656	10,712	10,960
Other non-current assets	1,202	116	1,148	387
Total assets	$ 182,072	$ 139,777	$ 158,295	$ 177,564
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	$ 3,219	$ 1,334	$ 2,853	$ 3,504
Accrued expenses and other current liabilities	5,744	4,533	6,957	7,093
Total current liabilities	8,963	5,867	9,810	10,597
Long-term liabilities:				
Long-term debt	26,281	26,078	26,416	26,348
Other long-term liabilities	284	54	208	247
Total liabilities	35,528	31,999	36,434	37,192
Commitments and contingencies (Note 9)				
Stockholders' equity:				
Common stock, $0.001 par value, 300,000,000 authorized as of September 30, 2023 and December 31, 2022; 135,339,836 and 114,046,345 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	137	116		
Common stock, $0.001 par value, 300,000,000 authorized as of March 31, 2024 and December 31, 2023; 138,176,641 and 138,143,545 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively			140	140
Additional paid-in capital	524,619	446,938	536,178	533,872
Accumulated other comprehensive loss	(942)	(605)	(742)	(271)
Accumulated deficit	(377,270)	(338,671)	(413,715)	(393,369)
Total stockholders' equity	146,544	107,778	121,861	140,372
Total liabilities and stockholders' equity	$ 182,072	$ 139,777	$ 158,295	$ 177,564

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

Savara Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,		For the three months ended March 31,	
	2023	2022	2023	2022	2024	2023
Operating expenses:						
Research and development	$ 13,867	$ 8,151	$ 31,516	$ 20,253	$ 16,807	$ 8,738
General and administrative	4,147	2,376	10,816	7,687	5,636	3,366
Depreciation and amortization	30	8	45	24	32	8
Total operating expenses	18,044	10,535	42,377	27,964	22,475	12,112
Loss from operations	(18,044)	(10,535)	(42,377)	(27,964)	(22,475)	(12,112)
Other income (expense)						
Interest income (expense)	1,444	152	2,917	(702)		
Foreign currency exchange (loss) gain	1	(8)	64	21		

Interest income					1,353	765
Foreign currency exchange gain (loss)					(21)	29
Tax credit income	—	5	797	795	797	761
Total other income, net	1,445	149	3,778	114	2,129	1,555
Net loss	$ (16,599)	$ (10,386)	$ (38,599)	$ (27,850)	$ (20,346)	$ (10,557)
Net loss per share:						
Basic and diluted	$ (0.10)	$ (0.07)	$ (0.24)	$ (0.18)	$ (0.11)	$ (0.07)
Weighted-average common shares outstanding:						
Basic and diluted	164,342,634	152,773,015	158,444,739	152,771,302	182,550,109	152,781,580
Other comprehensive income (loss):						
Loss on foreign currency translation	(318)	(668)	(286)	(1,621)		
Gain (loss) on foreign currency translation					(220)	130
Unrealized gain (loss) on short-term investments	(5)	77	(51)	9	(251)	14
Total comprehensive loss	$ (16,922)	$ (10,977)	$ (38,936)	$ (29,462)	$ (20,817)	$ (10,413)

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

Savara Inc. and Subsidiaries

Condensed Consolidated Statements of Changes in Stockholders' Equity

Periods Ended September 30, 2023 March 31, 2024 and 2022 2023

(In thousands, except share amounts)

(Unaudited)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance on December 31, 2022	**114,046,345**	**$ 116**	**$ 446,938**	**$ (338,671)**	**$ (605)**	**$ 107,778**
Issuance of common stock upon exercise of stock options	17,129	—	27	—	—	27
Issuance of common stock for settlement of RSUs	1,813	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(551)	—	(1)	—	—	(1)
Stock-based compensation	—	—	864	—	—	864
Foreign exchange translation adjustment	—	—	—	—	130	130
Unrealized gain on short-term investments	—	—	—	—	14	14
Net loss	—	—	—	(10,557)	—	(10,557)
Balance on March 31, 2023	**114,064,736**	**$ 116**	**$ 447,828**	**$ (349,228)**	**$ (461)**	**$ 98,255**
Issuance of common stock upon exercise of stock options	84,375	—	103	—	—	103
Issuance of common stock for settlement of RSUs	1,812	—	—	—	—	—

Repurchase of shares for minimum tax withholdings	(468)	—	—	—	—	—
Stock-based compensation	—	—	958	—	—	958
Foreign exchange translation adjustment	—	—	—	—	(98)	(98)
Unrealized loss on short-term investments	—	—	—	—	(60)	(60)
Net loss	—	—	—	(11,443)	—	(11,443)
Balance on June 30, 2023	**114,150,455**	**$ 116**	**$ 448,889**	**$ (360,671)**	**$ (619)**	**$ 87,715**
Issuance of common stock and pre-funded warrants in registered direct offering, net of offering costs (1)	21,000,000	21	74,853	—	—	74,874
Issuance of common stock for settlement of RSUs	176,813	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(51,042)	—	(182)	—	—	(182)
Issuance of common stock upon exercise of stock options	63,610	—	64	—	—	64
Stock-based compensation	—	—	995	—	—	995
Foreign exchange translation adjustment	—	—	—	—	(318)	(318)
Unrealized loss on short-term investments	—	—	—	—	(5)	(5)
Net loss	—	—	—	(16,599)	—	(16,599)
Balance on September 30, 2023	**135,339,836**	**$ 137**	**$ 524,619**	**$ (377,270)**	**$ (942)**	**$ 146,544**

(1) As discussed in *Note 8. Stockholders' Equity*, the Company sold (i) an aggregate of 21,000,000 shares of the Company's common stock, par value $0.001 per share and (ii) pre-funded warrants to purchase an aggregate of 5,666,667 shares of the Company's common stock at an exercise price, equal to the par value, of $0.001 per share.

	Stockholders' Equity					
	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total

Balance on December 31, 2023	**138,143,545**	**$ 140**	**$ 533,872**	**$ (393,369)**	**$ (271)**	**$ 140,372**
Issuance of common stock upon exercise of stock options	31,914	—	51	—	—	51
Issuance of common stock for settlement of RSUs	1,563	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(381)	—	(2)	—	—	(2)
Stock-based compensation	—	—	2,257	—	—	2,257
Foreign exchange translation adjustment	—	—	—	—	(220)	(220)
Unrealized loss on short-term investments	—	—	—	—	(251)	(251)
Net loss	—	—	—	(20,346)	—	(20,346)
Balance on March 31, 2024	**138,176,641**	**$ 140**	**$ 536,178**	**$ (413,715)**	**$ (742)**	**$ 121,861**

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

Savara Inc. and Subsidiaries

Condensed Consolidated Statements of Changes in Stockholders' Equity (continued)

Periods Ended September 30, 2023 March 31, 2024 and 2022 2023

(In thousands, except share amounts)

(Unaudited)

Stockholders' Equity	**Stockholders' Equity**
Common Stock	**Common Stock**

	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance on December 31, 2021	**114,036,892**	**$ 116**	**$ 4,489,898**	**$ (300,521)**	**$ 5**	**$ 4,489,898**
Issuance of common stock for settlement of RSUs	3,688	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(720)	—	(1)	—	—	(1)
Stock-based compensation	—	—	574	—	—	574

Foreign exchange translation adjustment	—	—	—	—	(208)	(208)
Unrealized loss on short-term investments	—	—	—	—	(88)	(88)
Net loss	—	—	—	(8,300)	—	(8,300)
Balance on March 31, 2022	**114,039,860**	**$ 116**	**$ 445,471**	**$ (308,821)**	**$ (291)**	**$ 136,475**
Balance on December 31, 2022	**114,046,345**	**$ 116**	**$ 446,938**	**$ (338,671)**	**$ (605)**	**$ 107,778**
Issuance of common stock upon exercise of options	17,129	—	27	—	—	27
Issuance of common stock for settlement of RSUs	1,812	—	—	—	—	—

Repurchase of shares for minimum tax withholdings	(401)	—	—	—	—	—		(551)	—	(1)	—	—	(1)
Stock-based compensation	—	—	456	—	—	456		—	—	864	—	—	864
Foreign exchange translation adjustment	—	—	—	—	(745)	(745)		—	—	—	—	130	130
Unrealized gain on short-term investments	—	—	—	—	20	20		—	—	—	—	14	14
Net loss	—	—	—	(9,164)	—	(9,164)		—	—	—	(10,557)	—	(10,557)
Balance on June 30, 2022	**114,041,271**	**$ 116**	**$ 445,927**	**$ (317,985)**	**$ (1,016)**	**$ 127,042**							

Issuance of common stock for settlement of RSUs	1,813	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(442)	—	(1)	—	—	(1)
Stock-based compensation	—	—	45	—	—	45
Foreign exchange translation adjustment	—	—	—	—	(668)	(668)
Unrealized gain on short-term investments	—	—	—	—	77	77
Net loss	—	—	—	(10,386)	—	(10,386)

			4			1
			4			1
Balance	114		6,	(3		6,
on	,04	1	3	28	(1,	5
Septembe	2,6	1	7	,3	60	1
r 30, 2022	42	$ 6	$ 6	$ 71)	$ 7)	$ 4
Balance on March 31, 2023	114,064,736	$ 116	$ 447,828	$ (349,228)	$ (461)	$ 98,255

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

Savara Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	For the nine months ended September 30,		For the three months ended March 31,	
	2023	2022	2024	2023
Cash flows from operating activities:				
Net loss	$ (38,599)	$ (27,850)	$ (20,346)	$ (10,557)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	45	24	32	8
Amortization of right-of-use assets	64	101	35	15
Foreign currency gain	(64)	(21)		
Foreign currency gain (loss)			21	(29)
Amortization of debt issuance costs	203	266	68	68
(Accretion) amortization on premium to short-term investments	(3,345)	432		
Accretion on premium to short-term investments			(1,370)	(924)

Stock-based compensation	2,817	1,480	2,257	864
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	1,142	1,257	243	261
Non-current assets	(792)	(828)	(814)	(756)
Accounts payable and accrued expenses and other current liabilities	3,071	(764)	(770)	(976)
Net cash used in operating activities	(35,458)	(25,903)	(20,644)	(12,026)
Cash flows from investing activities:				
Purchase of property and equipment	(272)	(9)	(10)	(4)
Purchase of available-for-sale securities, net	(155,415)	(16,004)	(30,697)	(30,091)
Maturity of available-for-sale securities	92,000	116,593	41,500	24,000
Sale of available-for-sale securities, net	—	11,276		
Net cash provided by (used in) investing activities	(63,687)	111,856	10,793	(6,095)
Cash flows from financing activities:				
Repayment of long-term debt (1)	—	(26,350)		
Proceeds from long-term debt, net (1)	—	26,438		
Issuance of common stock and pre-funded warrants in registered direct offering, net of offering costs	74,874	—		
Proceeds from exercise of stock options	194	—		
Proceeds from exercise of stock options, net			51	27
Repurchase of shares for minimum tax withholdings	(183)	(2)	(2)	(1)
Net cash provided by financing activities	74,885	86	49	26
Effect of exchange rate changes on cash and cash equivalents	(150)	(210)	2	(21)
Increase (decrease) in cash and cash equivalents	(24,410)	85,829		
Decrease in cash and cash equivalents			(9,800)	(18,116)
Cash and cash equivalents beginning of period	52,100	34,012	26,585	52,100
Cash and cash equivalents end of period	$ 27,690	$ 119,841	$ 16,785	$ 33,984
Supplemental disclosure of cash flow information:				
Cash paid for interest	$ 1,504	$ 1,186	$ 536	$ 464

(1) As discussed in *Note 6. Long-term Debt*, the Amended Loan Agreement (as defined herein) executed on April 21, 2022 was accounted for as a modification. The Company used the proceeds from the Amended Loan Agreement to repay the outstanding amounts under the Loan Agreement (as defined herein) from Silicon Valley Bank.

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

Savara Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Organization and Nature of Operations

Description of Business

Savara Inc. (together with its subsidiaries “Savara,” the “Company,” “we” or “us”) is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. The Company’s lead sole program, molgramostim nebulizer solution (“molgramostim”), a novel inhaled biologic, is a granulocyte-macrophage colony-stimulating factor in Phase 3 development for autoimmune pulmonary alveolar proteinosis (“aPAP”). The Company and its wholly-owned domestic and foreign subsidiaries operate in one segment with its principal office in Langhorne, Pennsylvania, though a significant portion of employees work remotely.

Since inception, Savara has devoted its efforts and resources to identifying and developing its product candidates, recruiting personnel, and raising capital. Savara has incurred operating losses and negative cash flow from operations and has no product revenue from inception to date. The Company has not yet commenced commercial operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) as defined by the Financial Accounting Standards Board (“FASB”). The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments that are necessary to fairly present the statements of financial position, operations and cash flows for the periods presented. The results of operations for interim periods shown in this report are not necessarily indicative of the results to be expected for the year ending December 31, 2023 December 31, 2024 or for any other future annual or interim period.

Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted from these condensed consolidated financial statements, as permitted by rules and regulations of the U.S. Securities and Exchange Commission (the “SEC”). The Company believes the disclosures made in these condensed consolidated financial statements are adequate to make the information herein not misleading. The Company recommends that these condensed consolidated financial statements be read in conjunction with its audited consolidated

financial statements and related notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023. The Company's significant accounting policies are described in Note 2 to the audited consolidated financial statements. There have been no changes to the Company's significant accounting policies since the date of those financial statements.

Principles of Consolidation

The interim condensed consolidated financial statements of the Company are stated in U.S. dollars and are prepared under U.S. GAAP. These condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The financial statements of the Company's wholly-owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency is reported in *Accumulated other comprehensive loss* in the condensed consolidated balance sheet. All intercompany transactions and accounts have been eliminated in consolidation. The condensed consolidated balance sheet at December 31, 2022 December 31, 2023 has been derived from the Company's audited consolidated financial statements at that date but does not include all of the information and notes required by U.S. GAAP for complete financial statements.

Liquidity

As of September 30, 2023 March 31, 2024, the Company had an accumulated deficit of approximately $377.3 413.7 million. The Company used cash in operating activities of approximately $35.5 20.6 million during the nine three months ended September 30, 2023 March 31, 2024. The cost to further develop and obtain regulatory approval for any drug is substantial and, as noted below, the Company may have to take certain steps to maintain a positive cash position. Although the Company has sufficient capital to fund many of its planned activities, it may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, its product candidate and begin to commercialize any approved product.

The Company is currently focused on the development of molgramostim for the treatment of aPAP and believes such activities will result in the continued incurrence of significant research and development and other expenses related to this program. If the clinical trial for the Company's product candidate fails or produces unsuccessful results and the product candidate does not gain regulatory approval or, if approved, fails to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods.The Company intends to cover its future operating expenses through cash and cash equivalents on hand, short-term investments, and potentially, through a combination of equity offerings, debt financings, government or other third-party funding, and other collaborations and strategic alliances with partner companies. The Company cannot be sure that

additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders.

The Company's cash and cash equivalents of $27.7 16.8 million and short-term investments of $140.6 126.3 million as of September 30, 2023 March 31, 2024 are sufficient to fund the Company's operations for at least the next twelve months subsequent to the issuance date of these condensed consolidated financial statements. The Company may continue to raise additional capital as needed through the issuance of additional equity securities and potentially through borrowings and strategic alliances with partner companies. However, if such additional financing is not available timely and at adequate levels, the Company will need to reevaluate its long-term operating plans. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company currently maintains depository accounts and has a debt facility with Silicon Valley Bank, as acquired by First Citizens BancShares, Inc. (Nasdaq: FCNCA) on March 27, 2023 through an agreement with the Federal Deposit Insurance Corporation ("FDIC"). The acquisition included all of the assets and liabilities of Silicon Valley Bank, including all bank deposits, and allowed Silicon Valley Bank to continue its operations.

In order to mitigate risks associated with our banking deposits, the Company maintains a significant portion of its liquidity in U.S. Treasury money market funds and other short-term investments with custodial services provided by U.S. Bank, N.A., refer to *Note 5. Short-term Investments* and *Note 7. Fair Value Measurements*. The Company continues to monitor the circumstances surrounding First Citizens BancShares, Inc. and its acquisition of Silicon Valley Bank and has not experienced nor anticipates any material impacts on its financial condition or operations.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Management's estimates include, but are not limited to, those related to the accrual and prepayment of research and development expenses and general and administrative costs, certain financial instruments recorded at fair value, the valuation of stock-based compensation, and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience, changes in circumstance and facts, and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Accordingly, actual results could be materially different from those estimates.

Risks and Uncertainties

The product candidate being developed by the Company requires approval from the U.S. Food and Drug Administration ("FDA") or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's product candidate will receive the necessary approvals. If the Company is denied regulatory approval of its product candidate, or if approval is delayed, it may will have a material adverse impact on the Company's business, results of operations, and its financial position.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of drug candidates, raising additional capital, development of competing drugs

and therapies, protection of proprietary technology, and market acceptance of the Company's products. product. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

Concentration of Credit Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. These investments were made in accordance with our investment policy which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is the preservation of to preserve principal and maintenance of liquidity that is sufficient to meet cash flow requirements, while at the same time maximizing total return on investments the income we receive without significantly increasing risk. We maintain our cash and cash equivalents and marketable securities with a limited number of financial institutions. Deposits held with the financial institutions may from time to time exceed the amount of insurance provided on such deposits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and marketable securities to the extent recorded on the consolidated balance sheets. In order to mitigate such risks associated with our banking deposits, the Company maintains a significant portion of its liquidity in U.S. Treasury money market funds and other short-term investments.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the Chief Executive Officer. We have one operating segment, specialty pharmaceuticals within the respiratory system.

Recent Accounting Pronouncements

There are no recent accounting pronouncements issued by the FASB, the American Institute of Certified Public Accountants, or the SEC that are believed by the Company's management to have a material effect, if any, on the Company's condensed consolidated financial statements.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023

Prepaid contracted research and development costs	$ 531	$ 1,822	$ 1,566	$ 2,167
R&D tax credit receivable	780	792	796	814
Prepaid insurance	201	231	133	176
VAT receivable	171	162	146	191
Deposits and other	162	71	503	280
Total prepaid expenses and other current assets	**$ 1,845**	**$ 3,078**	**$ 3,144**	**$ 3,628**

Prepaid Contracted Research and Development Costs

As of September 30, 2023 March 31, 2024, *Prepaid contracted research and development costs* are primarily comprised of contractual prepayments associated with the Company's clinical trial for molgramostim for the treatment of aPAP. This includes prepaid amounts paid under agreements with contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), contract research and contract development and manufacturing organizations ("CDMOs") and other outside service providers that provide services in connection with the Company's research and development activities.

R&D Tax Credit Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS, as of September 30, 2023 March 31, 2024. Under Danish tax law, Denmark remits a research and development tax credit equal to 22% of qualified research and development expenditures, not to exceed established thresholds. During the year ended December 31, 2022 December 31, 2023, the Company generated a Danish tax credit of $0.8 million, which is included in *Prepaid expenses and other current assets* and is expected to be received in the fourth quarter of 2023. 2024. During the nine three months ended September 30, 2023 March 31, 2024, the Company generated a Danish tax credit of $0.8 million, which is recorded in *Other non-current assets* in the condensed consolidated balance sheet and is expected to be received in the fourth quarter of 2024. 2025.

4. Accrued Expenses and Other Current Liabilities

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

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Accrued compensation	$ 2,179	$ 2,365	$ 757	$ 4,046
Accrued contracted research and development costs	2,621	1,322	4,355	2,166
Accrued general and administrative costs	805	782	1,698	738
Lease liability	139	64	147	143
Total accrued expenses and other current liabilities	**$ 5,744**	**$ 4,533**	**$ 6,957**	**$ 7,093**

Accrued Contracted Research and Development Costs

As of September 30, 2023, *Accrued contracted research and development costs* are primarily comprised of costs associated with molgramostim for the treatment of aPAP, including expenses resulting from obligations under agreements with CROs, CMOs, and other outside service providers that provide services in connection with the Company's research and development activities.

Accrued Compensation

As of September 30, 2023 March 31, 2024, *Accrued compensation* includes amounts to be paid to employees for salary, bonuses, vacation and non-equity performance-based compensation. At the end of any period, the amounts accrued for such compensation may vary due to many factors including, but not limited to, timing of payments to employees and vacation usage usage.

Accrued Contracted Research and Development Costs

As of March 31, 2024, . *Accrued contracted research and development costs* are primarily comprised of costs associated with molgramostim for the treatment of aPAP, including expenses resulting from obligations under agreements with CROs, CMOs, and other outside service providers that provide services in connection with the Company's research and development activities.

5. Short-term Investments

The Company’s investment policy seeks to preserve capital and maintain sufficient liquidity to meet operational and other needs of the business. The following table summarizes, by major security type, the Company’s investments (in thousands):

As of September 30, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As of March 31, 2024	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**

Short-term investments								
U.S. government securities	$ 140,623	$ 3	$ —	$ (62)	$ 140,564	$ 126,319	$ 22	$ (83)	$ 126,258
Total short-term investments	**$ 140,623**	**$ 3**	**$ —**	**$ (62)**	**$ 140,564**	**$ 126,319**	**$ 22**	**$ (83)**	**$ 126,258**

As of December 31, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value

As of December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 73,784	$ 8	$ (16)	$ 73,776	$ 135,541	$ 194	$ (1)	$ 135,734
Total short-term investments	**$ 73,784**	**$ 8**	**$ (16)**	**$ 73,776**	**$ 135,541**	**$ 194**	**$ (1)**	**$ 135,734**

The Company has classified its investments as available-for-sale securities. These securities are carried at estimated fair value with the aggregate unrealized gains and losses related to these investments reflected as a part of *Accumulated other comprehensive loss* in the condensed consolidated balance sheet. Classification as short-term or long-term is based upon whether the initial maturity of the debt securities is less than or greater than twelve months.

There were no significant realized gains or losses related to investments for the nine three months ended September 30, 2023 March 31, 2024 and 2022. 2023.

6. Long-term Debt

On April 28, 2017, the Company and its subsidiary, Aravas Inc. (“Aravas”), entered into a loan and security agreement with Silicon Valley Bank, as amended by the First Amendment on October 31, 2017, the Second Amendment on December 4, 2018, the Third Amendment on January 31, 2020, and the Fourth Amendment on March 30, 2021 (the “Loan Agreement”), pursuant to which Silicon Valley Bank provided a term loan to us in the principal amount of $25.0 million.

On April 21, 2022, the Company and its subsidiary, Aravas Inc. (“Aravas”) entered into an Amended and Restated Loan and Security Agreement (the “Amended Loan Agreement”), as co-borrowers, and Silicon Valley Bank, as lender (the “Lender”), which amended and restated the Loan Agreement in its entirety. The Amended Loan Agreement provides for a $26.5 million term loan facility. The Company used the proceeds from the Amended Loan Agreement to repay outstanding amounts under the Loan Agreement, including principal of $25.0 million, a prepayment fee of $0.1 million, and an end of term charge of $1.4 million.

Pursuant to the Amended Loan Agreement, the loan has an interest-only monthly payment through April 21, 2026 (the “Interest-Only Period”) and thereafter equal monthly installments of principal plus interest over 12 months until April 21, 2027 (the “Maturity Date”). However, the Company may elect to extend the Interest-Only Period until the Maturity Date if it maintains cash and cash equivalents equal to at least 1.75 times the outstanding principal amount of the loan during the fifth year. If the Interest-Only Period is extended, all principal and unpaid interest is due and payable on the Maturity Date.

The loan bears interest at a floating rate equal to the greater of (i) 3% and (ii) the prime rate reported in The Wall Street Journal, minus a spread of 0.5%. Savara The Company is obligated to pay customary closing fees and a final payment of 2.75% of the principal amount advanced under the facility. The Company may prepay the loan in whole or in part at any time, subject to a prepayment fee of 1.0% if prepaid between the first and second anniversaries of the closing date. Following the second anniversary, there is no prepayment fee.

The Lender was granted a perfected first priority lien in all of the Company's assets with a negative pledge on intellectual property. The Amended Loan Agreement contains customary affirmative and negative covenants, including among others, covenants that limit the Company's and its subsidiaries’ ability to dispose of assets, permit a change in control, merge or consolidate, make acquisitions, incur indebtedness, grant liens, make investments, make certain restricted payments, and enter into transactions with affiliates, in each case subject to certain exceptions.

Additionally, the Amended Loan Agreement contains an affirmative covenant providing that if the Company’s balance of cash and cash equivalents falls below $40.0 million, the Company is required to maintain cash and cash equivalents equal to at

least (i) six months of operating expenses and (ii) 1.2 times the outstanding principal amount of the loan (or 1.75 in the final year of the loan if the Interest-Only Period is extended).

IN ACCORDANCE WITH FASB ASC TOPIC 470-50, 9*Debt – Modifications and Extinguishments*, the Company evaluated the Amended Loan Agreement to determine whether it should be accounted for as a modification or extinguishment. As a result of this analysis, the Amended Loan Agreement was accounted for as a modification. Accordingly, no

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gain or loss is recognized.

Approximately $0.1 million of fees paid to the Lender were capitalized and will be amortized over the term of the Amended Loan Agreement. Expenses paid to third parties associated with the Amended Loan Agreement were immediately expensed and recorded in the *Interest income (expense)* line item in our consolidated statement of operations.

On March 10, 2023, the FDIC took control and was appointed receiver of Silicon Valley Bank, and on March 27, 2023, First Citizens BancShares, Inc. announced that it had entered into an agreement with the FDIC to purchase all of the assets and liabilities of Silicon Valley Bank. As such, the Company is monitoring the impact on the Amended Loan Agreement and does not expect any material impacts to its facility or operations.

Summary of Carrying Value

The following table summarizes the components of the long-term debt carrying value, which approximates the fair value (in thousands):

Future minimum payments due during the year ended December 31,	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
2023	—	—		
2024	—	—	$ —	$ —
2025	—	—	—	—
2026	17,667	17,667	17,667	17,667
2027	9,562	9,562	9,562	9,562
Total future minimum payments	27,229	27,229	27,229	27,229
Unamortized end of term charge	(519)	(630)	(445)	(482)
Debt issuance costs	(394)	(478)	(338)	(366)
Debt discount related to warrants	(35)	(43)	(30)	(33)
Total debt	26,281	26,078	26,416	26,348
Current portion of long-term debt	—	—	—	—
Long-term debt	$ 26,281	$ 26,078	$ 26,416	$ 26,348

7. Fair Value Measurements

The Company uses a three-tier fair value hierarchy to classify measures and disclose all assets and liabilities measured reports certain financial instruments at fair value on a recurring basis as well as assets and liabilities measured at evaluates its financial instruments subject to fair value measurements on a non-recurring recurring and nonrecurring basis to determine the appropriate level in periods subsequent which to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value.

The three tiers are defined as follows:

- Level 1 – Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities classify th in active markets;
- Level 2 – Observable inputs other than quoted prices in active markets that are observable either directly or indirectl the marketplace for identical or similar assets and liabilities; and
- Level 3 – Unobservable inputs that are supported by little or no market data, which require the Company to develop own assumptions.

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each reporting period.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

Certain assets and liabilities are measured at fair value on a nonrecurring basis. These assets and liabilities are not measured at fair value on an ongoing basis, but are subject to fair value adjustments annually or whenever events or circumstances indicate that the carrying value of those assets may not be recoverable. These assets and liabilities can include acquired in-process research and development ("IPR&D") and other long-lived assets that are written down to fair value if they are impaired.

IPR&D is considered an indefinite-lived intangible asset and is assessed for impairment annually, or more frequently if impairment indicators exist. In accordance with ASU 2017-04, *Intangibles – Goodwill and Other (Topic 350)*, the Company utilizes a two-step method, which allows the Company to first assess qualitative factors before performing a quantitative assessment of the fair value of a reporting unit. If it is determined on the basis of qualitative factors that the fair value of the IPR&D is more likely than not less than the carrying value, a quantitative impairment test is required.

During the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, the Company experienced a decrease of approximately $0.2 million and a decrease an increase of approximately $1.5 0.2 million, respectively, in the carrying value of IPR&D due to foreign currency translation.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company determined that certain investments in debt securities classified as available-for-sale securities were Level 1 financial instruments.

From time to time, the Company also invests Additional investments in corporate debt securities, commercial paper, and asset-backed securities which are considered Level 2 financial instruments because the Company has access to quoted prices but does not have visibility to the volume and frequency of trading for all of these investments. For the Company's investments, a market approach is used for recurring fair value measurements and the valuation techniques use inputs that are observable, or can be corroborated by observable data, in an active marketplace.

The fair value of these instruments as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023 was as follows (in thousands):

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
As of September 30, 2023				
Cash equivalents:				
U.S. Treasury money market funds	$ 27,025	$ —	$ —	$ 27,025
Short-term investments:				
U.S. government securities	140,561	—	—	140,561
As of December 31, 2022				
Cash equivalents:				
U.S. Treasury money market funds	$ 48,804	$ —	$ —	$ 48,804
Short-term investments:				
U.S. government securities	73,776	—	—	73,776

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
As of March 31, 2024				
Cash equivalents:				

U.S. Treasury money market funds	$ 16,027	$ —	$ —	$ 16,027
Short-term investments:				
U.S. government securities	126,258	—	—	126,258
As of December 31, 2023				
Cash equivalents:				
U.S. Treasury money market funds	$ 17,270	$ —	$ —	$ 17,270
Short-term investments:				
U.S. government securities	135,734	—	—	135,734

The Company did not transfer any assets measured at fair value on a recurring basis to or from Level 1, Level 2, and Level 3 during the three months ended March 31, 2024 and 2023.

8. Stockholders' Equity

Registered Direct Offering of Common Stock

On July 17, 2023, the Company sold (i) an aggregate of 21,000,000 shares of the Company's common stock (the "Common Stock") for $3.00 per share which represented a 1% premium over the closing price on that date and (ii) pre-funded warrants to purchase an aggregate of 5,666,667 shares of Common Stock at an exercise price of $0.001 per share (the "2023 Pre-Funded Warrants") for $2.999 per warrant pursuant to a Registered Direct Offering (the "July 2023 Offering"). The Common Stock and 2023 Pre-Funded Warrants were offered by the Company pursuant to its existing shelf registration statement (File No. 333-257709) filed with the SEC on July 6, 2021 and declared effective on July 16, 2021.

The Company determined that the securities issued in the July 2023 Offering were free-standing and that the 2023 Pre-Funded Warrants meet the equity classification requirements pursuant to ASC 480, *Distinguishing Liability from Equity*, ASC 815, *Derivatives and Hedging* and Subtopic 815-40, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. The 2023 Pre-Funded Warrants were sold at the same price as the underlying common stock, less $0.001 (which represents the exercise price of the warrants).

The July 2023 Offering resulted in net proceeds to the Company of approximately $74.9 million, after deducting final underwriting discounts, commissions, and other estimated offering expenses, as follows (in thousands):

Financial instruments	Proceeds	Proceeds
Common stock	$ 63,000	$ 63,000
Pre-funded warrants	16,994	
2023 Pre-funded warrants		16,994
Total	79,994	79,994

Offering expenses	$ (5,120)	$ (5,120)
Net proceeds	$ 74,874	$ 74,874

The Company intends to use the net proceeds for working capital and general corporate purposes, which include, but are not limited to, the funding of clinical development of and pursuing regulatory approval for molgramostim, investing in our commercialization infrastructure, commercial launch preparation activities in the United States and European Union, and administrative expenses.

Evercore Common Stock Sales Agreement

On July 6, 2021, the Company entered into a Common Stock Sales Agreement with Evercore Group L.L.C. ("Evercore"), as sales agent (the "Sales Agreement"), pursuant to which the Company may offer and sell, from time to time, through Evercore, shares of Savara's common stock, par value $0.001 per share (the "Shares"), having an aggregate offering price of not more than $60.0 million. The Sales Agreement was effective on July 16, 2021, the date the Registration Statement was declared effective by the SEC. The Shares will be offered and sold pursuant to the Registration Statement. Subject to the terms and conditions of the Sales Agreement, Evercore will use commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions. The Company has provided Evercore with customary indemnification rights, and Evercore will be entitled to a commission at a fixed commission rate equal to 3% of the gross proceeds per Share sold. Sales of the Shares, if any, under the Sales Agreement may be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. The Company has no obligation to sell any of the Shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement.

During the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, the Company did not sell any shares of common stock under the Sales Agreement.

Common Stock Reserved for Issuance

The Company's shares of common stock reserved for issuance as of the periods indicated were as follows:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
April 2017 Warrants	24,725	24,725	24,725	24,725
June 2017 Warrants	41,736	41,736	41,736	41,736
December 2018 Warrants	11,332	11,332	11,332	11,332
2017 Pre-funded Warrants	775,000	775,000	775,000	775,000
Pre-funded PIPE Warrants	5,780,537	5,780,537	5,780,537	5,780,537

2021 Pre-funded Warrants	32,175,172	32,175,172	32,175,172	32,175,172
2023 Pre-funded Warrants	5,666,667	—	5,666,667	5,666,667
Stock options outstanding	8,551,117	7,933,184	9,794,317	9,633,067
Issued and nonvested RSUs	2,281,812	1,942,250	3,626,687	3,488,250
Total shares reserved	**55,308,098**	**48,683,936**	**57,896,173**	**57,596,486**

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of September 30, 2023 March 31, 2024:

Expiration Date	Shares Underlying Outstanding Warrants		Exercise Price
October 2024	775,000	$	0.01
April 2027	24,725	$	2.87
June 2027	41,736	$	2.87
December 2028	11,332	$	2.87
None	43,622,376	$	0.001
	44,475,169		

Accumulated Other Comprehensive Income (Loss) Information

The components of accumulated other comprehensive income (loss) as of the dates indicated and the change during the period were (in thousands):

	Foreign Exchange Translation Adjustment	Unrealized Gain (Loss) on ST Investments	Total Accumulated Other Comprehensive Income (Loss)	Foreign Exchange Translation Adjustment	Unrealized Gain (Loss) on ST Investments	Total Accumulated Other Comprehensive Income (Loss)
Balance, December 31, 2021	$ 54	$ (49)	$ 5			
Change	$ (648)	$ 38	$ (610)			

Balance, December 31, 2022	$ (594)	$ (11)	$ (605)	$ (594)	$ (11)	$ (605)
Change	$ (286)	$ (51)	$ (337)	$ 133	$ 201	$ 334
Balance, September 30, 2023	$ (880)	$ (62)	$ (942)			
Balance, December 31, 2023				$ (461)	$ 190	$ (271)
Change				$ (220)	$ (251)	$ (471)
Balance, March 31, 2024				$ (681)	$ (61)	$ (742)

9. Commitments and Contingencies

Manufacturing and Other Commitments and Contingencies

The Company is subject to various royalties and manufacturing and development payments related to its product candidate, molgramostim. Under a manufacture and supply agreement with the active pharmaceutical ingredients (“API”) manufacturer for molgramostim, as amended on December 7, 2022 and December 13, 2023, the Company must make certain payments to the API manufacturer upon achievement of the milestones outlined in the table set forth below. Additionally, upon first receipt of marketing approval by the Company from a regulatory authority in a country for a product containing the API for therapeutic use in humans and ending the earlier of (i) ten (10) years thereafter or (ii) the date a biosimilar of such product is first sold in such country, the Company shall pay the API manufacturer a royalty equal to low-single digits of the net sales in that country.

Additionally, the Company is subject to a purchase requirement under which for ten years following the date of receipt of approval by a regulatory authority of the first regulatory filing for the marketing and sale of the first molgramostim product in any country, each year, the Company will purchase from the API manufacturer the API required to produce a percentage of such molgramostim product it sells (the “Purchase Requirement”); provided, however, that the Purchase Requirement will no longer apply if (i) the price charged by the API manufacturer exceeds a certain price charged by an alternative supplier, (ii) there is a shortage of supply, or (iii) API manufacturer at any time fails to materially fulfill a purchase order of the Company.

Similarly, the Company may become subject to additional milestone payments for the achievement of certain manufacturing protocols of molgramostim pursuant to a services agreement entered into on December 21, 2022 with a second source product manufacturer, as well as, an integrated contract research and CDMO, Contract development and manufacturing organization, pursuant to a service agreement, serving as an additional source of manufacturing of molgramostim drug substances. As of September 30, 2023 March 31, 2024, the Company had no significant obligations for any such milestone payments to either of these additional source product manufacturers.

The Company is also subject to certain contingent milestone payments, disclosed in the following table, payable to the manufacturer of the nebulizer used to administer molgramostim. In addition to these milestones, the Company will owe a royalty of three-and one-half percent (3.5%) to the manufacturer of the nebulizer based on net sales.

The following table summarizes manufacturing commitments and contingencies as of the period indicated (in thousands):

	September 30, 2023	March 31, 2024
Molgramostim manufacturer:		
Achievement of certain milestones related to validation of API and regulatory approval of molgramostim	$ 2,300	$ 1,300
Molgramostim nebulizer manufacturer:		
Achievement of various development activities and regulatory approval of nebulizer utilized to administer molgramostim	529	540
Total manufacturing and other commitments	**$ 2,829**	
Total manufacturing and other commitments and contingencies		**$ 1,840**

The milestone commitments disclosed above reflect the activities that have (i) not been met or incurred; (ii) not been remunerated; and (iii) not accrued, as the activities are not deemed probable or reasonably estimable, as of September 30, 2023 March 31, 2024.

Further, in February 2024, the Company entered into a master services agreement with an additional second source manufacturer to provide development and manufacturing services related to API for the Company's molgramostim product candidate in accordance with the terms of separate scope of work agreements to be entered into by the parties and to perform a manufacturing campaign for process performance qualification of the API of molgramostim. Under that master services agreement, work orders and subsequent change orders, the Company is currently obligated to pay the second source manufacturer, in total, estimated fees of $17.2 million of which approximately $1.4 million has been paid and/or accrued through March 31, 2024. These costs are subject to various cancellation fees ranging from ten percent (10%) to one hundred percent (100%) of the cost of the respective activity based upon the timing of the commencement date and status of the activity.

Contract Research

As part of its development of molgramostim for the treatment of aPAP, the Company entered into a Master Services Agreement (“MSA”) with Parexel International (IRL) Limited (“Parexel”) pursuant to which Parexel will provide contract research services related to clinical trials. Contemporaneously with entering the MSA, a work order was executed with Parexel, under which they will provide services related to the IMPALA-2 trial. Under that work order and subsequent change orders, the Company will pay Parexel service fees, pass-through expenses, and investigator fees estimated to be approximately $37.0 41.5 million over the course of the IMPALA-2 clinical trial.

Operating Lease

We are obligated under an operating lease, as amended, for commercial real estate located in Langhorne, Pennsylvania, the Company’s headquarters. On February 28, 2023, the Company entered into the first amendment (the “Lease Amendment”) to its existing lease agreement, dated July 7, 2021 and which originally commenced on October 1, 2021. The Lease Amendment commenced on July 1, 2023, continues through June 30, 2026, or an additional thirty-six months, expands the existing office space, and increases the average monthly rent to an average of approximately $14.5 thousand, paid over monthly installments during the Lease Amendment term.

As of September 30, 2023, the carrying value of the right-of-use assets for the operating lease increased to $0.4 million, which is reflected in *Other non-current assets* and the carrying value of the lease liabilities for the operating lease increased to $0.4 million, of which approximately $0.1 million related to the current portion of the lease liabilities is recorded in *Accrued expenses and other current liabilities* and $0.3 million related to the non-current portion of the lease liabilities is recorded in *Other long-term liabilities*.

Risk Management

The Company maintains various forms of insurance that the Company's management believes are adequate to reduce the exposure to certain risks associated with operating the Company’s business to an acceptable level.

10. Stock-Based Compensation

Equity Incentive Plans

2008 Stock Option Plan

The Company adopted the Savara Inc. Stock Option Plan (the “2008 Plan”), pursuant to which the Company reserved shares for issuance to employees, directors, and consultants. The 2008 Plan includes (i) the option grant program providing for both incentive and non-qualified stock options, as defined by the Internal Revenue Code, and (ii) the stock issuance program

providing for the issuance of awards that are valued based upon common stock, including restricted stock, dividend equivalents, stock appreciation rights, phantom stock, and performance units. The 2008 Plan also allows eligible persons to purchase shares of common stock at an amount determined by the plan administrator. Upon a participant's termination, the Company retains the right to repurchase nonvested shares issued in conjunction with the stock issuance program at the fair market value per share as of the date of termination.

The Company had previously issued incentive and non-qualified options and restricted stock to employees and non-employees under the 2008 Plan. The terms of the stock options, including the exercise price per share and vesting provisions, were determined by the board of directors. Stock options were granted at exercise prices not less than the estimated fair market value of the Company's common stock at the date of grant based upon objective and subjective factors including: third-party valuations, preferred stock transactions with third parties, current operating and financial performance, management estimates, and future expectations.

The Company no longer issues stock-based awards under the 2008 Plan.

Amended and Restated 2015 Omnibus Incentive Option Plan

The Company operates the Amended and Restated 2015 Omnibus Incentive Plan, as amended and restated with approval by the Company's stockholders in June 2018 and amended with approval by our stockholders in May 2020, June 2022 and June 2023 (the "2015 Plan"). The 2015 Plan provides for the grant of incentive and non-statutory stock options, as well as share appreciation rights, restricted shares, restricted stock units ("RSUs"), performance units, shares, and other stock-based awards. Share-based awards are subject to terms and conditions established by the board of directors or the compensation committee of the board of directors. As of September 30, 2023 March 31, 2024, the number of shares of common stock available for grant under the 2015 Plan was 4,724,988 1,007,502 shares.

Under both the 2008 Plan and 2015 Plan, stock options typically vest quarterly over four years and expire ten years from the grant date and RSUs typically vest quarterly over four years or cliff vest after two years.

2021 Inducement Equity Incentive Plan

The Company adopted the 2021 Inducement Equity Incentive Plan in May 2021 and amended it in September 2021, September 2022, December 2022, March 2023, and June 2023 and February 2024 (as amended, the "Inducement Plan"). The Inducement Plan provides for the grant of non-statutory stock options, restricted stock, RSUs, stock appreciation rights, performance units, and performance shares. Each award under the Inducement Plan is intended to qualify as an employment inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4). As of September 30, 2023 March 31, 2024, the number of shares of common stock available for grant under the Inducement Plan was 540,592 475,592 shares.

Under the Inducement Plan, stock options typically vest quarterly over four years and expire ten years from the grant date and RSUs typically cliff vest after two years.

Stock-Based Awards Activity

The following table provides a summary of stock-based awards activity for the nine three months ended September 30, 2023 March 31, 2024:

Stock Options:

Outstanding at December 31, 2022 December 31, 2023	**7,933,184 9,633,067**
Granted	920,000 195,000
Exercised	(171,067 33,750)
Expired/cancelled/forfeited	(131,000 —)
Outstanding at September 30, 2023 March 31, 2024	**8,551,117 9,794,317**

The total compensation cost related to non-vested stock options not yet recognized as of September 30, 2023 March 31, 2024, was $4.7 8.3 million, which will be recognized over a weighted-average period of approximately 3.0 3.2 years**.**

RSUs:

Outstanding at December 31, 2022 December 31, 2023	**1,942,250 3,488,250**
Granted	520,000 140,000
Vested	(179,419 1,563)
Forfeited	(1,019 —)
Outstanding at September 30, 2023 March 31, 2024	**2,281,812 3,626,687**

The total compensation cost related to unvested RSUs not yet recognized as of September 30, 2023 March 31, 2024, was $1.7 9.3 million, which will be recognized over a weighted-average period of approximately 1.2 1.5 years**.**

Stock-Based Compensation

Stock-based compensation expense is included in the following line items in the accompanying statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands):

	Three months ended September 30,		Nine months ended September 30,		Three months ended March 31,	
	2023	**2022**	**2023**	**2022**	**2024**	**2023**
Research and development	$ 329	$ 62	$ 863	$ 309	$ 1,303	$ 255

General and administrative	666	388	1,954	1,171	954	609
Total stock-based compensation	**$ 995**	**$ 450**	**$ 2,817**	**$ 1,480**	**$ 2,257**	**$ 864**

11. Related Parties

As an investor with the right to designate a member of the Company's board of directors, Bain Capital Life Sciences Fund II, L.P., BCIP Life Sciences Associates, LP and their affiliates (collectively "Bain") has significant influence over the Company and is thereby considered a related party.

Pursuant to the July 2023 Offering (as further discussed in *Note 8. Stockholders' Equity*), Bain acquired 5,666,667 of 2023 Pre-Funded Warrants.

12. Net Loss per Share

Basic and diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common stock and pre-funded warrants outstanding during the period without consideration of common stock equivalents. For periods in which the Company generated a net loss, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.

The following equity instruments were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	Nine months ended September 30,		Three months ended March 31,	
	2023	2022	2024	2023
Awards under equity incentive plan	8,551,117	5,851,153	9,794,317	8,439,119
Non-vested restricted shares and restricted stock units	2,281,812	1,090,062	3,626,687	2,140,437
Warrants to purchase common stock	77,793	77,793		
Warrants to purchase common stock(*)			77,793	77,793
Total	**10,910,722**	**7,019,008**	**13,498,797**	**10,657,349**

** Pre-funded warrants are excluded herein.*

The following table calculates basic earnings per share of common stock and diluted earnings per share of common stock for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands, except share and per share amounts):

	Three months ended September 30,		Nine months ended September 30,		Three months ended March 31,	
	2023	2022	2023	2022	2024	2023
Net loss	(16,5 $ 99)	(10,3 $ 86)	(38,5 $ 99)	(27,8 $ 50)	$ (20,346)	$ (10,557)
Net loss attributable to common stockholders	(16,5 99)	(10,3 86)	(38,5 99)	(27,8 50)	(20,346)	(10,557)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	(16,5 99)	(10,3 86)	(38,5 99)	(27,8 50)	(20,346)	(10,557)
Weighted-average common shares outstanding, basic and diluted	164, 342, 634	152, 773, 015	158, 444, 739	152, 771, 302	182,550,109	152,781,580
Basic and diluted EPS	**$ (0.10)**	**$ (0.07)**	**$ (0.24)**	**$ (0.18)**	**$ (0.11)**	**$ (0.07)**

13. 12. Subsequent Events

The Company has evaluated subsequent events through the date these condensed consolidated financial statements were issued and determined there were no additional events that required disclosure or recognition in these condensed consolidated financial statements.

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

Cautionary Statement Concerning Forward-Looking Statements

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements contained herein that involve risks and uncertainties, such as Savara's plans, objectives, expectations, intentions, and beliefs should be considered forward-looking statements. Savara's actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to the following: the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the risks associated with the process of conducting clinical trials and developing, obtaining regulatory approval for and commercializing drug candidates that are safe and effective for use as human therapeutics, the timing and ability to raise additional capital as needed to fund continued operations, natural disasters, pandemics, geopolitical events (including the war between Russia and Ukraine and the war in the Middle East), and those discussed in the section entitled "Risk Factors" in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on March 30, 2023 March 7, 2024, all of which are difficult to predict.

Statements made herein are as of the date of the filing of this Quarterly Report with the SEC and should not be relied upon as of any subsequent date. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

The following discussion and analysis of the financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report and the consolidated financial statements and related notes in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

Overview

Savara Inc. (together with its subsidiaries “Savara,” the “Company,” “we,” “our” or “us”) is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. Our lead sole program, molgramostim, is an inhaled biologic, specifically, inhaled granulocyte-macrophage colony-stimulating factor in Phase 3 development for aPAP. Savara, together with its wholly-owned subsidiaries, which include Aravas Inc. and Savara ApS, operate in one segment with its principal office in Langhorne, Pennsylvania as of September 30, 2023 March 31, 2024, though a majority of our employees work remotely.

Since inception, we have devoted our efforts and resources to identifying and developing our product candidates, recruiting personnel, and raising capital. We have incurred operating losses and negative cash flow from operations and have no product revenue from inception to date. From inception to September 30, 2023 March 31, 2024, we have raised net cash proceeds of approximately $467.8 million $476.7 million, primarily from public offerings of our common stock, private placements of convertible preferred stock, and debt financings.

We have never been profitable and have incurred operating losses every year since inception. Our net losses for the three months ended September 30, 2023 March 31, 2024 and 2022 2023 were $16.6 million $20.3 million and $10.4 million $10.6 million, respectively, and the net loss for the year ended December 31, 2022 December 31, 2023 was $38.2 million $54.7 million. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of approximately $377.3 million $413.7 million. Our operating losses primarily resulted from expenses attributed to our research and development programs and from general and administrative costs associated with our operations.

We have chosen to operate by outsourcing our manufacturing and most of our clinical operations. We expect to incur significant additional expenses and continue to incur operating losses for at least the next several years as we continue the clinical development of, and seek regulatory approval for, our primary product candidate. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to the timing of clinical development programs and efforts to achieve regulatory approval.

As of September 30, 2023 March 31, 2024, we had cash and cash equivalents of $27.7 million $16.8 million and short-term investments of $140.6 million $126.3 million. We will continue to require additional capital to continue our clinical development and potential commercialization activities. Although we have sufficient capital to fund many of our planned activities, we may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, our product candidate and begin to commercialize any approved product. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidate.

Recent Events

July 2023 Public Offering

On July 17, 2023, we sold (i) an aggregate of 21,000,000 shares of the Company's common stock (the "Common Stock") for $3.00 per share which represented a 1% premium over the closing price on that date and (ii) pre-funded warrants to purchase an aggregate of 5,666,667 shares of Common Stock at an exercise price of $0.001 per share (the "2023 Pre-Funded Warrants") for $2.999 per warrant pursuant to a Registered Direct Offering (the "July 2023 Offering"). The Common Stock and 2023 Pre-Funded Warrants were offered by the Company pursuant to its existing shelf registration statement (File No. 333-257709) filed with the SEC on July 6, 2021 and declared effective on July 16, 2021. The July 2023 Offering resulted in net proceeds to the Company of approximately $74.9 million, after deducting final underwriting discounts, commissions, and other estimated offering expenses.

International Conflicts

In February 2022, Russia commenced a military invasion of Ukraine, and in October 2023, Israel declared war on Hamas in Gaza. The ongoing conflict and political and physical conditions in Ukraine, Russia, Israel and Gaza as well as in neighboring or involved countries, organizations and governments, may disrupt our supply chain and increase our costs, which may adversely affect our ability to conduct our ongoing clinical trial and impact patients' ability to partake in our clinical trial. While we do not believe these conflicts will have a material impact on our current operations, given the evolving hostilities and their potential expansion beyond Ukraine, Russia, Israel, Gaza and the Middle East, the full impact of the conflicts remain uncertain.

Continued Funding of Federal Government Operations

On September 30, 2023, the U.S. Congress passed, and President Biden signed a continuing resolution ("HR 5860") allowing the U.S federal government to continue operating at current spending levels for forty-five days. Following HR 5860, the U.S. Congress has until November 17, 2023, to finalize and pass the U.S. government's fiscal year 2024 budget or risk the cessation of certain operations of the federal government (also known as a government shutdown). The impact of a potential government shutdown to our operations is uncertain; however, we are actively assessing and monitoring the potential impacts and situation.

Financial Operations Overview

Research and Development Expenses

The largest component of our operating expenses has historically been our investment in research and development activities. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- expenses incurred under agreements with contract research organizations ("CROs"), consultants, and clinical trial si that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of our clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies; and
- internal costs that are associated with activities performed by our research and development organization and gener benefit our molgramostim product candidate and program. Where appropriate, such internal costs consist primarily o
    - o personnel costs, which include salaries, benefits and stock-based compensation expense;

- facilities and other expenses, which include expenses for maintenance of facilities; facilities and depreciation expense; and
- regulatory expenses and technology license fees related to development activities.

We expect research and development expenses will remain significant in the future as we advance our molgramostim product candidate through clinical trials and pursue regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing activities, including investing in the development of a second source manufacturer and clinical supplies.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidate(s). candidate. The probability of success of our product candidate(s) candidate may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability, and commercial viability. As a result, we are unable to accurately determine the

duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of molgramostim.

General and Administrative Expenses

General and administrative G&A expenses consist primarily consist of salaries, benefits, and related costs for personnel in executive, finance and accounting, legal, and investor relations, and relations; as well as professional and consulting fees for accounting, legal, investor relations, business development, commercial strategy and research, human resources, and information technology services. Other general and administrative G&A expenses include facility lease and insurance costs.

Other Income (Expense), Net

Other income (expense) includes amortization expense related to capitalized debt issuance costs and debt discount under our Amended Loan Agreement executed with Silicon Valley Bank during April 2022 (the “Amended Loan Agreement”). Refer to *Note 6. Long-term Debt* in the notes to the condensed consolidated financial statements included in this Quarterly Report. Interest expense is typically reported net of interest income which includes interest earned on our cash, cash equivalent, and short-term investment balances. Other income (expense) also includes net unrealized and realized gains and losses from foreign currency transactions, foreign exchange derivatives not designated as hedging, refundable tax credits generated by some of our foreign subsidiaries, and securities subject to fair value accounting as well as any other non-operating gains and losses.

Critical Accounting Policies and Estimates

There have not been any material changes during the nine three months ended September 30, 2023 March 31, 2024, to the methodology applied by management for critical accounting policies previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023. Please read *Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates* in our Annual Report

on Form 10-K for the year ended December 31, 2022 December 31, 2023, for further description of our critical accounting policies.

Results of Operations – Comparison of Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

	For the Three Months Ended September 30,		Dollar	For the Three Months Ended March 31,		Dollar
	2023	2022	Change	2024	2023	Change
	(in thousands)			(in thousands)		
Operating expenses:						
Research and development	$ 13,867	$ 8,151	$ 5,716	$ 16,807	$ 8,738	$ 8,069
General and administrative	4,147	2,376	1,771	5,636	3,366	2,270
Depreciation and amortization	30	8	22	32	8	24
Total operating expenses	18,044	10,535	7,509	22,475	12,112	10,363
Loss from operations	(18,044)	(10,535)	(7,509)	(22,475)	(12,112)	(10,363)
Other income, net	1,445	149	1,296	2,129	1,555	574
Net loss	**$ (16,599)**	**$ (10,386)**	**$ (6,213)**	**$ (20,346)**	**$ (10,557)**	**$ (9,789)**

Research and Development

Research and development expenses increased by $5.7 million $8.1 million, or 70.1% 92.3%, to $13.9 million $16.8 million for the three months ended September 30, 2023 March 31, 2024 from $8.2 million $8.7 million for the three months ended September 30, 2022 March 31, 2023. This increase is primarily due to the performance of tasks related to our molgramostim program, which includes approximately $2.5 million $4.3 million of costs related to our chemistry, manufacturing, and controls activities, $1.8 million primarily driven by initiatives at our second drug substance manufacturers, $1.0 million of costs related

to our IMPALA-2 trial, including CRO-related activities, $0.5 million $0.6 million of costs related to regulatory affairs and quality assurance, and $0.9 million $2.2 million due to an increase in personnel and related costs.

General and Administrative

General and administrative expenses increased by $1.8 million $2.3 million, or 74.5% 67.4%, to $4.1 million $5.6 million for the three months ended September 30, 2023 March 31, 2024 from $2.4 million $3.4 million for the three months ended September 30, 2022 March 31, 2023. The increase is due to the strategic addition of personnel for key positions and related costs to facilitate the management of our business and operations of approximately $1.2 million and $0.6 million, certain commercial activities of approximately $1.1 million, and other overhead of $0.6 million. primarily driven by patient advocacy activities.

Other Income, Net

Other income, net increased by $1.3 million $0.6 million to $1.4 million $2.1 million for the three months ended September 30, 2023 March 31, 2024 from $0.1 million $1.6 million for the three months ended September 30, 2022 March 31, 2023. The increase is primarily related to the increase in *Interest income* during the three months ended September 30, 2023 March 31, 2024 as a result of both an increase in our short-term investments following the July 2023 Offering and an increase in market interest rates.

Results of Operations – Comparison of Nine Months Ended September 30, 2023 and 2022

	Nine months ended September 30,		Dollar Change
	2023	2022	
		(in thousands)	
Operating expenses:			
Research and development	$ 31,516	$ 20,253	$ 11,263
General and administrative	10,816	7,687	3,129
Depreciation and amortization	45	24	21
Total operating expenses	42,377	27,964	14,413
Loss from operations	(42,377)	(27,964)	(14,413)
Other income, net	3,778	114	3,664
Net loss	**$ (38,599)**	**$ (27,850)**	**$ (10,749)**

Research and Development

Research and development expenses increased by $11.3 million, or 55.6%, to $31.5 million for the nine months ended September 30, 2023 from $20.3 million for the nine months ended September 30, 2022. This increase is primarily due to performance of tasks related to our molgramostim program which includes approximately $5.1 million of costs related to our chemistry, manufacturing, and controls activities, $3.8 million of costs related to our IMPALA-2 trial, including CRO-related

activities, $0.7 million of costs related to quality assurance, and $1.9 million due to an increase in personnel and related costs. This increase is partially offset by a $0.2 million decrease in departmental overhead spend.

General and Administrative

General and administrative expenses increased by $3.1 million, or 40.7%, to $10.8 million for the nine months ended September 30, 2023 from $7.7 million for the nine months ended September 30, 2022. The increase is primarily attributable to the strategic addition of personnel and related costs for key positions to facilitate the management of our business and operations of approximately $2.3 million and and certain commercial activities of approximately $0.8 million.

Other Income, Net

Other income, net increased by $3.7 million to $3.8 million for the nine months ended September 30, 2023 from $0.1 million for the nine months ended September 30, 2022. The change is primarily related to the increase in *Interest income* during the nine months ended September 30, 2023 as a result of both an increase in our short-term investments following the July 2023 Offering various equity financings and an increase in market interest rates.

Liquidity and Capital Resources

As of September 30, 2023 March 31, 2024, we had $27.7 million $16.8 million of cash and cash equivalents, $140.6 million $126.3 million in short-term investments, and an accumulated deficit of approximately $377.3 million $413.7 million. As discussed in *Note 6. Long-term Debt* in the notes to the condensed consolidated financial statements included in this Quarterly Report, we entered into a Loan Agreement with Silicon Valley Bank during the year ended December 31, 2017. During April 2022, we entered into an Amended Loan Agreement with Silicon Valley Bank (the "Amended Loan Agreement") that provided for a $26.5 million term loan facility, the proceeds of which were used to refinance all outstanding obligations under the Loan Agreement. our pre-existing loan agreement with Silicon Valley Bank.

We have used and intend to use our liquidity and capital for working capital and general corporate purposes, which include, but are not limited to, the funding of clinical development of and pursuing regulatory approval for our product candidate and general and administrative expenses. As we continue to progress on the IMPALA-2 trial, we will continue to monitor our liquidity and capital requirements.

Cash Flows

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

	Nine months ended September 30,		Three months ended March 31,	
	2023	2022	2024	2023
	(in thousands)		(in thousands)	
Cash used in operating activities	$ (35,458)	$ (25,903)	$ (20,644)	$ (12,026)
Cash provided by (used in) investing activities	(63,687)	111,856	10,793	(6,095)
Cash provided by financing activities	74,885	86	49	26

Effect of exchange rate changes on cash and cash equivalents	(150)	(210)	2	(21)
Net change in cash and cash equivalents	**$ (24,410)**	**$ 85,829**	**$ (9,800)**	**$ (18,116)**

20 19

Cash flows from operating activities

Cash used in operating activities for the nine three months ended September 30, 2023 March 31, 2024 was $35.5 million $20.6 million, consisting of a net loss of $38.6 million $20.3 million and net $3.4 million $1.3 million in changes due to operating assets and liabilities. This was partially offset by approximately $0.3 million $1.0 million of net noncash charges (comprised of depreciation and amortization including right-of-use assets, amortization accretion on premium to short-term investments, amortization of debt issuance costs, foreign currency, and stock-based compensation).

Cash flows from investing activities

Cash used in provided by investing activities of $63.7 million $10.8 million for the nine three months ended September 30, 2023 March 31, 2024 was primarily associated with cash used for purchases proceeds from the maturities of short-term investments partially offset by proceeds from the maturities cash used for purchases of short-term investments.

Cash flows from financing activities

Cash provided by financing activities of $74.9 million was minimal for the nine three months ended September 30, 2023 was primarily the result of net proceeds from the July 2023 Offering. March 31, 2024.

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize our product candidate. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture, and clinical trials of, and seeking regulatory approval for, our product candidate. In addition, subject to obtaining regulatory approval of our product candidate, we anticipate we may need additional funding in connection with our continuing operations.

As of September 30, 2023 March 31, 2024, we had cash, cash equivalents, and short-term investments of approximately $168.3 million $143.0 million. Although we have sufficient capital to fund our planned activities, including those discussed in *Note 9. Commitments – Manufacturing and Other Commitments and Contingencies*, in the notes to the condensed

consolidated financial statements included in this Quarterly Report, we may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, our product candidate and to begin commercialization of any approved product. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidate.

On July 17, 2023, we sold (i) an aggregate of 21,000,000 shares of Common Stock for $3.00 per share, which represented a 1% premium over the closing price on that date and (ii) 2023 Pre-Funded Warrants to purchase an aggregate of 5,666,667 shares of Common Stock at an exercise price of $0.001 per share for $2.999 per warrant pursuant to a Registered Direct Offering. The Common Stock and 2023 Pre-Funded Warrants were offered by the Company pursuant to its existing shelf registration statement\. The July 2023 Offering resulted in net proceeds to the Company of approximately $74.9 million, after deducting final underwriting discounts, commissions, and other estimated offering expenses.

Although we believe we are well capitalized based on our current operations, until we can generate a sufficient amount of product revenue to finance our cash requirements, we may finance our future cash needs primarily through the issuance of additional equity securities and potentially through borrowings, grants, and strategic alliances with partner companies. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts or grant rights to develop and market our product candidate to third parties that we would otherwise prefer to develop and market ourselves.

Recent Accounting Pronouncements

See *Note 2. Summary of Significant Accounting Policies – Recent Accounting Pronouncements*, of the condensed consolidated financial statements in this Quarterly Report for a discussion of recent accounting pronouncements and their effect, if any, on us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We have market risk exposure related to our cash, cash equivalents, and short-term investment securities. Such interest-earning instruments carry a degree of interest rate risk; however, we have not been exposed, nor do we anticipate being exposed, to material risks due to changes in interest rates. A hypothetical 1% change in interest rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements. Additionally, our investment securities are fixed income instruments denominated and payable in U.S. dollars and have short-term maturities, typically less than twelve months, and typically carry credit ratings of “A” at a minimum by two of three Nationally Recognized

Statistical Rating Organizations, specifically Moody's, Standard & Poor's, or Fitch. As such, we do not believe that our cash, cash equivalents, and short-term investment securities have significant risk of default or illiquidity.

We also have interest rate exposure related to our long-term debt. Refer to *Note 6. Long Term Debt* of the unaudited condensed consolidated financial statements in this quarterly report on Form 10-Q for additional discussion. The Amended Loan Agreement with Silicon Valley Bank bears interest equal to the greater of (i) 3% and (ii) the prime rate reported in The Wall Street Journal, minus a spread of 0.5%, which was 8.0% on September 30, 2023 March 31, 2024. Changes in the prime rate would have impacted our interest expense associated with our secured term loan. If a 10% change in interest rates from the interest rates on September 30, 2023 March 31, 2024, were to have occurred, this change would not have had a material effect on our interest expense with respect to outstanding borrowed amounts.

We have ongoing operations in Europe and pay those vendors in local currency, including Euros or Danish Krone. At times, we seek to limit the impact of foreign currency fluctuations through the use of derivative instruments and short-term foreign currency forward exchange contracts not designated as hedging instruments. We did not recognize any significant exchange rate losses during the nine three months ended September 30, 2023 March 31, 2024 and 2022. 2023. A 10% change in the Euro-to-dollar or Krone-to-dollar exchange rate on September 30, 2023 March 31, 2024, would not have had a material effect on our results of operations or financial condition.

Inflation Additionally, inflation generally affects us by increasing our cost of labor, supplies and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

The Company currently maintains depository accounts and has a debt facility with Silicon Valley Bank, as acquired by First Citizens BancShares, Inc. On March 10, 2023, the FDIC took control of Silicon Valley Bank and created the National Bank of Santa Clara to hold the deposits of Silicon Valley Bank after Silicon Valley Bank was unable to continue its operations. On March 27, 2023, First Citizens BancShares, Inc. (Nasdaq: FCNCA) announced that it had entered into an agreement with the FDIC to purchase all of the assets and liabilities of Silicon Valley Bank and all bank deposits.

In order to mitigate risks associated with our banking deposits, the Company maintains a significant portion of its liquidity in U.S. Treasury money market funds and other short-term investments with custodial services provided by U.S. Bank, N.A. The Company continues to monitor the circumstances surrounding First Citizens BancShares, Inc. and its acquisition of Silicon Valley Bank and has not experienced, and does not anticipate, any material impacts on its financial condition or operations.

Despite the aforementioned bank failure, we do not believe that we are currently exposed to material changes in the risks related to our cash, cash equivalents, and short-term investment securities, interest rates of our long-term debt, or foreign currency exchange rates. We are cautiously and actively monitoring potential risks associated with these instruments.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management has evaluated, under the supervision and with the participation of our Chief Executive Officer and Chief Financial and Administration Officer, the effectiveness of our disclosure controls and procedures as of September 30,

2023 March 31, 2024, pursuant to and as required by Rule 13a-15(b) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2023 March 31, 2024, our disclosure controls and procedures, as defined by Rule 13a-15(e) under the Exchange Act, were effective and designed to ensure that (i) information required to be disclosed in our reports filed or submitted under the Exchange Act (i) is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (ii) information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial and Administration Officer, we assessed the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). As a result of that assessment, management concluded that our internal control over financial reporting was effective as of September 30, 2023 March 31, 2024 based on criteria in *Internal Control – Integrated Framework* (2013) issued by the COSO.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the nine three months ended September 30, 2023 March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors. We are not currently a party to any material pending litigation or other material legal proceeding.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report, you should carefully consider the risk factors and other cautionary statements described under the heading "Item 1A. Risk Factors" included in the Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, and the risk factors and other cautionary statements contained in our

other filings with the SEC, which could materially affect our business, financial condition or future results. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition, or future results. There have been no material changes in our risk factors from those described in the Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, or our other SEC filings.

Item 2. Unregistered Sales of Equity Securities, and Use of Proceeds and Issuer Purchases of Equity Securities. Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

During the quarter ended September 30, 2023 March 31, 2024, no officer or director of the Company adopted or terminated any contract, instruction, or written plan for the purchase or sale of securities of the Company's common stock that is intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement as defined in 17 CFR § 229.408(c).

Item 6. Exhibits.

An Exhibit Index has been attached as part of this report and is incorporated by reference.

Exhibit Index

Exhibit Number	Description

3.1	Composite Amended and Restated Certificate of Incorporation, as amended, of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-3 filed on July 6, 2021).
3.2	Amended and Restated Bylaws of Savara, Inc, dated March 28, 2023 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 30, 2023).
4.1 10.1+	Form of Pre-Funded Warrant Master Services Agreement (the "Agreement"), dated February 13, 2024, by and between Fujifilm Diosynth Biotechnologies UK Limited, Fujifilm Diosynth Biotechnologies Texas, LLC, and Fujifilm Diosynth Biotechnologies U.S.A., Inc. and Savara Inc.
10.2	Savara Inc. 2021 Inducement Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report Registration Statement on Form 8-K S-8 filed on July 13, 2023 March 7, 2024).
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 and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation With Embedded 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 Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
+	Indicates portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K.

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.

Savara Inc.

Date: November 9, 2023 May 9, 2024

By: /s/ Matthew Pauls

Matthew Pauls

Chief Executive Officer and Chair of the Board of Directors

(Principal Executive Officer)

Date: November 9, 2023 May 9, 2024

By: /s/ David Lowrance

David Lowrance

Chief Financial and Administrative 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) is the type the registrant treats as private or confidential. [***] indicates where such information has been omitted.

(1) FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED

(2) FUJIFILM DIOSYNTH BIOTECHNOLOGIES TEXAS, LLC

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

AND

(4) Savara Aps

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**"); and

(4) **Savara ApS** incorporated and registered in Denmark whose registered office is at Lundgrens Advokatpartnersetskab Tuborg Boulevard 12 2900 Hellerup Hovedstaden (the "**Customer**").

BACKGROUND

(A) Fujifilm (as defined below) is a biopharmaceutical contract development and manufacturing organizatior Customer wishes to appoint Fujifilm to carry out development and manufacturing services in relation to cer the Customer's products.

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

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 the purposes hereof (and clause 15.2), "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 and/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;
"Ancillary Charges"	has the meaning given to it in clause 8.2;

“Ancillary Services”	has the meaning given to it in Schedule 1 (Charges);
“Applicable Laws”	applicable law (which, for the avoidance of doubt, includes applicable common law), regulations, and binding guidance which applies in the jurisdiction in which the Program is being performed or where Fujifilm Services or Ancillary Services are 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 [***];
“Batch”	a quantity of Product that is produced from a run of the Process;
“Batch Cancellation Fee”	the Batch Cancellation Fee described in Schedule 1;
“Batch Fee”	if the Batch Fee is clearly described in the applicable SoW the Batch Fee for that SoW shall be the Batch Fee described in the SoW, however, if the Batch Fee is not clearly described in the applicable SoW it will be deemed to be, in respect of any Batch under that SoW, all Charges for Fujifilm Services in respect of the Manufacturing Stages carried out in connection with that Batch which are described in the applicable SoW;
“Business Day”	a day other than a Saturday, Sunday or a day on which the New York Stock Exchange is closed and, where a notice is being given or obligation performed under this Agreement or a SoW to which FDBK is a party, a public holiday in England;

“cGMP”	Represents principles and practices applied to the manufacture of pharmaceutical materials as supported by the following cGMPs for drugs, as applicable to the material being manufactured (e.g. non-sterile bulk API / Drug Substance(s)): (i) the U.S. Federal Register volume 66 No 186 the FDA Regulations 21 CFR Part 11, 210, 211, 600 and 610 and ICH Q7; (ii) the Rules governing medicinal products in the European Union under the EC, 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, Part III GMP related documents, Annexes and Part IV GMP requirements for Advanced Therapy Medicinal Products, as applicable to the Product manufactured; and (iii) United Kingdom Human Medicines Regulations 2012 (HMR, SI 2012/1916, as amended), Guidelines on Good Manufacturing Practice, Parts and Annexes as EudraLex, Volume 4 above;

“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;
“Change”	has the meaning given to it in clause 14;
“Charges”	has the meaning set out in clause 8.2;
“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 Drug Substances of similar nature, complexity and developmental stage in the same or similar circumstances as the Product;
“Competitor”	a contract development and/or manufacturing organization in the biopharmaceutical industry;

“Confidential Information”	the fact and terms of this Agreement and 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 including any ideas; business methods; finance; prices, business, financial, marketing or development plans; products or services, know-how or other matters connected with products or services manufactured and/or marketed; customer lists or details; computer systems and software; which is (in each case) provided to, or obtained by, one party from the other. For clarity, Confidential Information of Customer includes Customer Background IP and Customer Foreground IP;
“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), plasmids, 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;
“Consumables Delay”	Has the meaning given to it in clause 15.1.2;
“Customer Foreground IP”	all Foreground IP that constitutes an improvement or modification or derivative which is specific to, or requires use of, the Customer’s Background IP, Customer’s Confidential Information or Customer’s Materials which have been provided to Fujifilm by the Customer pursuant to the Program in each case, obtained or developed by any party hereto (or any of its subcontractors);
“Delay”	has the meaning given to it in clause 15.1.1;

“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;

"Disposition"	the Stage during which (i) the Product is tested for compliance versus the Product Specification; (ii) all production instruction and analytical records relating to cGMP manufacture of each cGMP Batch prepared by Fujifilm are reviewed; and (iii) a Fujifilm recommendation for Product release or reject is made; in each case as applicable;
"Drug Product"	the final dosage form of product which is, or 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, contains the active ingredient(s) 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"	the date of final signature by all parties to this Agreement being the date the last signing party signs this Agreement;
"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"	(a) FDBK: Belasis Avenue, Billingham, TS23 1LH, England (b) FDBT: 100 Discovery Drive, Suite 200 College Station, Texas 77845 United States of America; or (c) FDBU: 101 J Morris Commons Lane, Morrisville, North Carolina 27560, United States of America, or such other Fujifilm facility specifically identified and agreed to by Customer in a Scope of Work;
"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, cyber-attack, currency restrictions but shall not include the failure of Drug Product in clinical trials or failure of Drug 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 (alone or jointly) in the course of the performance of a Program;
“Fujifilm”	FDBK, FDBT and/or FDBU as the context requires in accordance with clause 1.4;
“Fujifilm Foreground IP”	all Foreground IP other than Customer Foreground IP;
“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 disregard of the need to use reasonable care, which is likely to cause foreseeable grave injury or harm to persons, property, or both;
“Historic Documents”	any historic contractual documentation which cover the same subject matter as a Program as identified in the relevant SoW;
“Indemnify”	on demand to indemnify and hold harmless and keep indemnified, and held harmless, the party to be indemnified and held harmless on an after tax basis;
“Intellectual Property Right”	any current and future intellectual property rights and interests including patents, utility models, designs, design rights, copyright (including rights in software), 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;
[***]	[***]

“Liabilities”	any (i) liabilities of any nature, whether accrued, absolute, contingent or otherwise and whether in contract, tort (including negligence) or otherwise; (ii) losses, costs (including internal costs/overheads), damages, fines or expenses including reasonable legal fees; and (iii) claim, demand, proceeding, action or cause of action including those by third parties; in each case howsoever arising. “**Liability**” shall be construed accordingly;

“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;
“Material Review Board” or “MRB”	a cross-functional committee, led by quality assurance, that consists of representation from program management, quality control (as applicable), and manufacturing. Customer representation is required;
“Materials”	Has the meaning given to it in clause 7.1;
“Modifications”	a modification to a Facility; or equipment (including Process specific qualification and installation of existing equipment), required in order to perform a Process and detailed in the applicable Scope of Work;
“Non-Conforming Batch”	a cGMP Batch which has not been produced in accordance with cGMP and/or does not meet the Product Specification;
“Non-Manufacturing Stage”	any Stage of a Program, which is not a Manufacturing Stage, including (for clarity) the production and testing of Demonstration Batches;
“Process”	the particular process used, or to be used for manufacture of the Product, as set forth in the Process Specification;
“Process Specification”	the Process operating parameters and specifications as documented in the regulatory submission and/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 and/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, reagent, intermediate or molecule) created during and as a result of performing the Process. The name of the relevant Product is identified in the applicable Scope of Work;
“Product Specification”	the Product specification for Product which is documented in a QA Document;

“Program”	a program of work as set out in the applicable Scope of Work (or more than one Scope of Work, as the case may be) to be carried out by Fujifilm in accordance with the terms of this Agreement;
“Program Cancellation Fee”	an amount equal to the sum of: (i) the relevant Batch Cancellation Fee in respect of every cancelled Manufacturing Stage in the Program; and (ii) the amount calculated under clause 15.3.1(b) in respect of cancelled Non-Manufacturing Stages in the Program;
“Program Manager”	the Program manager appointed by each of Fujifilm and the Customer under the applicable SoW;
“Program Plan”	the Program plan controlled by Fujifilm’s Program Manager and communicated to the Customer regularly including prior to any relevant Program management meetings;
“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 or any cGMP documents agreed by the parties in writing;
"Regulatory Authority"	the U.S. Food and Drug Administration, the European Medicines Agency, the Medicines & Healthcare products Regulatory 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;
"Scope of Work" or "SoW"	the document setting out the detail of the Fujifilm Services and/or Ancillary Services to be undertaken by Fujifilm for the Customer;
"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. For the purposes of clause 10, a sub-stage described in a SoW (for example a Stage that is described by the Stage number and a suffix such as Stage 1A) shall be deemed to be an independent Stage in its own right;
"Subcontracted Work"	work subcontracted by Fujifilm under clause 22.3 but excluding any work subcontracted between FDBK, FDBT and/or FDBU;

"Tax"	any and all taxes, charges, levies, assessments and other fees of any kind imposed by any governmental or other authority (including, but not limited to, value added tax, sales tax or any other similar type of turnover tax); and
"Willful Misconduct"	a knowing violation of a reasonable and uniformly enforced rule or policy. It means intentionally doing that which should not be done or intentionally failing to do that which should be done, knowing that injury may result or recklessly disregarding the possibility that injury may result.

1.2. In this Agreement (except where the context otherwise requires) 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.

1.3. Where a provision requires agreement, consent and/or approval of a party, such agreement, consent approval, unless expressly stated otherwise, may not be unreasonably withheld, delayed or conditioned.

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

1.5. Insofar as this Agreement or a Scope of Work obliges any party to this Agreement to negotiate, take actio do something, that party shall conduct such communications, negotiations, take such action or do such th good faith acting professionally and, in the case of Fujifilm, using Commercially Reasonable Efforts to achie result contemplated in this Agreement. There shall be a general obligation on the parties to act in good fai with professionalism in relation to the matters contemplated in this Agreement.

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

1.7. In the case of conflict or ambiguity between the terms of this Agreement or any specific Scope of Work a terms of the QA Documents, the terms of the QA Documents shall prevail solely in relation to cGMP matters subject to clause 10.12.

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

1.9. The parties agree that all Scopes of Work, Changes, notices and other documents or correspondence und Agreement and the Quality Agreement shall be in English.

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 Scope of Works) shall be entered into by the parties for the provision of each Program. A purchase order which is issued by the Customer shall be treated exclusively as a finance tool for the purposes of raising invoices and any terms set out, or referred to, on such purchase order shall have no effect and shall not bind Fujifilm.

2.2. The provisions of this Agreement shall apply to each Scope of Work and no Scope of Work shall be effec 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 Scope of Work constitutes a separate contract.

2.4. This Agreement is non-exclusive in nature and, subject always to clause 11, nothing herein will preve Customer from engaging other third parties to perform services that are the same or similar to those 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, provide 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 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 o Agreement.

4. PERFORMANCE OF PROGRAMS

4.1. Fujifilm shall carry out the Fujifilm Services and each Program, or parts of a Program, [***] using Comme Reasonable Efforts and in accordance with:

4.1.1. the terms of this Agreement and any Scope of Work;

4.1.2. Applicable Laws;

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

4.1.4. the Process Specification for the applicable cGMP Batch (if any).

4.2. Fujifilm shall retain appropriately qualified and trained personnel with the requisite knowledge and experie undertake the Program in accordance with this Agreement.

4.3. The parties agree that it shall not be considered a breach of this Agreement, or any Scope(s) of Work, by Fu an objective of a Program is not achieved provided that Fujifilm has complied with its obligations set out in 4.1. Notwithstanding any contrary provisions in this Agreement or any Scope(s) of Work, the parties acknov and agree that the services to be performed during the Programs are by their nature developmental an Fujifilm cannot (and consequently does not) guarantee to the Customer the achievement of a successful ou for a Program, production of Conforming Batches or production of a specified volume of Product. At Custo request Fujifilm will provide reasonable information regarding why an objective of a Program has not been m

4.4. Each Scope of Work contains assumptions on which Fujifilm's ability to perform the Program depends. assumption set out in the Scope of Work proves to be incorrect or actual circumstances differ from an assur (including if such assumption cannot be met at such time as Fujifilm reasonably requires to enable it to perfo obligations) then Fujifilm will provide Customer with prompt written notice (email acceptable) of such cha assumptions, and the parties shall agree to a reasonable Change to account for the change in assumption.

4.5. The Customer shall:

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

4.5.2. comply with Applicable Laws in respect of its performance, including export laws and regulations, this Agreement, any Scopes of Work, and the Quality Agreement, and in respect of handling, us distribution of the Product; and

4.5.3. promptly provide all assistance, information, and advice and do all acts which Fujifilm may reaso request to enable Fujifilm to comply with its obligations and responsibilities under this Agreemen 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 Q 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 Q Agreement is executed and, to the extent applicable, any other relevant QA Documents are approv both parties.

5.2. Regulatory Assistance

5.2.1. The Customer shall provide Fujifilm with a copy of the Customer's Chemistry, Manufacturing and Co section of any submission to a Regulatory Authority supporting the Customer's regulatory filing activit the applicable Drug Product, Drug Substance or Process which relates to or contains information abo Process; the Facility (including Fujifilm equipment); the Fujifilm Services and/or the Ancillary Se ("CMC Section") in accordance with the Quality Agreement. The Customer shall not submit a CMC S without Fujifilm's written approval in relation to any information regarding, or impacting, Fujifilm inc any information regarding the Process, equipment, controls and analytics or any information provi the Customer by Fujifilm related to or in accordance with the Quality Agreement. [***]

5.2.2. During each Program the Customer may request assistance from Fujifilm in respect of the CMC Se subject to payment by the Customer of a reasonable commercial rate for such assistance and Fu reasonable expenses. However, no advice or assistance given by Fujifilm shall be deemed to 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 Customer in support of its regulatory filing activities within 30 calendar days of the request. If the Cus requires copies of the laboratory documents, provision of these will be subject to discussio 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 and/or Drug Product subject to clause 5.2.6 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;

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

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

(each a "**Fujifilm Regulatory Responsibility**").

5.2.5. Fujifilm will not, except to the extent required by Applicable Law or any Regulatory Authority, i correspondence directly with any Regulatory Authority regarding the Product without, in each instan only to the extent not prohibited by Applicable Law or any Regulatory Authority, providing the Cus with as much prior notice as possible.

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

5.2.7. The Customer shall not make any change to its regulatory filings, including its Investigational New application, which may have an impact on any Fujifilm Regulatory Responsibility without prior w agreement with Fujifilm (not to be unreasonably withheld or delayed).

5.3. No Debarment.

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

5.3.2. If during the Term, Fujifilm or any of its officers, directors, or its employees performing services und Agreement becomes so debarred, suspended, excluded, sanctioned, or otherwise declared inel Fujifilm will promptly notify the Customer. To the extent that Fujifilm itself becomes so deb suspended, excluded, sanctioned, or otherwise declared ineligible, the Customer may terminat Agreement and any relevant SoWs. To the extent a Fujifilm officer, director, employee performing se under this Agreement becomes so debarred, suspended, excluded, sanctioned or otherwise de ineligible, Fujifilm shall remove the individual from performing services under this Agreement.

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

6.1. Each cGMP Batch will be determined to be a Conforming Batch or a Non-Conforming Batch.

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

6.3. In respect of Conforming Batches, Fujifilm will complete Disposition, issue a certificate of analysis and a Cert of Compliance, and any other documentation required by the QA Documents. The Customer will have the r inspect the Batches following delivery of the Batch to determine if they are Conforming or Non-Confo Batches. [***]

6.4. If a Batch is a Non-Conforming Batch and the cause of that Batch being a Non-Conforming Batch is not a failure by Fujifilm to comply with clause 4.1 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 the Non-Conforming Batch (such as analysis of the Batch) or manufacture of a replacement cGMP Batch 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 4.1 then Fujifilm shall use Commercially Reasonable Efforts to manufacture a replacement cGMP Batch ("**Replacement Batch**") as soon as is reasonably practicable ensuring that the Customer is treated equitably (giving due consideration to patient care and safety) in any asset re-scheduling that may be undertaken to accommodate this. In these circumstances:

6.5.1. the Customer shall pay for:

(a) all Charges in respect of the original Non-Conforming Batch in accordance with the SoW (that any installments of the Charges which are not due until a trigger which occurs after the that the Non-Conforming Batch is determined to be a Non-Conforming Batch shall become instead on completion of the relevant trigger in relation to the Replacement Batch, for exar delivery); and

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

6.5.2. the parties shall mutually agree on the new manufacturing schedule for any Batches so affected, pro that Fujifilm uses its Commercially Reasonably Efforts to make available sufficient slots for the manuf of such Batches as soon as reasonably practicable ensuring that the Customer is treated equitably (due consideration to patient care and safety) in any asset re-scheduling that may be undertak accommodate this.

6.6. [***]

6.7. In respect of any Program in which an Engineering Batch is not executed prior to manufacture of the first cGMP Batch in such Program, if the first cGMP Batch is a Non-Conforming Batch, it will be deemed that the cause of such Batch being a Non-Conforming Batch is not a failure of Fujifilm to comply with clause 4.1 and clause 6.4 shall apply, unless the cause of the cGMP Batch being a Non-Conforming Batch is Fujifilm's Gross Negligence or Wilful Misconduct, in which case clause 6.5 shall apply.

6.8. If the Customer requests delivery of a Non-Conforming Batch, the parties shall agree in writing (in a Chang fair consideration payable for that Non-Conforming Batch. Fujifilm agrees to deliver a Non-Conforming Batch Customer on the express condition that it (i) will not be used for human or clinical trials; (ii) will be labeled a for Human Use"; and (iii) is subject to the Customer's indemnity given under clause 10.8.

6.9. If the parties cannot agree if a Batch is a Conforming Batch or a Non-Conforming Batch and/or if the caus Batch being a Non-Conforming Batch is not agreed by the parties, then this clause 6.9 shall apply:

6.9.1. the parties will first exhaust the investigation/resolution options set out in the Quality Agreement inc reference to the MRB under the Quality Agreement and transparent disclosure of all applicable repor analysis on which their respect opinion is based;

6.9.2. if the MRB is unable to resolve this matter then the documentation related to the applicable Batch v reviewed by an independent cGMP consultant acceptable to both parties (acting reasonably). The re such independent review will be binding for both parties solely for the purpose of determining wheth Batch is a

Non-Conforming Batch and/or if a Non-Conforming Batch is caused by a failure by Fujifilm to comply with clause 4.1;

6.9.3. if the independent cGMP consultant finds that the Batch is not a Non-Conforming Batch or that the

Conforming Batch was not caused by a failure by Fujifilm to comply with clause 4.1, the Customer w Fujifilm for the Batch in question in accordance with clause 6.4 plus the reasonable cost to Fujifilm investigation;

6.9.4. if the independent cGMP consultant finds that the Batch is a Non-Conforming Batch and that the Conforming Batch is caused by a failure by Fujifilm to comply with clause 4.1, the remedial procedu out in clause 6.5 will be applied; and

6.9.5. unless otherwise agreed by the parties, the costs associated with the independent cGMP consultant paid by the party against whom the independent cGMP consultant finds.

6.10. In the event that either party becomes aware of information that may require a recall of any Product, such shall notify the other party in writing within twenty-four (24) hours of becoming aware of such information. Customer is required by a Regulatory Authority or voluntarily chooses to initiate a recall, the Customer shall Fujifilm. Customer shall control the conduct of any recall (including any determination as to whether a re required) and shall implement and coordinate all activities reasonably necessary in connection with such including making all contact with relevant Regulatory Authorities. Fujifilm shall reasonably cooperate Customer and provide assistance to Customer, as reasonably requested, in conducting such recall in accor with the protocols and procedures contained in the Quality Agreement.

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 and/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 2020) and clauses 7.2 to 7.7 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 2020)) following notification, of at least 2 (two) Business Days, by Fujifilm to the Customer that it will make those Materials available for collection (the "**Delivery Date**") in accordance with an indicative delivery schedule which shall be agreed by the parties' Program teams in advance.

7.3. For the avoidance of doubt, and unless otherwise expressly agreed by the parties in writing, Fujifilm will not make a cGMP Batch available for collection by the Customer until both: (a) Disposition is complete; and (b) the Customer's quality assurance team has approved such Product for release in a written notice, following conduct of Customer's final disposition and release activities (including any release testing required); provided that such final disposition and release must be completed by Customer within [***] of Fujifilm first making available to Customer all production instruction and analytical records relating to the manufacture of such Product, together with the results of any testing of such Product (collectively, the "**Disposition Documentation**"). [***] For the avoidance of doubt, Materials for which a licence is required

under clause 11.3 will not be made available for collection by the Customer until a licence has been signed by the parties.

7.4. If the Customer fails to collect Materials within two (2) Business Days of the Delivery Date, Fujifilm will is further notice to the Customer [***]. If the Customer has still not collected the Materials on the date that Business Days prior to the expiry of the [***], Fujifilm shall be entitled (at its discretion) to continue to sto Materials at the Customer's risk and expense, or destroy the Materials at the Customer's risk and expens provided that Fujifilm has issued a further notice to Customer warning that the Materials will be dest Notwithstanding the foregoing, Fujifilm shall be under no obligation to store the Materials if the Custome breach of its obligations under clause 8.4.

7.5. Risk in Material shall pass to the Customer on the Delivery Date; save for risk in (a) Process-Specific-Equi or Process-Specific Consumables in relation to which risk shall pass as set forth in clause 7.7 and (b) Mate which a licence is required under clause 11.3 in relation to which risk shall pass on the date on which F notifies the Customer it would have made the Materials available for collection if a licence had been signed parties.

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

7.7. Title to, and risk in, the Process-Specific Equipment and/or Process-Specific Consumables purchased b Customer in accordance with Schedule 1 shall pass to the Customer on the earlier of (a) when Fujifil received payment in full (in cash or cleared funds) for such items in accordance with paragraph 3.1 of Sche or (b) the Delivery Date.

7.8. From time to time Fujifilm may agree to store Materials (including intermediate Product for future processi Customer. If Fujifilm agrees to store Materials the parties will enter into a storage agreement on Fujifilm's sta terms.

7.9. Delivery of any materials which the Customer is required to supply to Fujifilm pursuant to the SoW sh delivered to Fujifilm DDP, the Facility (Incoterms 2020). 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 Fujifilm to carry out se concerning the research and development, testing, manufacture and Disposition of the Product by Fujifilm u

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

8.2. The Customer shall pay to Fujifilm for each Program:

8.2.1. the Batch Fee(s);

8.2.2. the fees for the Fujifilm Services (other than the Batch Fee(s)) as set out in the relevant Scope of and

8.2.3. the fees for Ancillary Services in accordance with Schedule 1 (the "**Ancillary Charges**"),

together the"**Charges**".

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

8.4. The Customer shall pay each invoice issued to it by Fujifilm within 30 (thirty) days of the date of invoice, in fu in cleared funds in the currency specified in the SoW by electronic transfer to the financial institution speci the relevant invoice.

8.5. The Charges are exclusive of any Tax which may apply and which shall be payable by the Customer to Fuji the rate prescribed by law. For clarity, tax on Fujifilm's income, personnel, and assets will be the sole respon 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 provic Fujifilm or the Product, e.g. due to a change of law or practice or interpretation of the existing legislation or r determination of a relevant tax legislation or tax practice, then the Customer agrees that Fujifilm shall be er where Tax is imposed on a supply by Fujifilm under or in connection with this Agreement, to invoice the Cus (in a valid Tax invoice) for a sum equal to the amount of the Tax which becomes due on that supply and an and/or interest which is being levied on Fujifilm in relation to the outstanding sums and/or non-paymen 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 in respect of third p which relate to the purchase, importation, exportation, sale or other distribution of any materials del 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, ar unless required by law. If withholding tax is deducted then the Customer will provide all documer 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 sum to Fujif the due date for payment:

8.8.1. the Customer may (to be determined by Fujifilm in its discretion) be charged interest on the ov amount at the rate of [***]. Such interest shall be payable in respect of the period from the due dat actual payment of the overdue amount (whether before or after judgment) in accordance with claus [***]; and

8.8.2. (except where the Customer has complied with its obligations in clause 8.9 below) Fujifilm may not Customer that if it does not pay, Fujifilm will suspend work on the Program, including, without limi delivery of Materials, in respect of which payment is overdue, and if payment is not made within 10 Business Days of such notice, Fujifilm may suspend such work until payment has been made in full.

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 its receipt of the invoice in which such disputed a is included giving reasonable details of the dispute; 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.

8.10. If the Customer fails to pay any sum which is not the subject of a bona fide dispute under clause 8.9 wh same is due in accordance with clause 8.4 then Fujifilm may elect, at its discretion, to treat such non-payme material breach of either the relevant SoWs under clause 15.5.1 or a material breach of this Agreement clause 15.2.1.

8.11. A party shall not be entitled to withhold, set off or reduce payment of any amounts payable under this Agre

by any amounts which it claims are owed to it by another party under this Agreement or any other agreement

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 re power and authority to execute and deliver this Agreement and to perform its obligations hereunder; a

9.1.2. subject to Customer complying with its payment obligations under clause 8, title to Product will pass Customer under this Agreement free and clear of any security interest, lien, or other encumbrance; ar

9.1.3. to Fujifilm's knowledge, the use by Fujifilm or the Customer of Fujifilm's Background IP or Fu Foreground IP 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 permitted to be limited or excluded by law, including fraud or fraudulent misrepresentation or liability for de personal injury caused by its negligence. [***].

10.2. EXCEPT IN RESPECT OF BREACH BY FUJIFILM OF CLAUSE 13 (CONFIDENTIALITY) OR LIAE ARISING UNDER CLAUSE 12.1 (IPR INDEMNITY) AND SUBJECT ALWAYS TO CLAUSES 10.3, 10.8, 10.10, and 10.11: FUJIFILM'S TOTAL LIABILITY, WHETHER OR NOT ARISING PURSUANT TO AN INDEM IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR BREACH OF STATUTORY D MISREPRESENTATION, RESTITUTION OR OTHERWISE ARISING UNDER THIS AGREEMENT OR A S OF WORK OR IN CONNECTION WITH THE PERFORMANCE OR

CONTEMPLATED PERFORMANCE OF THIS AGREEMENT OR A SCOPE OF WORK SHALL IN ALL CIRCUMSTANCES BE LIMITED AS FOLLOWS:

10.2.1. TO THE EXTENT THERE HAS BEEN NO GROSS NEGLIGENCE OR WILLFUL MISCONDUC FUJFILM:

(a) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WI

NON-MANUFACTURING STAGE, FUJIFILM'S TOTAL LIABILITY SHALL BE LIMITED TO AND

(b) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WIT MANUFACTURING STAGE (INCLUDING LIABLITY RELATING TO THE MANUFACTURE OR FAILURE TO MANUFACTURE, A BATCH), FUJIFILM'S TOTAL LIABILITY TO CUSTO SHALL BE LIMITED TO [***]; OR

10.2.2. TO THE EXTENT THERE HAS BEEN GROSS NEGLIGENCE OR WILLFUL MISCONDUCT BY FUJ

(a) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WIT NON-MANUFACTURING STAGE, FUJIFILM'S TOTAL LIABILITY TO CUSTOMER SHALL LIMITED TO [***]; AND

(b) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WIT MANUFACTURING STAGE, (INCLUDING LIABLITY RELATING TO THE MANUFACTURE OR FAILURE TO MANUFACTURE, A BATCH), FUJIFILM'S TOTAL LIABILITY TO CUSTO SHALL BE LIMITED TO [***]; AND

10.2.3. IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER ANY SCOPE OF WORK, FUJIF TOTAL LIABILITY TO CUSTOMER SHALL BE LIMITED IN AGGREGATE PER CALENDAR YEA [***]; AND

10.2.4. IN RESPECT OF ANY OTHER LIABILITY RELATING TO THIS AGREEMENT FALLING OUTSIDE SCOPE OF CLAUSES 10.2.1 AND 10.2.2, FUJIFILM'S TOTAL LIABILITY TO CUSTOMER SHA LIMITED PER CALENDAR YEAR TO [***].

10.3. [***]UNDER NO CIRCUMSTANCES SHALL FUJIFILM BE LIABLE, WHETHER IN CONTRACT, (INCLUDING NEGLIGENCE), FOR BREACH OF STATUTORY DUTY OR OTHERWISE, ARISING UNDER CONNECTION WITH THIS AGREEMENT FOR: LOSS OF PROFIT; LOSS OF BUSINESS; DEPLETIO GOODWILL; LOSS OF ANTICIPATED SAVINGS; LOSS OR CORRUPTION OF DATA OR INFORMATIO ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR PURE ECONOMIC LOSS, COSTS, DAMAGES, CHA OR EXPENSES.

10.4. [***].

10.5. 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 except to the extent those Liabilities have arisen pursuant to the Gross Negligence or Willful Misconduct of Fujifilm in which case Fujifilm shall bear such Liabilities up to the amounts for which Fujifilm is liable to the Customer under clause 10.2.2 and the Customer's Indemnity of Fujifilm under this clause 10.5 shall apply to any Liabilities arising thereafter.

10.6. 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) [***], except to the extent that Fujifilm is liable under clause 12.1.

10.7. Liability for Fujifilm Services: Fujifilm shall Indemnify Customer from and against [***] up to the amounts for Fujifilm is liable to the Customer under clause 10.2.2.

10.8. Liability for Non-Conforming Batches:

10.8.1. THE PROVISIONS OF CLAUSE 6 SHALL APPLY TO NON-CONFORMING BATCHES AND FUJ SHALL HAVE NO LIABILITY IN RESPECT OF NON-CONFORMING BATCHES EXCEPT TO CO WITH CLAUSE 6.

10.8.2. FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TI WHATSOEVER (WHETHER AS TO COMPLIANCE WITH CGMP OR OTHERWISE) IN RESPEC NON-CONFORMING BATCHES OR THE USE BY THE CUSTOMER OF NON-CONFORMING BATC

10.8.3. If the Non-Conforming Batch is delivered to the Customer pursuant to clause 6 at the Customer's re the Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Af arising out of or resulting from the use of that Non-Conforming Batch after delivery to the Customer.

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

10.9. Liability for Demonstration and Engineering Batches

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

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

10.9.3. The Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Af arising out of or resulting from the use of the Demonstration Batches or Engineering Batches.

10.9.4. The Customer uses any material produced in a Demonstration Batch or Engineering Batch at its ow and shall undertake such tests as are necessary in order to satisfy itself that such materials are fit f purposes for which the Customer proposes to use such materials. Customer expressly agrees that P produced pursuant to a Demonstration Batch or an Engineering Batch is not suitable, and will not be for human consumption or use or in clinic trials.

10.10. FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TI WHATSOEVER IN RESPECT OF ANY ADVICE OR ASSISTANCE GIVEN BY FUJIFILM IN CONNECTION THE USE OF THE PRODUCT IN OR AS A DRUG PRODUCT (INCLUDING ADVICE OR ASSIST RELATED TO ANY REGULATORY APPROVAL).

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

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

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

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

10.15. 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:

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

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

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

10.15.4 the Indemnified Party shall fully cooperate and assist the Indemnifying Party, at the Indemnifying P cost and expense, in relation to the Indemnity Claim (without limiting the extent of the Indemnity).

10.16. Each party shall maintain adequate insurance (which may be through self-insurance) to enable it to sati Liabilities under this Agreement as they arise.

11. INTELLECTUAL PROPERTY

11.1. Subject to clause 11.2 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, worldwide licence to use Customer's Background IP f exclusive purpose of performance of the Program. Customer warrants that, to its knowledge, the use by Fujif its Authorized Third Parties) of Customer's Background IP in accordance with this clause 11.2 shall not i any third party's Intellectual Property Rights.

11.3. Fujifilm shall not be obliged to deliver any materials (including any cell bank or cell paste) comprising [***] and until a licence is granted in writing on terms to be agreed under the relevant Background IP. Fujifilm sh entitled to charge the Customer for storage of any such materials which would have been delivered under 7.2 if a licence had been granted under this clause 11.3 until the time that such licence is granted. Cus

acknowledges that storage may be at a third party storage facility unless Fujifilm and Customer have agr writing otherwise.

11.4. All title to and all rights and interest in any Customer Foreground IP shall vest in Customer. Fujifilm hereby a 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 h 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 exec documents and do all such further acts as the requesting party may reasonably require to perfect the assig under clause 11.4 or 11.5.

11.7. Fujifilm grants to Customer a royalty free, non exclusive, worldwide licence to use the Fujifilm Foreground I the exclusive purpose of manufacturing the Product.

12. **INTELLECTUAL PROPERTY INDEMNITY**

12.1. Fujifilm shall fully Indemnify the Customer from and against all Liabilities incurred by the Customer or its Af arising out of any third party claim that Fujifilm's use of Fujifilm's Background IP or Foreground IP in performi Program infringes such 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 a out of any third party claim that:

12.2.1. Fujifilm's use of (i) materials provided by the Customer to Fujifilm or (ii) Customer's Intellectual Pr Rights, in accordance with this Agreement; or

12.2.2. (excluding Liabilities in relation to which Fujifilm Indemnifies the Customer pursuant to clause 12. development or manufacture of the Product and/or any other

deliverables which are an output of the Program or the use of the Process in accordance with this Agreement,

infringes such 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 requ Indemnifying Party to prove that it has adequate financial means to pay out under the indemnity prov provided for in those clauses (for example by way of set aside capital or insurance). If the Indemnifying cannot so prove it has the financial standing to meet its obligations with respect to the Indemnities und applicable clause then the Indemnified Party has the option to terminate this Agreement on written no Fujifilm exercises its option to terminate under this clause 12.3 then (without prejudice to the survival relevant Indemnity obligations) such termination shall be treated as a termination under clause 15.3.2.

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:

(a) complying with its obligations under this Agreement and each SoW;

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

(c) 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 Rec Party's:

(a) Affiliates;

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

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

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

the "**Authorized Third Parties**".

13.2. The parties acknowledge and agree that the Disclosing Party Authorized Third Parties may disclo Confidential Information directly to the Receiving Party or its Authorized Third Parties and that such disc shall be governed by this clause 13. 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 30 (thirty) days of receipt of the Disclosing Party's written request (includin termination of this Agreement and any SoW):

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

13.3.2. expunge and/or make irretrievable all Confidential Information of the Disclosing Party from any compu other similar device in which it is stored and, if further requested, certify in writing signed by an auth representative that it has done the same (provided that this clause 13.3.2 shall not apply to automa archived electronic files or electronic back-ups made in the ordinary course of business, on secured servers, which cannot reasonably be deleted and such electronic files shall be retained subject 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 Confi Information (and, if further requested, certify in writing signed by an authorized representative that 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 Regulatory Authority 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 inform being disclosed by the Receiving Party or its Authorized Third Parties in breach of this Agreement (that any compilation of otherwise public information in a form not publicly known shall still be treat Confidential Information);

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

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

13.4.4. was lawfully in the possession of the Receiving Party before the information was disclosed b Disclosing Party;

13.4.5. is developed by or for the Receiving Party independently of the information disclosed by the Disc Party; or

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

13.5. Receiving Party may disclose Confidential Information of Disclosing Party when necessarily required pursua statutory or regulatory obligation, but then only to the extent of such required disclosure and save th Receiving Party shall, to the extent it is lawful to do so, give prompt notice to the Disclosing Party of any potential disclosure and allow the Disclosing Party a reasonable opportunity to limit such disclosure.

13.6. Customer may use and disclose Confidential Information of Fujifilm solely to the extent necessa communications with existing or prospective Customer's investors, sub-licensees or commercial partners pro that: [***].

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. Fujifilm will use Commercially Reasonable Efforts to prepare a draft Change [***] following agreement with the Customer on the need for a Change.

14.2. If the parties are unable to agree the terms of a Change and the dispute resolution process set out in clau has been unsuccessfully exhausted Fujifilm may terminate the relevant SoW(s) and such termination sh deemed to be for the Customer's convenience and clause 15.3 shall apply.

14.3. Without prejudice to clause 15.4, if there is a change to Applicable Law that comes into effect after the Ef Date that adversely affects, or is reasonably likely to adversely affect, production of Product by the Process conducted in accordance with Fujifilm's standard operating procedures or methods, and within the de constraints of the Facility, then the parties will enter into a mutually agreed upon Change to accommodat change of Applicable Law; the cost of which shall be allocated as follows:

14.3.1. If the change to Applicable Law specifically relates to the Product or Process, then Customer will be for the costs of the Change; and

14.3.2. if the change to Applicable Law specifically relates to the Facility as it is operated by Fujifilm acro customer base or the general manufacturing activities carried out by Fujifilm at the Facility, then Fujifi be liable for the costs of the Change; and

14.3.3. if the change to Applicable Law does not fall within either of clauses 14.3.1 or 14.3.2, the parti negotiate in good faith and agree on how those costs will be borne.

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 Program Plan (a "**Delay**") and the parties cannot agree to a Change to accommodate that Delay:

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

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

15.1.2. Notwithstanding anything to the contrary in this Agreement or the applicable Scope of Work, in the event that, despite Fujifilm having exercised Commercially Reasonable Efforts to procure all necessary Consumables, such Consumables are not available in the quantities or at the time as

may be required to manufacture a Batch for Customer pursuant to Fujifilm's current asset plan, Fujifilm's obligation to manufacture and deliver such Batch, and Customer's obligation to take delivery and pay for such Batch, shall in each case be delayed until such time as sufficient Consumables are available for the manufacture of such Batch ("**Consumables Delay"**). The Customer agrees that:

(a) it will use reasonable efforts to assist Fujifilm to procure Consumables that are subject Consumables Delay (which may include agreeing to allow Fujifilm to procure those Consuma from an alternative supplier); and

(b) if it requires Fujifilm to take specified action to mitigate a potential Consumables Delay and action of itself causes a Delay then clause 15.1.1 will apply; and

(c) Consumables which Customer agrees to provide to Fujifilm under a SoW are excluded from definition of Consumables Delay and will be subject to clause 15.1.1.

15.1.3. The parties' Program teams shall mutually agree on the new manufacturing schedule for any Ba affected by a Consumables Delay, provided that Fujifilm shall use its Commercially Reasonably Effo make available sufficient slots for the manufacture of such Batches as soon as reasonably po ensuring that the Customer is treated equitably (giving due consideration to patient care and safety) asset re-scheduling that may be undertaken to accommodate this.

15.2. Termination of this Agreement as a whole

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

(a) the other party commits a material breach of clauses 8.4, 11, 13, 20 and such breach:

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

(ii) is capable of cure, and the breaching party fails to commence and diligently purs remedy of the breach as soon as reasonably possible [***]such cure period sha

suspended during any time that a party seeks resolution of a dispute as to wheth alleged material breach occurred pursuant to clause 17;

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

(c) the other party is reasonably determined by the terminating party to be in material breach (two) or more contracts it has entered into with the terminating party (including any Scop Works); or

(d) the other party or the person controlling the other party has a change in control and the controlling entity is reasonably considered by the party giving notice either to be its c competitor or not to have reasonable financial creditworthiness.

15.3. Termination by the Customer for Convenience

15.3.1. The Customer may cancel one or more Non-Manufacturing Stages for convenience by giving written to Fujifilm in which case:

(a) the Non-Manufacturing Stage(s) shall terminate but in all other respects the SoW shall contin full force;

(b) the Customer shall pay Fujifilm the Charges that are due for the Fujifilm Services that have performed and [***] of the Charges for the Fujifilm Services that have not yet been perfor under the relevant Non-Manufacturing Stage(s) [***] plus: (i) any Ancillary Charges owe respect of Ancillary Services that have been performed, and (ii) such portion of any Anc Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm already incurred or has committed to later incur under a non-cancellable order, unrecover costs and expenses; and

in the event Customer terminates this Agreement or the Program where there are only Non-Manufacturing Stages contracted, the relevant SoW(s) shall terminate and this clause 15.3.1 shall apply when determining cancellation fees.

15.3.2. The Customer may cancel one or more Manufacturing Stage for convenience by giving written no Fujifilm in which case:

(a) the cancelled Manufacturing Stage(s) shall terminate but in all other respects the SoW continue in full force;

(b) the Customer shall pay the Charges that are due for the Fujifilm Services that have performed, the relevant Batch Cancellation Fee plus: (i) any Ancillary Charges owed in respe Ancillary Services that have been performed, and (ii) such portion of any Ancillary Charges relate to any element of an unperformed Ancillary Service for which Fujifilm has already incu or has committed to later incur under a non-cancellable order, unrecoverable costs and exper

15.3.3. The Customer may cancel a Program which includes Manufacturing Stages for convenience by written notice to Fujifilm in which case:

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

(b) the Customer shall pay the Charges that are due for the Fujifilm Services that have performed, the Program Cancellation Fee plus: (i) any Ancillary Charges owed in respe Ancillary Services that have been performed, and (ii) such portion of any Ancillary Charges relate to any element of an unperformed Ancillary Service for which Fujifilm has already incu or has committed to later incur under a non-cancellable order, unrecoverable costs and exper

15.3.4. If a critical Stage, or more than one Stage, under a Program which includes Manufacturing Sta cancelled and that has the effect of cancelling that Program as a whole (as determined by Fujifilm reasonably) then clause 15.3.3 shall apply instead of clauses 15.3.1 and/or 15.3.2.

15.4. Termination of a Program Due to Technical Issues.

15.4.1. With respect to a Program, Fujifilm may terminate a Program at any time up to commencement Manufacturing Stages for such program by giving written notice to the Customer if Fujifilm reasc believes that it will be unable to carry out and complete such Program in accordance with the Sc Work(s) due to discovery of a factor (other than a breach by Fujifilm of clause 4.1) which:

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

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

(c) is likely to have a material adverse effect on a customer's Product licence (being the lic authorizing marketing of a medicinal product granted by a Regulatory Authority (also known "Marketing Authorisation" in Europe)) or Manufacturing Licence (being the licence to manufa biotechnology-derived Drug Substances issued to Fujifilm by the applicable Regulatory Auth as a result of the Product being introduced into the Facility and that customer was a custom 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 Fujifilm terminates a Program under clause 15.4.1 then the Customer shall pay the Charges that a for the Fujifilm Services that have been performed and [***] of the Program Cancellation Fee plus: Ancillary Charges owed in respect of Ancillary Services that have been performed, and (ii) such por any Ancillary Charges that relate to any element of an unperformed Ancillary Service for which Fujifil already incurred or has committed to later incur under a non-cancellable order, unrecoverable cos expenses.

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 to the other party, specifying the nature of the material breach and, if the breaching party [***]that th period shall be suspended during any time that a party seeks resolution of a dispute as to wheth alleged material breach occurred pursuant to clause 17), then the non-breaching party shall have the 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 without prejudice to Fujifilm's other rights and remedies, the Program Cancellation Fee shall be paya the Customer to Fujifilm plus: (i) any Ancillary Charges owed in respect of Ancillary Services that been performed, and (ii) such portion of any Ancillary Charges that relate to any element unperformed Ancillary Service for which Fujifilm has already incurred or has committed to later incur a non-cancellable order, unrecoverable costs and expenses.

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 rela 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 whi 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 or any Scope of Work shall be without prejudice to the right 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 lice granted under or pursuant to this Agreement shall cease to have effect save as (and to extent) expressly provided for in this clause 15;

(b) the provisions of the following clauses together with any provision which expressly o implication is intended to come into or remain in force on or after termination shall continue i force and effect clauses 1, 8, 10, 11, 12, 13, 15, 17, 19, and 24; and

(c) the Customer shall immediately pay to Fujifilm all of Fujifilm's outstanding unpaid invoices interest and, in respect of Fujifilm Services and Ancillary Services supplied but for whic invoice has been submitted, Fujifilm may submit an invoice, which shall be payable withi (thirty) days of receipt.

16. **FORCE MAJEURE**

16.1. Subject to clause 16.2, no party shall be liable to the other(s) in respect of, and neither party will be entitled remedy from any party affected by the Force Majeure Event for, any delay or non-performance of such af party's obligations under any Scope of Work (except for the payment of money) arising from a Force M Event.

16.2. If a party is delayed or prevented from performing its obligations due to a Force Majeure Event such party sh

16.2.1. give notice of such delay or prevention due to the Force Majeure Event to the non-affected parties as as reasonably practical stating the commencement date and extent of such delay or prevention, the

thereof and its estimated duration;

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

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

16.3. If the delay or prevention caused by the Force Majeure Event in question continues for more than [***] any p the affected Scope of Work may give notice in writing to the other(s) to terminate that Scope of Work. The no terminate must specify the termination date, which must not be less than 5 (five) Business Days after the d which the notice is given, and once such notice has been validly given, that Scope of Work will terminate c 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 th 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 t decision of each party's Program Manager;

(b) if the dispute is not resolved within 10 (ten) Business Days of its referral to the Prog Managers it shall be referred to the decision of Fujifilm's Chief Business Officer and Customer's Chief Operating Officer; and

(c) if the dispute is not resolved within 10 (ten) Business Days of its referral to Fujifilm's C Business Officer and the Customer's Chief Operating Officer it shall be referred to the decisi each party's President or Chief Executive Officer (as applicable/appropriate).

17.3. **Arbitration:**

17.3.1. Except as otherwise set forth in this Agreement, any dispute, claim or controversy arising out of or re to this Agreement or the breach, termination, enforcement, interpretation or validity thereof (includ issues or disputes regarding the existence, validity, scope or applicability of this agreement to arbitrat arbitrability of any claims, and the proper parties to the arbitration) shall be determined either:

(a) in the case of disputes involving FDBU and/or FDBT, by confidential arbitration in New York, York and the arbitration shall be administered by JAMS pursuant to its Comprehensive Arbitr Rules and Procedures; or

(b) in the case of disputes involving FDBK only, by confidential arbitration in London under J International Arbitration Rules; or

(c) in the case of disputes involving FDBK and FDBU and/or FDBT, by confidential arbitration in York under JAMS International Arbitration Rules,

in each case before three arbitrators. Judgment on the Award may be entered in any court having jurisdiction.

17.3.2. The arbitration shall be conducted and the award shall be rendered in the English language arbitrators will have no authority to award any damages prohibited by this Agreement or any remed could not have been awarded by a Court having jurisdiction. The arbitrators' decisions and awards sh provided in writing and shall include the basis on which they are made. The award rendered b arbitrators shall be final, non-appealable and binding on the parties. Judgment on the award m entered in any court having jurisdiction. In addition, each party hereby submits to the non-exc jurisdiction of the courts located in New York, USA or London, England (as applicable an as determi accordance with clause 17.3.1 above) for purposes of determining the arbitrability of any dispute, ca such party to appear for and participate in such arbitration, and enforcing any award granted b 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 & RECORDS**

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 Quality Agreement provided that access by the Customer and/or its representatives to records, inforn and systems shall be on a supervised basis, subject to the Customer complying with the securit confidentiality requirements of Fujifilm to protect information which relates to anything other tha Programs and shall be limited to a [***].

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

18.1.3. If Fujifilm is in material breach of clause 4.1.3 of this Agreement or if the Customer reasonably be that Fujifilm is in material breach of clause 4.1.3 of this Agreement, the Customer may upon reasonable written notice to Fujifilm carry out an audit on the same basis as in clauses 18.1.1 and 18

18.1.4. Additional audits (other than those carried out pursuant to clauses 18.1.1and 18.1.3) may be carried the same basis as in clauses 18.1.1 and 18.1.2 subject to (i) payment of Fujifilm's costs and expense the agreement of a commercial rate; and (ii) the Customer ensuring such audit will not delay or d Fujifilm's operations at the Facility.

18.1.5. Subject to any restrictions in the relevant SoW and subject always to clause 13, during a Program, Customer's reasonable request from time to time, [***]

18.2. Financial evidence and assistance:

18.2.1. Together with each invoice issued by Fujifilm to the Customer hereunder, Fujifilm shall provide reaso detailed documentation to validate the amounts included on each invoice which are subject to the tr mechanism contemplated in Schedule 1. The Customer may request reasonable additional vali information provided that (i) the Customer shall not request evidence validating a given amount mor once, save where Fujifilm has been unresponsive to the Customer's original request (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 Fujifilm'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 party and requires information to demonstrate proper payment of Fujifilm invoices under a SoW.

18.3. Fujifilm will generate and maintain complete and accurate records (including, files, certificates, and authoriza and samples as set out in the Quality Agreement.

19. **NOTICES**

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

19.2. Any notice given under clauses 3, 8, 10, 12, 13, 15, 16, 17, 18, 19.2, 20, 21 or 22 shall only be effective if writing, sent to a party's identified individual at the below address or email address (or such other address, address or individual as that party may notify the other in accordance with this clause 19) and is gi accordance with clauses 19.3 to 19.5 below.

19.3. Notices shall be sent as follows:

(a)If to Fujifilm:
Chief Executive Officer
FUJIFILM Diosynth Biotechnologies
Belasis Avenue
Billingham, TS23 1LH
England
[***]
With a copy to:
General Counsel
FUJIFILM Diosynth Biotechnologies
Belasis Avenue
Billingham, TS23 1LH
England

[***]

(b)If to Customer:

Chief Financial and Administrative Officer
Dave Lowrance
1717 Langhorne Newton Rd, Suite 300
Langhorne, Pennsylvania 19047
Email: [***]
With a copy to:
Sr. VP Legal Affairs
Kate McCabe
1717 Langhorne Newton Rd, Suite 300
Langhorne, Pennsylvania 19047
Email: [***]

19.4. Notice may be given by hand or sent by email, recorded delivery, registered post or airmail and will be deer 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 d evidenced by postal receipt); and

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

provided that, (a) 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 and (b) all notices delivered by hand, recorded delivery/registered post or registered airmail must also be sent via email.

19.5. In proving service of a notice it will be sufficient to prove that delivery was made or that the envelope cont the notice or document was properly addressed and posted (either by prepaid first class recorded delivery p

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 Sanctio Export/Import Laws and ensure that it has in place appropriate controls and safeguards to prevent any being taken by it that would amount to or result in a violation of or non-compliance with any Sanctio Export/Import Laws.

20.2. The Customer shall provide all information that Fujifilm may reasonably require from time to time in orc Fujifilm to assess and/or manage its compliance with Sanctions and Export/Import Laws (including provis end-user statements or applicable Authorizations and notifying Fujifilm of any restrictions or export comp 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 transf Product, software, technology or Confidential Information: (i) unlawfully to any country in respect of wh Sanctions Authority maintains Sanctions or a Sanctioned Person; (ii) in a manner that would expose Fujifilm risk of negative consequences under Sanctions; or (ii) in violation of Export/Import Laws.

20.4. If any Authorization is required so that the performance of a Program does not contravene any Sanctio Export/Import Laws, the Customer will at its own cost and expense obtain that Authorization and Fujifilm provide any commercially reasonable assistance (including reasonable information) that the Customer may r for the purposes of obtaining that Authorization. The Customer's rights and Fujifilm's obligations unde Agreement or any SoW in relation to that Program shall immediately be suspended if any required Authoriza not obtained. In the event that the Customer's rights and Fujifilm's obligations are suspended for more than (30) calendar days, a Program may be terminated immediately by Fujifilm giving written notice to the Custo Fujifilm terminates a Program under this clause 20.4 then the Customer shall pay the Charges that are due Fujifilm Services that have been performed during that Program and [***] of the Program Cancellation Fee p any Ancillary Charges owed in respect of Ancillary Services that have been performed, and (ii) such portion Ancillary Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm has a incurred or has committed to later incur under a non-cancelable order, unrecoverable costs and expenses.

20.5. The Customer shall Indemnify Fujifilm against any and all Liabilities which Fujifilm incurs as a result 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 comp standards, including basic human rights, not engaging in any activity, practice or conduct which would con an offence under anti-slavery legislation in the United Kingdom or the U.S.A, encouraging fair and equal trea for all persons, the provision of safe and healthy working conditions, respect for the environment, the adop appropriate management systems and the conduct of business in an ethical manner. In performing its duties this Agreement, each party acknowledges the value and importance of performance and ethical behaviou performance under this Agreement.

21.2. Each party warrants that on the Effective Date and each SoW Effective Date, it, its directors, officers or empl have not offered, promised, given, authorized, solicited or accepted any undue pecuniary or other advanta any kind (or implied that they will or might do any such thing at any time in the future) in any way connecte this Agreement or a SoW and that it has taken reasonable measures to prevent subcontractors, agents or 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 c with and that they will take reasonable measures to ensure that their subcontractors, agents or other third p will comply with all applicable anti-corruption legislation including the Bribery Act 2010 and the Foreign C Practices Act 1977.

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 an corruption legislation including the Bribery Act 2010 and the Foreign Corrupt Practices Act 1977.

22. **ASSIGNMENT AND SUB-CONTRACTING**

22.1. A party may, on written notice to the other, assign or transfer all of its rights and responsibilities unde 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 par reasonable financial creditworthiness and, in the case of assignment by Customer, is not a Competito

22.1.3. a purchaser of all or substantially all of assets to which this Agreement relates provided that such party has reasonable financial creditworthiness (for the avoidance of doubt, any Customer assignee market capitalization greater than that of Customer as of the Effective Date shall be deemed to “reasonable financial creditworthiness”) and, in the case of assignment by Customer, is not a Comp or

22.1.4. In the case of the Customer: an exclusive licensee of the Product provided that (i)such third par reasonable financial creditworthiness and, in the case of assignment by Customer, is not a Competit (ii) that the Customer no longer requires services from Fujifilm under this Agreement.

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 t subcontract manufacture, processing or handling of Product, Fujifilm will obtain the Customer's written co (which may be by signature of the relevant SoW(s) which specify that an obligation will be sub-contra Notwithstanding the foregoing, Fujifilm may utilize on-site third party personnel, such as temporary emplo contractors and consultants, to perform Fujifilm Services without obtaining the prior consent of the Customer.

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

23. **GENERAL**

23.1. Entire agreement: This Agreement and the Historic Documents 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. 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 and the Historic Documents, 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 Agre by executing a counterpart and all the counterparts taken together will constitute one and the 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 signature page) by email (in PDF, JPEG or other agreed format) shall take effect as delivery of an exe counterpart of this Agreement. If this method of delivery is adopted, without prejudice to the validity Agreement so made, each party shall provide the others with the original of such counterpart as so 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 SoW in any press releases, advertising or sales promotional material or in any publication without prior written permission of such party(ies). Such consent shall not be unreasonably withheld. 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 SoW 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.

24. **GOVERNING LAW**

24.1. Subject to clause 24.2, the formation, existence, construction, performance, validity and all aspects whatsoe this Agreement or any term of it and any issues, disputes or claims arising out of or in connection with it (w contractual or non-contractual in nature) shall be governed by, and construed in accordance with, English law

24.2. Any Scope of Work entered into by FDBT or FDBU and any dispute or claim (including non-contractual dispu claims) arising out of or in connection with such Scope of Work, this Agreement or their subject matter or forn shall be governed by, and construed in accordance with the State Law of Delaware.

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

Schedule 1 Charges [Intentionally omitted.][1]

[1] Omitted schedule to be provided to the Securities and Exchange Commission upon request.

Signature Page

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

Signature: /s/ Vincent Romeo

Title: Interim Site Head

Date: 2/12/2024

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

Signature: /s/ Chris Vannais

Title: Chief Operating Officer

Date: 2/12/2024

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

Signature: /s/ Jonathan Haigh

Title: Head of UK Site

Date: 2/12/2024

SIGNED for and on behalf of **SAVARA APS**:

Signature: /s/ Dave Lowrance	**Signature:**
Title: CFO	**Title:**
Date: 2/13/2024	**Date:**

Exhibit 31.1

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

I, Matthew Pauls, certify that:

1. I have reviewed this Form 10-Q of Savara Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedur 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, particular 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 th report our conclusions about the effectiveness of the disclosure controls and procedures, as of the er of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023 May 9, 2024

/s/ Matthew Pauls

Matthew Pauls

Chief Executive Officer and Chair of the Board of Directors
(Principal Executive Officer)

Exhibit 31.2

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

I, David Lowrance, certify that:

1. I have reviewed this Form 10-Q of Savara Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedur 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, particular 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 th

report our conclusions about the effectiveness of the disclosure controls and procedures, as of the er of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023 May 9, 2024

/s/ David Lowrance

David Lowrance

Chief Financial and Administrative Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Savara Inc. (the “Company”) on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Matthew Pauls, principal executive officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act o

1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November May 9, 2023 2024

/s/ Matthew Pauls

Matthew Pauls

Chief Executive Officer and Chair of the Board of Directors

(Principal Executive Officer)

In connection with the Quarterly Report of Savara Inc. (the “Company”) on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, David Lowrance, principal financial officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act o 1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November May 9, 2023 2024

/s/ David Lowrance

David Lowrance

Chief Financial and Administrative Officer

(Principal Financial and Accounting Officer)

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