UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

X

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

For the quarterly period ended March 31, 2021

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 (State or other jurisdiction of incorporation or organization)		84-1318182 (I.R.S. Employer Identification No.)
6836 Bee Cave Road, Building III, Suite 200		
Austin, TX		78746
(Address of principal executive offices)		(Zip Code)
(Regist	(512) 614-1848 rant's telephone number, including area code)	
	N/A	
Securities registered pursuant to Section 12(b) of the Act:	Trading	

Title of each class	Symbol(s)	Name of each exchange on which registered
Common Stock, 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 (\S 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes \boxtimes No \square

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	\boxtimes	Smaller reporting company	X
		Emerging growth company	

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

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

As of May 13, 2021, the registrant had 113,643,271 shares of common stock, \$0.001 par value per share, outstanding.

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

	Ma	rch 31, 2021	December 31, 2020
Assets			
Current assets:			
Cash and cash equivalents	\$	55,982	\$ 22,880
Short-term investments		136,731	59,308
Prepaid expenses and other current assets		2,089	2,933
Total current assets		194,802	 85,121
Property and equipment, net		124	156
In-process R&D		11,676	12,218
Other non-current assets		1,028	 250
Total assets	\$	207,630	\$ 97,745
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	\$	2,723	\$ 2,595
Accrued expenses and other current liabilities		4,484	5,579
Total current liabilities		7,207	 8,174
Long-term liabilities:			
Debt facility		25,244	25,104
Other long-term liabilities		58	84
Total liabilities		32,509	 33,362
Commitments and Contingencies			
Stockholders' equity:			
Common stock, \$0.001 par value, 200,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 113,578,654 and 54,152,955 shares issued and outstanding			
as of March 31, 2021 and December 31, 2020, respectively		114	55
Additional paid-in capital		442,246	320,893
Accumulated other comprehensive income		485	942
Accumulated deficit		(267,724)	 (257,507)
Total stockholders' equity		175,121	 64,383
Total liabilities and stockholders' equity	\$	207,630	\$ 97,745

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 Mont	ns Ended	March 31,
		2021		2020
Operating expenses:				
Research and development	\$	7,589	\$	13,200
General and administrative		2,778		2,982
Depreciation and amortization		47		58
Total operating expenses		10,414		16,240
Loss from operations		(10,414)		(16,240)
Other income, net:				
Interest expense, net		(593)		(160)
Foreign currency exchange gain (loss)		(57)		156
Tax credit income		847		821
Change in fair value of financial instruments				2
Total other income, net		197		819
Net loss	\$	(10,217)	\$	(15,421)
Net loss per share:			-	
Basic and diluted	\$	(0.13)	\$	(0.27)
Weighted-average common shares outstanding:				
Basic and diluted		76,992,407		57,364,265
Other comprehensive loss:				
Loss on foreign currency translation		(431)		(128)
Unrealized gain (loss) on short-term investments		(26)		17
Total comprehensive loss	\$	(10,674)	\$	(15,532)

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 March 31, 2021 and 2020 (In thousands, except share amounts) (Unaudited)

				Stockho	olders	' Equity			
		Common Sto	k				Ac	cumulated	
	Number of			Additional Paid-In	А	ccumulated	Con	Other oprehensive	
	Shares	Amount		Capital		Deficit		ome (Loss)	Total
Balance on December 31, 2020	54,152,955	\$5	5 5	\$ 320,893	\$	(257,507)	\$	942	\$ 64,383
Issuance of common stock and pre-funded warrants in public offering, net of offering costs (1)	57,479,978	5	7	121,770		—		—	121,827
Repurchase of outstanding pre-funded warrants	_	-	-	(3,909))			_	(3,909)
Net issuance of common stock upon exercise of stock warrants, net	1,737,450		2	2,544		—		—	2,546
Issuance of common stock for settlement of RSUs	5,563	-	_	_		_		_	
Issuance of common stock upon exercise of stock options	202,708	_	_	2		—		—	2
Stock-based compensation	_	-	-	946				_	946
Foreign exchange translation adjustment	—	-	-	—		—		(431)	(431)
Unrealized loss on short-term investments	—	-	_	—		—		(26)	(26)
Net loss	—	-	-	_		(10,217)		—	(10,217)
Balance on March 31, 2021	113,578,654	\$ 11	4 9	\$ 442,246	\$	(267,724)	\$	485	\$ 175,121

As discussed in Note 10, "Stockholders' Equity," the Company sold (i) an aggregate of 57,479,978 shares of the Company's common stock, par value \$0.001 per share and (ii) pre-funded warrants to purchase an aggregate of 32,175,172 shares of common stock at an exercise price of \$0.001 per share.

					Stockhol	ders	' Equity		
	Common Stock							Accumulated	
	Number of Shares	А	mount	1	dditional Paid-In Capital	Ao	ccumulated Deficit	Other Comprehensive Income (Loss)	Total
Balance on December 31, 2019	50,790,441	\$	52	\$	309,555	\$	(207,892)	\$ (17)	\$ 101,698
Issuance of common stock for settlement of RSUs	12,750		—		_		—	—	—
Issuance of common stock upon exercise of stock options	41,313		—		48		—	—	48
Closing costs for previous issuance of securities in private placement	_		—		(120)		—	_	(120)
Incremental cost due to modification of detachable warrants previously issued with debt instrument	—		—		28		—	—	28
Stock-based compensation	_		_		1,194			—	1,194
Foreign exchange translation adjustment	_		_		_		_	(128)	(128)
Unrealized gain on short-term investments	_		—		—		—	17	17
Net loss	_		—		_		(15,421)	—	(15,421)
Balance on March 31, 2020	50,844,504	\$	52	\$	310,705	\$	(223,313)	\$ (128)	\$ 87,316

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)

	F	or the Three Months	Ended March 31,	
		2021	2020	
Cash flows from operating activities:				
Net loss	\$	(10,217)	\$ ((15,421
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		47		58
Amortization of right-of-use assets		57		184
Acquired in-process research and development (Note 7)		_		5,367
Changes in fair value of financial instruments		—		(2
Noncash interest expense		_		133
Foreign currency loss (gain)		57		(156
Amortization of debt issuance costs		140		134
Accretion on discount to short-term investments		161		(69
Stock-based compensation		946		1,194
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		879		(195
Non-current assets		(863)		(821
Accounts payable and accrued expenses and other current liabilities		(781)		(3,180
Long-term liabilities		(23)		(305
Net cash used in operating activities		(9,597)	((13,079
Cash flows from investing activities:				
Purchase of property and equipment		—		(4
Purchase of in-process research and development (Note 7)		_		(3,247
Purchase of available-for-sale securities, net		(94,319)	((35,614
Maturities of available-for-sale securities		16,580		31,300
Sale of available-for-sale securities, net		_		5,780
Net cash used in investing activities		(77,739)		(1,785
Cash flows from financing activities:				
Repurchase of outstanding pre-funded warrants		(3,909)		
Repayment of debt facility				(514
Issuance of common stock and pre-funded warrants in public offering, net of offering costs		121.827		(-
Proceeds from exercise of stock options		2		48
Issuance of common stock upon exercise of warrants, net		2,546		_
Net cash provided by (used in) financing activities		120,466		(466
Effect of exchange rate changes on cash and cash equivalents		(28)		41
Increase (decrease) in cash and cash equivalents		33,102	((15,289
Cash and cash equivalents beginning of period		22,880		49,804
Cash and cash equivalents end of period	\$	()		34,515
Cash and cash equivalents end of period	ð	55,962	Þ	54,515
Non-cash transactions				
Common stock issued for acquired in-process research and development (Note 7)	\$	_ :	\$	(2,120
Supplemental disclosure of cash flow information:				
Cash paid for interest, including end of period charge due upon debt facility amendment	\$	484	\$	990

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 company focused on rare respiratory diseases. The Company's lead program, a nebulizer solution ("molgramostim"), is an inhaled granulocyte-macrophage colony-stimulating factor in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"). Previously, the Company's pipeline included vancomycin hydrochloride inhalation powder ("vancomycin") for persistent methicillin-resistant *Staphylococcus aureus* ("MRSA") lung infection in people living with cystic fibrosis ("CF") and inhaled liposomal ciprofloxacin (formerly referred to as Apulmiq) for non-CF bronchiectasis. The Company and its wholly-owned subsidiaries operate in one segment with its principal offices in Austin, Texas, USA.

Since inception, Savara has devoted substantially all of 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 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, 2021 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 SEC rules and regulations. 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, 2020. The Company's significant accounting policies are described in Note 2 to the audited consolidated financial statements. There have been no changes to our significant accounting policies since the date of those financial statements.

Certain prior period amounts have been reclassified for consistency with current period presentation.

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 income* in the condensed consolidated balance sheet. All intercompany transactions and accounts have been eliminated in consolidation.

Liquidity

As of March 31, 2021, the Company had an accumulated deficit of approximately \$267.7 million. The Company used cash in operating activities of approximately \$9.6 million during the three months ended March 31, 2021. 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 primarily focused on the development of molgramostim 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 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 \$56.0 million and short-term investments of \$136.7 million as of March 31, 2021 is sufficient to fund the Company's operations for the 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.

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 those related to the accrual of research and development and general and administrative costs, certain financial instruments recorded at fair value, contingent consideration, stock-based compensation, and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience 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 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. 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

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents and foreign exchange derivatives not designated as hedging instruments. The Company places its cash and cash equivalents with a limited number of high-quality financial institutions and at times may exceed the amount of insurance provided on such deposits.

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. Our chief operating decision maker is the chief executive officer. We have one operating segment, specialty pharmaceuticals within the respiratory system.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* which aims to simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 was effective on January 1, 2021 and did not have a material impact on our condensed consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)* which reduces the number of accounting models for convertible debt instruments and convertible preferred stock to simplify the accounting for convertible instruments and reduce the complexity. ASU 2020-06 also made targeted improvements to the disclosures for convertible instruments and earnings per share guidance. ASU 2020-06 was early adopted on January 1, 2021 and did not have a material impact on our condensed consolidated financial statements.

Recently Issued but not yet Adopted Accounting Pronouncements

There are no recent accounting pronouncements issued by the FASB, the AICPA, or the SEC that are believed by 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 consisted of (in thousands):

	March 31, 20	021	D	December 31, 2020
R&D tax credit receivable	\$	996	\$	1,042
Prepaid contracted research and development costs		232		591
VAT receivable		427		653
Prepaid insurance		213		453
Deposits and other		221		194
Total prepaid expenses and other current assets	\$	2,089	\$	2,933

R&D Tax Credit Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS, as of March 31, 2021. 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, 2020, the Company generated a Danish tax credit of \$0.9 million which is included in *R&D tax credit receivable* in the table above and is expected to be received in the fourth quarter of 2021. During the three months ended March 31, 2021, 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 2022.

The Company also recorded an Australian tax credit as provided by the Australian Taxation Office for qualified research and development expenditures incurred through our subsidiary, Savara Australia Pty. Limited. Under Australian tax law, Australia remits a research and development tax credit equal to 43.5% of qualified research and development expenditures, not to exceed established thresholds. During the year ended December 31, 2020, the Company generated an Australian tax credit of \$0.1 million which is included in *R&D tax credit receivable* in the table above and is expected to be received during the third quarter of 2021. The tax credit receivable recorded during the three months ended March 31, 2021 was not significant.

4. Accrued Expenses and Other Current Liabilities

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

	Mar	ch 31, 2021	De	2020
Accrued contracted research and development costs	\$	2,400	\$	2,627
Accrued compensation		1,069		1,920
Accrued general and administrative costs		876		853
Lease liability		139		179
Total accrued expenses and other current liabilities	\$	4,484	\$	5,579

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):

			Gross U	J nrealized	Gross U	nrealized	
As of March 31, 2021	Amo	rtized Cost	Gains		Losses		Fair Value
Short-term investments							
U.S. government securities	\$	13,218	\$	5	\$	—	\$ 13,223
Asset backed securities		9,633		1		(4)	9,630
Corporate securities		55,976				(28)	55,948
Commercial paper		57,930		—		—	57,930
Total short-term investments	\$	136,757	\$	6	\$	(32)	\$ 136,731
			Gross U	J nrealized	Gross U	nrealized	
As of December 31, 2020	Amo	rtized Cost		J nrealized ains		nrealized	 Fair Value
As of December 31, 2020 Short-term investments	Amo	rtized Cost					 Fair Value
	Amo \$	rtized Cost 13,296					\$ Fair Value 13,297
Short-term investments			G		Lo		\$
Short-term investments U.S. government securities		13,296	G		Lo		\$ 13,297
Short-term investments U.S. government securities Asset backed securities		13,296 2,559	G	ains1	Lo		\$ 13,297 2,559



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 income* in the condensed consolidated balance sheet. Classification as short-term or long-term is based upon whether the 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 three months ended March 31, 2021 and 2020.

6. Debt Facility

On April 28, 2017, the Company entered into a loan and security agreement with Silicon Valley Bank, as amended by the First Amendment to the Loan and Security Agreement on October 31, 2017, the Second Amendment to the Loan and Security Agreement on December 4, 2018 and the Third Amendment on January 31, 2020 (the "Loan Agreement"). The Company executed a fourth amendment (the "Fourth Amendment") to the Loan Agreement on March 30, 2021.

The Fourth Amendment provides that if by June 30, 2021, the Company does not have an ongoing phase 3 clinical trial evaluating its molgramostim product for the treatment of aPAP in which the first patient has been identified and dosed (the "Trial Requirement"), the interest-only period will end and principal plus interest will be due in equal monthly installments over 24 months. The first payment due on July 1, 2021 will include three principal payments. If the Trial Requirement is met, the first payment of principal plus interest will be due on July 1, 2022. Prior to the Fourth Amendment, the interest-only period would end if the Trial Requirement had not been met by March 31, 2021. Additionally, the Fourth Amendment increased the final payment percentage from 6.0% to 6.2%.

Silicon Valley Bank has been granted a perfected first priority lien in all of our assets with a negative pledge on our intellectual property. The Loan Agreement, as amended, contains customary affirmative and negative covenants, including among others, covenants limiting our ability and our 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 Loan Agreement contains an affirmative covenant requiring us to deliver evidence by June 30, 2021 of the receipt of gross cash proceeds of at least \$25 million from the exercise of currently outstanding warrants or the issuance of other equity securities, which was satisfied upon completion of the Public Offering, as defined and discussed in Note 10. "Stockholders' Equity."

The loan bears interest at the greater of (i) the prime rate reported in The Wall Street Journal, plus a spread of 3.0% or (ii) 7.75%. The Loan Agreement, as amended, will also require a prepayment fee (2.0% of funded amounts in months 13-24, and 1.0% thereafter), and an end of term charge equal to 6.2% of the amount of principal borrowed.

The Company paid minimal legal costs directly attributable to the original issuance of the debt instrument underlying the Loan Agreement and subsequent amendments. Such charges were accounted for as debt issuance costs and are being amortized to interest expense using the effective interest method through the scheduled maturity date.

Summary of Carrying Value

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

Future minimum payments due during the year ended December 31,	March 31, 2021	I	December 31, 2020
2021	\$ _	\$	_
2022	8,333		8,333
2023	18,167		18,167
Total future minimum payments	 26,500		26,500
Unamortized end of term charge	(1,028)		(1,134)
Debt issuance costs	(129)		(149)
Debt discount related to warrants	 (99)		(113)
Total debt	 25,244		25,104
Short-term debt	—		—
Long-term debt	\$ 25,244	\$	25,104

7. License Agreement

Effective March 31, 2020, the Company entered into a license and collaboration agreement (the "License") that provided Savara an exclusive, worldwide, royalty-bearing license to develop and sell or otherwise commercialize pharmaceutical preparations containing a type of inhaled liposomal ciprofloxacin ("Licensed Product").

During 2020, the Company paid the licensor (i) an upfront cash payment of approximately \$3.3 million and (ii) an upfront payment of one million shares of the Company's common stock valued at approximately \$2.1 million on the date of issuance upon effectiveness of the License (collectively, the "Upfront Payments"). The Company also agreed to pay the licensor (i) certain developmental milestone payments for the development of the Licensed Products upon regulatory approval for commercial sale and (ii) certain sales milestone payments upon the first achievement of defined annual global net sales (collectively, the "Contingent Consideration").

The Company accounted for the License as an asset acquisition in accordance with ASC 805, *Business Combinations*. Since the Licensed Product had not yet achieved regulatory approval and there is deemed to be no alternative future use, the Company recognized research and development expense of approximately \$5.4 million for the Upfront Payments during the three months ended March 31, 2020.

The Company formally announced the termination of any further development of the Licensed Product and, as such, determined that payment of the Contingent Consideration is not probable, and therefore, no related liability has been recorded.

8. Fair Value Measurements

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent 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 in active markets;
- Level 2 Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in 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 its own assumptions.

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. Based upon the ultimate scope and scale of the COVID-19 global pandemic, there may be material negative impacts to the assumptions made with respect to our IPR&D assets that could result in an impairment. For the three months ended March 31, 2021 and 2020, the impact of COVID-19 or other factors did not trigger any impairment indicators.

During the three months ended March 31, 2021 and 2020, the Company experienced a decrease of approximately \$0.5 million and \$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.

Additional investments in corporate debt securities, commercial paper, and asset-backed securities 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.

Foreign exchange derivatives not designated as hedging instruments are considered Level 2 financial instruments. The Company's foreign exchange derivative instruments are typically short-term in nature.



The fair value of these instruments as of March 31, 2021 and December 31, 2020 was as follows (in thousands):

	Active Iden	ed Prices in Markets for tical Assets Level 1)	Ob	gnificant Other servable Inputs Level 2)	U	Significant nobservable Inputs (Level 3)		Total
As of March 31, 2021							_	
Cash equivalents:								
U.S. Treasury money market funds	\$	73,398	\$		\$		\$	73,398
Asset backed securities (1)				(7,093)				(7,093)
Corporate securities (1)				(14,189)				(14,189)
Short-term investments:								
U.S. government securities		13,223		_				13,223
Asset backed securities				9,630				9,630
Corporate securities				55,948		_		55,948
Commercial paper				57,930				57,930
As of December 31, 2020								
Cash equivalents:								
U.S. Treasury money market funds	\$	21,872	\$	—	\$		\$	21,872
Short-term investments:								
U.S. government securities		13,297		—				13,297
Asset backed securities				2,559				2,559
Corporate securities				19,479				19,479
Commercial paper				23,973				23,973

(1) Trade pending as of March 31, 2021 which has been subsequently settled.

9. Derivative Financial Instruments

In the normal course of business, the Company is exposed to the impact of foreign currency fluctuations. The Company seeks to limit these risks by following risk management policies and procedures, including the use of derivatives. The Company's derivative contracts, which are not designated as hedging instruments, principally address short-term foreign currency exchange. The estimated fair value of the derivative contracts was based upon the relative exchange rate as of the balance sheet date. Accordingly, any gains or losses resulting from variances between this exchange rate and the exchange rate at the contract inception date were recognized in *Other income, net* in the condensed consolidated statements of operations and comprehensive loss. As of March 31, 2020, there was an asset of approximately \$6 million consisting of unsettled forward exchange contracts to purchase foreign currency and a corresponding liability of approximately \$6 million consisting of forward exchange contract obligations, resulting in a \$0.1 net derivative financial instrument, recorded at their estimated fair value in *Accrued expenses and other current liabilities* in the condensed consolidated balance sheet. There were no such derivative contracts as of March 31, 2021.

10. Stockholders' Equity

Public Offering of Common Stock

On March 15, 2021, the Company sold (i) an aggregate of 57,479,978 shares of the Company's common stock, par value \$0.001 per share (the "Common Stock") for \$1.45 per share, of which 11,694,150 shares were issued pursuant to the underwriters' option to purchase additional shares, and (ii) pre-funded warrants to purchase an aggregate of 32,175,172 shares of Common Stock at an exercise price of \$0.001 per share (the "Pre-Funded Warrants") for \$1.449 per warrant (collectively, the "Public Offering").

The Company determined that the securities issued in the Public Offering were free-standing and that the Pre-Funded Warrants did not contain any settlement obligations that would result in liability classification under ASC 480, *Distinguishing Liability from Equity* and ASC 815-40, *Contracts in Entity's Own Equity*. The shares encompassed in the 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 Public Offering resulted in net proceeds to the Company of approximately \$121.8 million, after deducting underwriting discounts, commissions and offering expenses, as follows (in thousands):

Financial instruments	Proceeds
Common stock	\$ 83,346
Pre-funded warrants	46,622
Total	129,968
Offering expenses	\$ (8,141)
Net proceeds	\$ 121,827

The Company intends to use the net proceeds from the Public Offering to fund the clinical trial of molgramostim for the treatment of aPAP and other general corporate purposes.

Warrant Repurchase

Immediately prior to the Public Offering, the Company entered into separate, privately-negotiated warrant repurchase agreements with certain holders of its outstanding milestone warrants, each dated as of December 24, 2019. The Company paid \$3.9 million (\$0.15 per share of Common Stock underlying each milestone warrant) to repurchase milestone warrants with 26,061,769 shares of Common Stock underlying such warrants, and the warrants were terminated. Following the warrant repurchase and exercises during the three months ended March 31, 2021, we have outstanding milestone warrants to purchase an aggregate of 3,474,902 shares of our common stock. The warrant repurchase was accounted for as an equity transaction and resulted in a reduction to *Additional paid-in capital* in the condensed consolidated statement of stockholders' equity.

Common Stock Reserved for Issuance

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

	March 31, 2021	December 31, 2020
Warrants acquired in April 2017 merger		403,927
Warrants converted in connection with April 2017 merger	72,869	72,869
April 2017 Warrants	24,725	24,725
June 2017 Warrants	41,736	41,736
December 2018 Warrants	11,332	11,332
2017 Pre-funded Warrants	775,000	775,000
Pre-funded PIPE Warrants	5,780,537	5,780,537
Milestone Warrants	3,474,902	31,274,121
2021 Pre-funded Warrants	32,175,172	—
Stock options outstanding	5,338,509	6,240,342
Issued and nonvested RSUs	460,709	509,397
Total shares reserved	48,155,491	45,133,986

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of March 31, 2021:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
72,869	\$ 8.98	June 2021
775,000	\$ 0.01	October 2024
24,725	\$ 2.87	April 2027
41,736	\$ 2.87	June 2027
11,332	\$ 2.87	December 2028
5,780,537	\$ 0.001	None
3,474,902	\$ 1.48	Earlier of December 2021 or 30 days after clinical milestone
32,175,172	\$ 0.001	None
42,356,273		

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):

	xchange Translation Adjustment	Gain (Loss) on ST /estments	Accumulated Other nensive Income (Loss)
Balance, December 31, 2019	\$ (65)	\$ 48	\$ (17)
Change	1,006	(47)	959
Balance, December 31, 2020	 941	1	 942
Change	(431)	(26)	(457)
Balance, March 31, 2021	\$ 510	\$ (25)	\$ 485

11. Commitments

Manufacturing and Other

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, Savara 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 Savara 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 years thereafter or (ii) the date a biosimilar of such product is first sold in such country, Savara shall pay the API manufacturer a royalty equal to low-single digits of the net sales in that country.

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. The decrease in the amount of the milestone payments from December 31, 2020 to March 31, 2021 was primarily related to removal of milestones related to a nebulizer system no longer planned to be utilized, slightly offset by an increase in the foreign currency exchange rate. 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 net sales.

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

	Marc	h 31, 2021
Molgramostim manufacturer:		
Achievement of certain milestones related to validation of API and regulatory approval of molgramostim	\$	2,300
Molgramostim nebulizer manufacturer:		
Achievement of various development activities and regulatory approval of nebulizer utilized		
to administer molgramostim		892
Total manufacturing and other commitments	\$	3,192

The milestone commitments disclosed above reflect the activities that have not been recognized at March 31, 2021 because they are not deemed probable and reasonably estimable.

On December 10, 2020, the Company announced that the Phase 3 trial of vancomycin in people living with cystic fibrosis who have MRSA lung infection did not meet the primary endpoint. On January 7, 2021 the Company issued a termination notice to GlaxoSmithKline Trading Services Limited ("GSK"), who manufactures the drug product from bulk vancomycin powder. On January 26, 2021, the Company and GSK entered a change order for termination costs associated with the closeout and wind down of vancomycin activities. During the three months ended March 31, 2021, the Company paid approximately \$0.8 million of research and development expense related to the termination of the manufacturing agreement.

Contract Research

On March 5, 2021, 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 our 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, the Company will pay Parexel service fees and pass-through expenses estimated to be approximately \$31 million over the course of the IMPALA 2 clinical trial.

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.

12. Stock-Based Compensation

A. 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 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.

2015 Omnibus Incentive Option Plan

The Company operates the 2015 Omnibus Incentive Plan (the "2015 Plan"), as amended and restated with approval by our stockholders in June 2018 and May 2020. 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, performance units, shares and other stock-based awards. Share-based awards are subject to terms and conditions established by our board of directors or the compensation committee of our board of directors. As of March 31, 2021, the number of shares of our common stock available for grant under the 2015 Plan was 2,089,762 shares.

Inducement Awards

The Company has granted equity awards under inducement grants filed in accordance with Nasdaq Listing Rule 5635(c)(4) exclusively to the Company's CMO as an inducement for the CMO to enter into employment with the Company.

Under both the 2008 Plan and 2015 Plan, stock option and restricted stock unit grants typically vest quarterly over three to four years and expire ten years from the grant date, and restricted stock grants vest on a quarterly basis over four years and expire ten years from the grant date.

B. Stock Option and Restricted Stock Units

The Company values stock options using the Black-Scholes-Merton option pricing model, which requires the input of subjective assumptions, including the risk-free interest rate, expected life, expected stock price volatility, and dividend yield. The risk-free interest rate assumption is based upon observed interest rates for constant maturity U.S. Treasury securities consistent with the expected term of the Company's employee stock options. The expected life represents the period of time the stock options are expected to be outstanding and is based on the simplified method. The Company uses the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options. Expected volatility is based on historical volatilities for publicly traded stock of comparable companies over the estimated expected life of the stock options. The Company assumes no dividend yield because dividends are not expected to be paid in the future, consistent with the Company's history of not paying dividends. The valuation of stock options is also impacted by the valuation of common stock.

Restricted stock units are valued at the closing market price of the Company's common stock on the date of grant.

C. Stock-Based Award Activity

The following table provides a summary of stock-based awards activity under the 2008 Plan and 2015 Plan for the three months ended March 31, 2021:

	Stock Options	RSUs	Total
Outstanding as of December 31, 2020	6,240,343	509,397	6,749,740
Granted	70,000		70,000
Exercised	(522,302)	(5,563)	(527,865)
Forfeited	(449,532)	(43,125)	(492,657)
Outstanding as of March 31, 2021	5,338,509	460,709	5,799,218

D. 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 months ended March 31, 2021 and 2020 (in thousands):

		Three Months Ended March 31,				
	20	21		2020		
Research and development	\$	464	\$	593		
General and administrative		482		601		
Total stock-based compensation	\$	946	\$	1,194		

13. 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:

	Three Months Endee	d March 31,
	2021	2020
Awards under equity incentive plan	5,338,509	4,473,477
Nonvested restricted shares and restricted stock units	460,709	302,875
Warrants to purchase common stock	3,625,564	33,131,798
Total	9,424,782	37,908,150

The following table calculates basic earnings per share of common stock and diluted earnings per share of common stock for the three months ended March 31, 2021 and 2020 (in thousands, except share and per share amounts):

	Three Months Ended March 31,			
		2021		2020
Net loss	\$	(10,217)	\$	(15,421)
Net loss attributable to common stockholders		(10,217)		(15,421)
Undistributed earnings and net loss attributable to				
common stockholders, basic and diluted		(10,217)		(15,421)
Weighted average common shares outstanding, basic				
and diluted		76,992,407		57,364,265
Basic and diluted EPS	\$	(0.13)	\$	(0.27)



MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the accompanying condensed consolidated financial statements and related notes. 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. 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, those identified below, natural disasters and pandemics (such as the scope, scale and duration of the impact of the novel coronavirus, COVID-19), 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, 2020, all of which are difficult to predict.

Overview

Savara Inc. (together with its subsidiaries "Savara," the "Company," "we," "our" or "us") is a clinical stage company focused on rare respiratory diseases. Our lead program, molgramostim nebulizer solution ("molgramostim"), is an inhaled granulocyte-macrophage colony-stimulating factor in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"). Savara, together with its wholly-owned subsidiaries, which includes Aravas Inc., Savara ApS, Drugrecure A/S, and Savara Australia Pty. Limited, operate in one segment with its principal office in Austin, Texas, USA.

Since inception, we have devoted substantially all of 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 March 31, 2021, we have raised net cash proceeds of approximately \$392.5 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 in each year since inception. Our net losses for the three months ended March 31, 2021 and 2020 were \$10.2 million and \$15.4 million, respectively, and for the year ended December 31, 2020 was \$49.6 million. As of March 31, 2021, we had an accumulated deficit of \$267.7 million. Our operating losses primarily resulted from expenses incurred in connection with 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 initiate and 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 March 31, 2021, we had cash and cash equivalents of \$56.0 million and short-term investments of \$136.7 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 candidates.

Recent Events

Parexel Master Service Agreement and Work Order

We entered into a Master Services Agreement ("MSA") with Parexel International (IRL) Limited ("Parexel") on March 5, 2021, pursuant to which Parexel will provide contract research services related to our clinical trials. Contemporaneously with entering the MSA, we executed a work order with Parexel, under which Parexel will provide services related to the IMPALA 2 trial. Under that work order, we will pay Parexel service fees and pass-through expenses estimated to be approximately \$31 million over the course of the IMPALA 2 clinical trial.

Public Offering

On March 15, 2021, we completed a public offering of common stock and pre-funded warrants for gross proceeds of approximately \$130 million and net proceeds, including underwriting commissions and expenses, of approximately \$122 million. We intend to use the proceeds to fund the clinical trial of molgramostim and other general corporate purposes, as discussed in Note 10, "Stockholders' Equity" in the notes to the condensed consolidated financial statements.

COVID-19

The continuing COVID-19 global pandemic poses significant risks to our business. As we commence enrollment of our Phase 3 trial for the use of molgramostim for the treatment of aPAP, there remains a general uncertainty regarding the impact of COVID-19 on



the aPAP patient population and physicians. Patients suffering from aPAP lung disease are prone to underlying lung conditions and are often treated by infectious disease specialists and pulmonologists. These treating physicians are on the front lines in addressing this global pandemic and must now, understandably, focus their attention on COVID-19.

Additionally, we are unable to quantify the impact this situation will have on our future financial performance, but the public health actions being undertaken to reduce the spread of the virus have created, and may continue to create, challenges and disruptions to our operations. Accordingly, we are adhering to government restrictions and operating out of an abundance of caution for the safety of our personnel and patients, including social distancing protocols and providing the ability for remote working for our personnel. Our employees are able to use our facilities at their discretion. For those who do choose to work from the office, all of our facilities have been appropriately evaluated and maintained for social distancing and sanitation. Additionally, management, on an on-going basis, is evaluating our liquidity position, communicating with and monitoring the actions of our service providers, manufacturers, and suppliers and reviewing our near-term financial performance as we manage Savara through the uncertainty related to COVID-19.

As of the date of this report:

- our personnel have restrictions on traveling, both in the interests of their health as well as federal, state, local, and international travel restrictions;
- due to government guidance, social restrictions, and out of abundance of caution for our employees' health, our office-based employees are primarily working remotely;
- our third-party service providers, manufacturers, and suppliers are experiencing similar restrictions which could negatively impact our supply chain and progress of our development pipeline; and
- government restrictions enacted as a result of COVID-19 and related safety concerns have and could delay recruitment of our clinical trials.

The COVID-19 pandemic remains extremely fluid and we are continuing to re-assess the impact on our operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus in various regions throughout the world. Where appropriate, we are making necessary operational and strategic decisions where possible, in an attempt to mitigate the negative impact of the virus on our operations.

Income Taxes and the CARES Act

In response to the COVID-19 pandemic, many governments are taking measures to provide aid and economic stimulus. These measures include deferring the due dates of tax payments or other changes to their income and non-income-based tax laws. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which was enacted on March 27, 2020 in the United States, includes many measures to assist companies, including temporary changes to income and non-income-based tax laws. Some of the key tax-related provisions of the bill include:

- eliminating the 80% of taxable income limitations by allowing corporate entities to fully utilize net operating loss ("NOL") carryforwards to offset taxable income in 2018, 2019, or 2020. The 80% limitation is reinstated for tax years after 2021;
- allowing NOLs originating in 2018, 2019 or 2020 to be carried back five years;
- increasing the net interest expense deduction limit to 50% of adjusted taxable income from 30% for tax years beginning January 1, 2021 and 2020;
- allowing taxpayers with alternative minimum tax credits to claim a refund in 2021 for the entire amount of the credit instead of recovering the credit through refunds over a period of years, as originally enacted by the Tax Cut and Jobs Act in 2017; and
- allowing companies to deduct more of their cash charitable contributions paid during calendar year 2021 by increasing the taxable income limitation from 10% to 25%.

In addition to the income tax provisions noted above, the CARES Act provides non-income tax provisions, such as allowing payments of the employer's portion of Social Security payroll taxes that would otherwise be due from the date of enactment through December 31, 2020 to be paid over the following two years. Other provisions will allow eligible employers subject to closure due to the COVID-19 pandemic to receive a 50% credit on qualified wages against their employment taxes each quarter with any excess credits eligible for refunds.

The Consolidated Appropriations Act extended and expanded the availability of the CARES Employee Retention credit through June 30, 2021. Subsequently, the American Rescue Plan Act of 2021 ("ARP"), enacted on March 11, 2021, extended and expanded the availability of the CARES Employee Retention credit through December 31, 2021; however, certain provisions apply only after December 31, 2020.

We have assessed the provisions of the CARES Act and ARP and do not believe the measures mentioned above materially impact us or are relevant to our tax reporting. However, we are continuing to assess these and other provisions of the CARES Act and ARP and any potential additional federal stimulus packages with regards to their impact on our tax reporting as well as any provisions which may benefit us or our employees.

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 CROs, consultants and clinical trial sites 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 generally benefit multiple programs.
 Where appropriate, these costs are allocated by product candidate and consist primarily of:
 - 0 personnel costs, which include salaries, benefits and stock-based compensation expense;
 - 0 facilities and other expenses, which include expenses for maintenance of facilities and depreciation expense; and
 - 0 regulatory expenses and technology license fees related to development activities.

The following table shows our research and development expenses for the periods indicated:

		Three Months Ended March 31,					
	202	21		2020			
		(in thousands)					
Product candidates:							
Molgramostim	\$	5,091	\$	4,989			
Vancomycin		2,498		2,844			
Other		—		5,367			
Total research and development expenses	\$	7,589	\$	13,200			

We expect research and development expenses will remain significant in the future as we advance our molgramostim product candidate into and through clinical trials and pursue regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing activities, including 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 candidates. The probability of success of our product candidates 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 expenses primarily consist of salaries, benefits, and related costs for personnel in executive, finance and accounting, legal and investor relations, and 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 expenses include facility lease and insurance costs.

Critical Accounting Policies and Estimates

There have not been any material changes during the three months ended March 31, 2021 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, 2020. Please read "Part II, Item 6. 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, 2020 for further description of our critical accounting policies.



Results of Operations — Comparison of Three Months Ended March 31, 2021 and 2020

	Three Months Ended March 31,				Dollar	
	2021		2020		Change	
	(in thousands)			ousands)		
Research and development	\$	7,589	\$	13,200	\$	(5,611)
General and administrative		2,778		2,982		(204)
Depreciation		47		58		(11)
Total operating expenses	1	10,414		16,240		(5,826)
Loss from operations	(1	10,414)		(16,240)		5,826
Other income, net		197		819		(622)
Net loss	\$ (1	10,217)	\$	(15,421)	\$	5,204

Research and Development

Research and development expenses decreased by \$5.6 million, or 42.5%, to \$7.6 million for the three months ended March 31, 2021 from \$13.2 million for the three months ended March 31, 2020. The decrease is largely attributable to \$5.4 million of costs for the acquisition of an inhaled liposomal ciprofloxacin (the "Licensed Product") in March 2020. There were no costs incurred related to the Licensed Product during the three months ended March 31, 2021.

General and Administrative

General and administrative expenses decreased by approximately \$0.2 million, or 6.8%, to \$2.8 million for the three months ended March 31, 2021 from \$3.0 million for the three months ended March 31, 2020. The decrease was primarily due to a decrease in noncash stock-based compensation and personnel costs for the three months ended March 31, 2021.

Other Income, Net

Other income, net decreased by \$0.6 million, or 75.9%, to \$0.2 million for the three months ended March 31, 2021 from \$0.8 million for the three months ended March 31, 2020. The decrease is primarily related to a decrease in investment income of approximately \$0.5 million, which is included in the *Interest expense*, *net* line item on the condensed consolidated statement of operations in this Quarterly Report. This decrease is primarily due to moving available-for-sale securities to money market accounts as a result of the market volatility caused by the COVID-19 pandemic, which resulted in decreased investment income due to lower interest rates.

Liquidity and Capital Resources

As of March 31, 2021, we had \$56.0 million in cash and cash equivalents, \$136.7 million in short-term investments and an accumulated deficit of \$267.7 million. We entered into a Loan and Security Agreement with Silicon Valley Bank during the year ended December 31, 2017, which was amended a fourth time in March 2021, under which we have drawn a total of \$25 million.

On March 11, 2021, we completed a public issuance of our common stock and pre-funded warrants for gross proceeds of approximately \$130 million and net proceeds, after deducting underwriting discounts, commissions and offering expenses, of approximately \$121.8 million as discussed in Note 10, "Stockholders' Equity" in the notes to the condensed consolidated financial statements included in this Quarterly Report. Since 2017, we have completed four public offerings with combined net proceeds, after deducting the underwriting discounts and commissions and offering expenses, of approximately \$257.2 million.

We have used and intend to use the net proceeds from these offerings 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 candidates and general and administrative expenses. Given the uncertainty created by the COVID-19 global pandemic, we will continue to monitor our liquidity and capital requirements.

Cash Flows

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

		Three Months Ended March 31,			
	2	021	2020		
		(in thousands)			
Cash used in operating activities	\$	(9,597) \$	(13,079)		
Cash used in investing activities		(77,739)	(1,785)		
Cash provided by (used in) financing activities		120,466	(466)		
Effect of exchange rate changes		(28)	41		
Net change in cash	\$	33,102 \$	(15,289)		

Cash flows from operating activities

Cash used in operating activities for the three months ended March 31, 2021 was \$9.6 million, consisting of a net loss of \$10.2 million as well as an \$0.8 million decrease in accrued liabilities mostly relating to the wind down or completion of our non-aPAP trials during 2020. This was partially offset by approximately \$1.4 million of noncash charges (comprised of depreciation and amortization including right-of-use assets, accretion on discount to short-term investments, amortization of debt issuance costs and stock-based compensation).

The cash used in operating activities decreased during the three months ended March 31, 2021 compared to the three months ended March 31, 2020 by approximately \$3.5 million. The decrease is primarily due to the strategic decision to discontinue our non-aPAP trials discussed above.

Cash flows from investing activities

Cash used in investing activities of \$77.7 million for the three months ended March 31, 2021 was primarily associated with cash used for purchases of short-term investments in excess of proceeds from the net sales and maturities of short-term investments. The increase in cash used for purchases of short-term investments drives the period over period increase.

Cash flows from financing activities

Cash provided by financing activities of \$120.5 million for the three months ended March 31, 2021 was primarily related to \$121.8 million in net proceeds from the public issuance of common stock and pre-funded warrants and \$2.5 million in net proceeds from the exercise of warrants. These increases were offset by the payment of \$3.9 million to repurchase outstanding warrants, as discussed in Note 10, "Stockholders' Equity" in the notes to the condensed consolidated financial statements included in this Quarterly Report.

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 March 31, 2021, we had cash, cash equivalents, and short-term investments of approximately \$192.7 million. Although we have sufficient capital to fund many of our planned activities, including those discussed in Note 11, "Commitments - Manufacturing and Other," of the condensed consolidated financial statements 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 candidates.

Although we are well capitalized, until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to 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 product candidates 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. The loan agreement bears interest at the greater of (i) prime rate reported in The Wall Street Journal, plus a spread of 3.0% or (ii) 7.75%. Changes in the prime rate may therefore affect our interest expense associated with our secured term loan. If a 10% change in interest rates from the interest rates on March 31, 2021 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 Denmark and pay those vendors in local currency (Danish Krone) or Euros. 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 three months ended March 31, 2021 and 2020. A 10% change in the Krone-to-dollar or Euro-to-dollar exchange rate on March 31, 2021 would not have had a material effect on our results of operations or financial condition.

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

Although 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 the effects of the COVID-19 pandemic on 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 Officer, the effectiveness of our disclosure controls and procedures as of December 31, 2020, 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 March 31, 2021, 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 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 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 March 31, 2021 based on criteria in Internal Control - Integrated Framework (2013) issued by the COSO.

As a smaller reporting company, we are not required to obtain an audit on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2021 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, 2020, and the risk factors and other cautionary statements contained in our other SEC filings, 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 or our other SEC filings.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Index

Exhibit Number	Description
4.1	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on March 11, 2021).
10.1	Executive Employment Agreement, dated March 9, 2021, between Savara Inc. and Badrul Chowdhury (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 10, 2021).
10.2	Form of Warrant Repurchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March <u>11, 2021).</u>
10.3	Fourth Amendment, dated March 30, 2021, to Loan and Security Agreement, dated April 28, 2017, as amended on October 31, 2017, December 4, 2018 and January 31, 2021, between the Registrant, Aravas Inc. and Silicon Valley Bank (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 1, 2021).
10.4*	Master Services Agreement by and between Savara Inc. and Parexel International (IRL) Limited, effective January 6, 2021
10.5*	Work Order under Master Services Agreement by and between Savara Inc. and Parexel International (IRL) Limited, effective January 6, 2021
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	<u>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.</u>
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 Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Confidential portions of this exhibit were redacted pursuant to Item 601(b)(10)(iv) 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.

Date: May 13, 2021

Date: May 13, 2021

Savara Inc.

By: /s/ David Lowrance

David Lowrance Chief Financial Officer (Principal Financial and Accounting Officer)

By: /s/ Matthew Pauls

Matthew Pauls Chief Executive Officer and Chairman (Principal Executive Officer)

Certain identified information in this document has been excluded because it is both (i) not material and (ii) is the type of information the issuer both customarily and actually treats as private and confidential. [***] indicates where such information has been omitted.

MASTER SERVICES AGREEMENT

This Master Services Agreement (this "**Agreement**") is effective as of January 6, 2021 (the "**Effective Date**"), and is by and between Savara Inc. ("**Client**"), a Delaware corporation with a principal place of business at 6836 Bee Cave Road, Building 3, Suite 200, Austin, TX 78746, and Parexel International (IRL) Limited ("**Parexel**"), a company organized under the laws of Ireland with a registered address at 70 Sir John Rogerson's Quay, Dublin 2, Ireland.

BACKGROUND

Parexel is a contract research organization providing a full range of contract research organization services for companies such as Client. Client and Parexel wish to enter into this Agreement to provide the terms and conditions under which Client may engage Parexel or its Affiliates (as defined below) from time to time, upon execution of a Work Order (as defined below), to provide services for Client's studies or projects as identified in the relevant Work Order.

NOW THEREFORE, the parties agree as follows:

1. **DEFINITIONS**

1.1. "Affiliate" means (a) in relation to Client, any company, partnership or other entity that directly or indirectly controls, is controlled by, or is under common control with Client and (b) in relation to Parexel, any direct or indirect subsidiaries of Parexel International Corporation or any company, partnership or other entity that is managed by such direct or indirect subsidiaries. For purposes of this definition, "control" means the beneficial ownership of more than fifty percent (50%) of the issued voting shares or the legal power to direct or cause the direction of the general management of the company, partnership or other entity in question, and "controlled" shall be construed accordingly.

1.2. "Applicable Law" means any international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, or ordinance that applies to either party or to a Project, the Services, or this Agreement, as well as the current good clinical practices guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice (**"ICH/GCP"**), and applicable version(s) of the World Medical Association Declaration of Helsinki, and, where applicable, rules governing distribution practice, manufacturing practice and good laboratory practice, and rules governing the collection and processing of Personal Data (including Data Protection Law) and the collection and storage of human tissue samples and the performance of DNA testing.

1.3. "Client Inventions" shall have the meaning given in Section 7.1.

1.4. "Covered Data" means Personal Data Processed on Client's behalf in connection with the performance of the Services as such Personal Data is set out in a Work Order or other mutually agreed written documentation, together with any other categories of Personal Data that are reasonably necessary to perform the Services.

1.5. "Direct Competitors" means for Parexel a third party or third parties who provide similar services to the services that Parexel provides to the pharmaceutical, medical device and biotechnology industry, excluding third parties whose primary business is quality assurance audits.

1.6. "Data Protection Law" means all applicable data protection law, including GDPR and the Health Insurance Portability and Accountability Act; and the terms 'controller' and 'processor' shall have the meanings given to them under GDPR.

1.7. "GDPR" means the General Data Protection Regulation (Regulation (EU) 2016/679.

1.8. "Personal Data" has the meaning given to that term under Data Protection Law (and, in the event of any conflict or inconsistency between applicable data protection laws, the meaning under GDPR will prevail to the extent of such conflict or inconsistency).

1.9. "Process" has the meaning given to that term under GDPR.

1.10. "Protocol" means a detailed written plan for the conduct of a clinical trial.

1.11. "Project" means a clinical trial of Client described by a Protocol or such other project for Client with respect to which Parexel provides Services pursuant to a Work Order.

1.12. "Regulatory Authority" means any supra-national, national or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement, including without limitation, the European Medicines Agency and the United States Food and Drug Administration.

1.13. "Study Data" shall have the meaning given in Section 7.1.

1.14. "Study Drug" or **"Study Device"** means all medications or medical devices used in a Project.

1.15. "Study Materials" means the Study Drug, Study Device and other supplied products and materials, including but not limited to an investigational or marketed pharmaceutical product (other than a Study Drug or Study Device) used as a reference in a Project.

2. SERVICES

2.1. Parexel will provide to Client the services set forth in the work order(s) executed by both parties ("**Work Order**"), substantially in the form of **Attachment A** hereto ("**Services**"). Parexel shall perform the Services in compliance with: (i) the Protocol, (ii) the terms and conditions of this Agreement, (iii) the terms and conditions of the applicable Work Order, (iv) Parexel's standard operating procedures ("**SOP**s"), which shall have been reviewed and agreed upon by Client, including any deviations thereto that would impact a Project, (v) all Applicable Laws and (vi) if agreed upon with Parexel, Client's reasonable written instructions. If any term in a Work Order conflicts with this Agreement, this Agreement will control except to the extent that the Work Order expressly states that such conflicting term prevails over this Agreement. To the extent that any Services relate to scientific matters, the Protocol will control the performance of such Services, and will take precedence over all other Project documents for such Services. Notwithstanding anything to the contrary in this Agreement, neither party nor its Affiliates shall have an obligation to order or provide Services in the absence of an executed Work Order.

2.2. Client and Parexel agree that any change to the details of a Work Order by Client or Parexel, or changes to Applicable Law directly impacting the Services and not anticipated by a Work Order, may require changes to the description of Services, budget, estimated timelines, or payment schedule. Any such required changes shall, if the parties agree to such changes, be reflected in either (i) an approved entry in a Change in Scope Log ("**CIS Log**"), in accordance with and in the form set forth in **Attachment B**, or (ii) a written amendment to the Work Order (a "**Change Order**"), in accordance with and in the form set forth in **Attachment C**. The parties to the Work Order agree to process such changes as follows:

(a) For each Work Order, Parexel shall generate and maintain a CIS Log showing all changes to the scope of Services and any associated changes to the budget. After each new entry, Parexel shall forward the updated CIS Log to Client and Client shall review the CIS Log and request any changes in writing within ten (10) business days of receipt of the CIS Log. A Client employee set forth in the Work Order which may be updated in writing by Client as necessary ("Savara Representative") shall

promptly (but not later than fifteen (15) business days after receipt) sign each applicable line item if such item is approved by Client. Upon approval by Client the amended scope of Services and any associated changes to the budget as reflected in signed CIS Log entries will be binding on both parties and shall be implemented. Once the aggregate amount of the CIS Log reaches a threshold that will be specified in the applicable Work Order, or if regulatory reasons require that the parties execute a Change Order, then a formal Change Order will be prepared, and signed by both parties. If any changes happen in such [***] period, a Change Order will be prepared irrespective of the threshold at the end of every [***] or as otherwise agreed upon in the respective Work Order, as well as upon the completion of Services.

(b) Parexel shall not be required to perform any services or incur any expenses that are not specifically set forth in a Work Order unless and until a Change Order is executed by the parties to the Work Order or a CIS Log is approved by the Client as set forth above in this Section.

2.3. If Parexel performs any changes in good faith upon Client's written request from the Savara Representative before the applicable entries in the CIS Log are approved or the applicable Change Order is executed, then Client will pay Parexel for the performance of such changes and any expenses related thereto. Upon request, Parexel will provide Client with [***]. In addition, if Client fails to approve a duly submitted CIS Log entry within [***] after Parexel has submitted such request, and/or if the parties fail to execute a formal Change Order within [***] after such formal Change Order has been submitted by Parexel to Client, then Parexel reserves the right, upon written notice to Client, to immediately terminate said activities.

2.4. If Parexel provides any Services in good faith upon Client's written request either (a) prior to execution by both parties of a start-up Work Order for such Services at the start of Parexel's engagement, or (b) following expiration of the start-up Work Order but prior to execution by both parties of a full Work Order for such engagement, then, in either such case, Client shall pay Parexel for the performance of such Services and any expenses related thereto, and all terms and conditions of this Agreement shall apply to such Services to the same extent as if such Services had been performed while the applicable start-up Work Order (or full Work Order, as the case may be) was executed and in full force and effect. In addition, Client acknowledges that Parexel is under no obligation to provide Services under either scenario (a) or (b) set forth in the preceding sentence, and Client agrees that Parexel may immediately terminate said activities at any time prior to the execution by both parties of the applicable start-up Work Order (as the case may be).

2.5. Parexel may use its Affiliates to perform any of its obligations under this Agreement or any Work Order In addition, any Affiliate of either party may execute a Work Order pursuant to this Agreement. Wherever an Affiliate of either party enters into a Work Order, for the purposes of such Work Order, all references in this Agreement to Client or Parexel, as the case may be, shall be read as if they were a reference to that Affiliate only, and only that Affiliate shall be deemed the party to this Agreement for the purpose of the Services provided under such Work Order. In all cases, Parexel is [***].

2.6. If, as part of the Services, Parexel provides online access to any software tools developed by Parexel (the "**Software**"), then the following terms and conditions shall apply: Client shall not copy, modify, transcribe, translate, sell, lease, rent, share, offer a subscription service or service bureau, or assign, or in any way transfer the Software or access to the Software, or any interest thereto, or use the Software for any purpose other than for Client's business purposes relating to the Project. Client shall not reverse engineer, disassemble or decompile the Software, except to obtain information necessary to provide programs interoperable with the Software, and provided that Client first requests from Parexel such information and Parexel is unable or unwilling to provide the information within a reasonable period of time. Client acknowledges that the Software is Parexel Intellectual Property (as defined in Section 7.2).

2.7. Each Work Order will identify certain key personnel as mutually agreed upon by Client and Parexel (collectively, "**Key Personnel**"). Parexel recognizes that Client's entry into this Agreement is

based in part on Client's reliance upon the assignment of such Key Personnel to Client's Projects. Parexel agrees [***]. Notwithstanding the foregoing, Client recognizes that [***]. Whenever practicable, Parexel shall give Client [***] notice prior to the departure of any Key Personnel from Client's Projects, and shall propose replacement personnel. Client shall have the right to approve or reject any replacement Key Personnel at its reasonable discretion, such approval not to be unreasonably withheld, conditioned or delayed; provided, however, that Parexel shall not be liable for any delays caused by Client's rejection of any Key Personnel. In addition, Client may request replacement of Key Personnel by written notice to Parexel if Client reasonably believes that Key Personnel are not performing Services to the reasonable satisfaction of Client. Parexel is responsible for [***]. Parexel shall submit the names and qualifications of proposed replacement Key Personnel to Client, Client will have [***] to approve such Key Personnel.

2.8. Obligations transferred to Parexel under a Work Order in accordance with 21 C.F.R. 312.52 will be set forth in a "Transfer of Obligations under 21 C.F.R. 312.52 and Applicable Foreign Equivalents" ("**TORO**"). Parexel will assume responsibility for transferred obligations set forth in the TORO and agrees to diligently carry out such transferred obligations in accordance with this Agreement and the applicable Work Order.

2.9. Client acknowledges and agrees that, unless set forth in a Work Order, this Agreement does not cover certain specialized services ("**Specialized Services**") which Parexel may provide in particular countries where a Project is conducted, such as, but not limited to, serving as legal representative, local sponsor, agent, qualified person, or senior scientific officer, and agrees that any such Specialized Services shall require and be subject to the parties' execution of a separate services agreement with respect to such Specialized Services. The parties will use commercially reasonable efforts to execute those Specialized Services Agreements determined by the parties to be necessary or desirable to enable the performance of Client's Projects promptly following the determination by Client in consultation with Parexel that such Specialized Services Agreement is necessary.

2.10. Client shall provide to Parexel, in advance of the execution of a Work Order, all information reasonably available to Client regarding known or reasonably foreseeable hazards (in particular safety and toxicology data) associated with any of the Study Materials, and thereafter any information that Parexel may reasonably request.

2.11. Client and Parexel agree that in those cases in which a Clinical Pharmacology Unit of Parexel conducts a Project or provides Services, the parties shall negotiate additional terms tailored to such Study or Services, and if they agree on the terms, shall memorialize them in an addendum hereto or in the applicable Work Order.

2.12. Client and Parexel agree that those cases where Services are identified in the relevant Work Order as clinical trial supplies and logistics services, the terms of **Attachment D** attached hereto shall also apply to those Services.

2.13. Parexel will perform the Services in accordance with Parexel's SOPs, report and file templates, personnel training curriculum and systems, unless specifically stated otherwise in a Work Order. Parexel's SOPs shall follow Applicable Law. To the extent not set forth in a Work Order, any Client request to use Client's SOPs or otherwise deviate from Parexel's SOPs or to require Parexel personnel to access or track training in Client's systems may result in a modification of the budget if such requests would result in rework or changes to the resource assumptions contained within the budget. Upon Client's reasonable request, Parexel will provide Client with access to SOPs either on site or electronically pursuant to Parexel's policies.

2.14. The parties will establish an executive committee (the "**Executive Committee**") that comprises at least one executive or corporate officer of each Party, as well as certain Key Personnel and Savara Representatives. The Executive Committee will provide a functional mechanism for Client's oversight of the Services in accordance with the Agreement, the applicable Work Orders, and Applicable Law. The Executive Committee will function at a strategic relationship level, across Projects and Studies for ongoing, overall assessment of Parexel's performance of the Services to ensure compliance with regulatory requirements and obligations under this Agreement and Work Orders, as well as

identification and resolution of project level and/or cross-project systemic issues. The composition of the Executive Committee and the scope and description of its activities will be determined by Client and confirmed by mutual agreement of the parties and may be documented in an ancillary document or plan.

3. THIRD-PARTY AGREEMENTS

3.1. If Client requests in writing that Parexel use a particular provider of materials or services in connection with the Services (a "**Client-Designated Vendor**"), then Parexel will contract with such Client-Designated Vendor unless Parexel [***], in which case Client may contract directly with such Client-Designated Vendor. Parexel shall not (a) have responsibility for the selection, instruction or supervision of any Client-Designated Vendor, or (b) be responsible for the acts, omissions, or performance (including willful misconduct) to the extent attributable to any Client-Designated Vendor. All Client Designated Vendor costs will be treated as a Pass Through Expenses and Parexel shall be responsible for payment to such Client Designated Vendor to the extent that Parexel has entered into a contract with such Client Designated Vendor or Parexel has agreed to act as payment agent pursuant to Section 4.5 and a Work Order.

3.2. Parexel will not subcontract or assign or delegate any Services to any third party, including any subcontractor, without first obtaining Client's written consent, which consent may be evidenced in the Work Order or Change Order. Any such third party shall be a "**Subcontractor**." Parexel is responsible for [***]. For avoidance of doubt, [***]. Parexel will make reasonable effort to allow Client to audit the records of the Services and inspect the facilities (if applicable) of its Subcontractors and any Client-Designated Vendors performing Services in support of the Project where such Services are performed. To the extent practicable, Parexel will [***]. Parexel shall use commercially reasonable efforts to [***] in the event of a breach by such third party. In the event of such a breach, Parexel shall [***].

3.3. If pursuant to the applicable Work Order, or as otherwise contracted, Parexel will negotiate clinical trial agreements ("**Clinical Trial Agreements**") with investigators, hospitals and/or research institutions (collectively, "**Sites**") on Client's behalf, using form(s) approved by Client and following any negotiation parameters provided by Client. Client shall have the right to approve all finalized Clinical Trial Agreements prior to execution. Parexel shall not, unless required by Applicable Law or as otherwise mutually agreed, be a party to any Clinical Trial Agreement.

3.4 If contracted to do so as part of the Services, Parexel will administer and disburse Investigator Grants as described in the applicable Work Order. Client will provide funds to Parexel in advance as set out in the Work Order. Parexel will provide quarterly standard reporting on accruals and forecasts to support any requested advance of any Investigator Grants. Parexel is not obligated to pay Investigator Grants if Client has not made sufficient advance funds available to Parexel to cover the Investigator Grants incurred by Parexel as set forth in the Work Order. If Client does not provide funds required by the Work Order to cover Investigator Grants incurred by Parexel, Client agrees that Parexel will not be responsible for any resultant delays in a study or Project. In no event will a Site or Site employee or contractor (such as a Principal Investigator) be construed to be Parexel's or Client's employee, subcontractor, agent, consultant, or representative. For the purposes of this section, "**Investigator Grants**" means all fees and expenses payable to investigators, hospitals and/or research institutions pursuant to a Clinical Trial Agreement.

4. PAYMENTS

4.1. Client will pay to Parexel the Service fees specified in the applicable Work Order up to the amount of the budget therein. Parexel understands and agrees that fees and payment schedules shall be set forth in a Work Order. Both parties agree to [***]. In addition to the payment of Service fees, Client will pay or reimburse Parexel for all items specifically set forth in the Budget as "Pass Through Expense." Examples of "Pass Through Expenses" may include: Investigator Grants and reasonable out-of-pocket expenses, including without limitation, printing, shipping, wire transfer fees, telephone, travel and lodging, incurred by Parexel or its Affiliates in providing the Services and any other payments made by Parexel or its Affiliates to third parties in connection with the Services and in each case set out in

the budget ("Pass-Through Expenses") which [***]. For clarity, [***]. All Pass-Through Expenses will be invoiced [***].

4.2. All invoiced amounts for Services performed in accordance with the terms and conditions of this Agreement and any Work Order are due net [***] from the receipt (including electronic receipt) of Parexel's invoice plus [***]. If Client identifies items in an invoice which are disputed, Client will notify Parexel in writing, noting its objection to the disputed item(s) with specificity, within [***] of the date of the invoice. If a dispute arises after the payment of an invoice, the parties will enter into good faith negotiations to resolve such dispute [***]. All disputes of which Client notifies Parexel in accordance with this Section shall be addressed as set forth in Section 18 below. Client will pay any undisputed portions of any invoice per the agreed upon payment terms. Parexel may charge interest on any unpaid invoice (including any undisputed portion of a disputed invoice) at the rate of [***] until such invoice(s) is paid in full. Payments will be made to Parexel in accordance with the instructions set forth in the applicable Work Order or such other written instructions as may be provided by Parexel from time to time.

4.3. Each party will be responsible for any taxes based on its own net income/profits and those of its Affiliates. All other taxes and duties incurred by Parexel or its Affiliates, including those pertaining to Parexel's Service fees or Pass-Through Expenses or incurred on the movement of Client's Study Materials ("**Taxes**"), will be the responsibility of Client and such Taxes are not included in any such fees or expenses. Parexel shall be entitled to invoice Client in respect of such Taxes without mark-up and Client shall pay to Parexel such Taxes in addition to any other payments due to Parexel. Parexel will reasonably cooperate with requests by Client to provide information or documents within Parexel's control, at Client's reasonable expense, to enable to Client to recover Taxes related to the Services provided under a Work Order to the extent permitted by law.

4.4. All payments due hereunder in accordance with the payment schedule of the applicable Work Order shall be made by Client in the currency that is used in the applicable Work Order (the "**Work Order Currency**"). The parties to the Work Order acknowledge and agree that all amounts set forth in the Work Order shall be in Work Order Currency. In determining the amount payable by Client under a Work Order for Pass-Through Expenses incurred by Parexel in a currency other than the Work Order Currency, Parexel will use a rate of exchange based on the www.oanda.com exchange rate on the date such Pass-Through Expenses are incurred by Parexel.

4.5. In addition to the requirement that Client advance funds for Investigator Grants as set forth in Section 3.4, to the extent that Parexel has agreed to act as payment agent for Client with respect to any third parties, or to the extent that Parexel has agreed to advance any payments to third parties in respect of Pass-Through Expenses, Parexel shall only be obligated to make such payments to third parties to the extent that Client has provided funds to Parexel for such payments in advance as set forth in the Work Order. In the event the funds advanced by Client as set out in the Work Order are expected to be insufficient to cover such payment, Parexel shall invoice Client for the additional amount required to meet such shortfall, and will provide reasonable documentation to support such amount. Client will pay to Parexel the additional amounts required in accordance with the payment terms set forth in Section 4.2. If Client does not provide funds in time to enable Parexel to make timely payments, the Client agrees to be liable for and to reimburse Parexel for any interest and other charges, costs, fees and expenses incurred by Parexel because of such late payment.

4.6. If Parexel does not perform a part of the Services as required under this Agreement, or if Parexel's performance of such part of the Services does not comply with this Agreement, and in either case, [***] then upon the parties mutual agreement, Parexel may [***]. If Parexel's performance is rendered impossible, [***], then Parexel may [***].

5. TERM AND TERMINATION

5.1. This Agreement will commence on the Effective Date and will terminate on the fifth (5th) anniversary of the Effective Date unless earlier terminated in accordance with this Agreement or extended by mutual signed written agreement of the parties. Any Work Order, the duration of which extends beyond the expiration or termination of this Agreement, will continue to be performed for the

term of such Work Order, and will continue to be governed by the terms of this Agreement, which terms shall remain in effect beyond the expiration or termination of this Agreement solely with respect to such Work Order.

5.2. Either party to this Agreement and/or any individual Work Order(s) may immediately terminate this Agreement and/or such individual Work Order(s), and/or Parexel may suspend performance of Services, for a material breach of this Agreement or the applicable Work Order(s) by the other party (the "**Breaching Party**"), provided that the Breaching Party fails to cure such material breach within ninety (90) days (or 30) days for payment breaches) after receipt of written notice specifying such material breach.

5.3. Either party to this Agreement and/or any individual Work Order(s) may immediately terminate this Agreement or such Work Order upon written notice to the other party upon the happening of any of the following events: (a) if continuation of the Services would pose an undue risk to the health and/or wellbeing of a Project participant, (b) if any certificate, authorization, approval or exemption from a Regulatory Authority required for the conduct of the Services is revoked, suspended, or expires without renewal, (c) if such party is of the reasonable opinion that the continuation of the Services would be in violation of Applicable Law, or (d) upon the other party's becoming insolvent and/or unable to pay all material debts when due, including without limitation if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent.

5.4. Client may terminate this Agreement or any Work Order for any reason on sixty (60) days prior written notice to the other party.

5.5. Upon receipt of notice of termination of this Agreement and/or any Work Order(s) by a party to this Agreement or such Work Order: (a) Parexel will, as soon as reasonably practicable within ICH/GCP, discontinue providing the applicable Services, except to the extent reasonably required to safely close out a Project and as mutually agreed upon by the parties ("**Closeout Services**"), and (b) will terminate existing third-party obligations to the extent practicable and cancelable. Upon expiration and/or termination of this Agreement and/or any Work Order and submission of an invoice in accordance with this Agreement, Client will pay Parexel for all Services performed, including without limitation, Closeout Services, non-cancelable costs and all Pass-Through Expenses incurred by Parexel up to and including the completion of Closeout Services. Any final payment still owed to Parexel, or any refund due Client, pursuant to this Section, will be made by Client or Parexel, as applicable, within [***] of the final reconciliation invoice(s) from Parexel.

5.6. Termination of this Agreement or of a Work Order for any reason shall not affect the rights of the parties that have accrued on or before termination.

6. CONFIDENTIALITY AND PRIVACY COMPLIANCE

6.1. "Confidential Information" means information that relates to the business, operations, products, or plans of a party that either is marked as "Confidential," "Proprietary" or the substantial equivalent at the time of disclosure or that a reasonable person would believe to be confidential and/or proprietary based on the circumstances of its disclosure. The terms of this Agreement and any Work Order, including without limitation, pricing, constitute the Confidential Information of both parties and may not be disclosed by either party except in accordance with this Section or the other party's prior written consent. Parexel Intellectual Property (as defined in Section 7.2) shall be the Confidential Information of Parexel. In addition, all information related to [***] are Client's Confidential Information. Confidential Information will not include information that (a) is or becomes part of the public domain through no fault of the recipient; (b) was in the recipient's rightful possession prior to disclosure by discloser; (c) is rightfully disclosed to the recipient by a third party with the right to disclose the information; or (d) is independently developed by the recipient without use of the discloser's Confidential Information.

6.2. In the event the receiving party (a) is required, in the opinion of its legal counsel, by Applicable Law including, without limitation, in accordance with (i) securities laws or regulations and the applicable rules of any public stock exchange or (ii) to defend or prosecute litigation, to disclose the disclosing party's Confidential Information, or (b) receives a subpoena, other validly issued administrative or judicial order, or a request pursuant to regulatory audit, requesting Confidential Information of the disclosing party, then in any such case the receiving party may, to the limited extent necessary to comply with the requirements of subsection (a) and/or (b), disclose the other party's Confidential Information. In such event, to the extent practicable and permitted by Applicable Law or the requesting government agency, the receiving party shall promptly notify the disclosing party in writing of such request and provide reasonable assistance to the disclosing party, at the disclosing party's expense, if the disclosing party wishes to seek a protective order or similar relief. Notwithstanding the foregoing to the contrary, Parexel acknowledges and agrees that Client may be required, in the opinion of its legal counsel, to publicly disclose certain terms of this Agreement or a Work Order by Applicable Law, or by regulation or rule of any stock exchange, such as in Forms 8-K, 10-Q and 10-K (each such disclosure a "**Public Disclosure**"). If Client is required to file a copy of this Agreement or any Work Order as an exhibit to such filing, Client will [***].

6.3. Client hereby agrees that Parexel may disclose Confidential Information to institutional review boards, ethics committees and any Regulatory Authority if Parexel reasonably believes such disclosure is necessary to protect the health and well-being of study subjects, to ensure substantial compliance with Applicable Law, or to maintain the scientific integrity of the Project, provided that Parexel first issues a notice in accordance with the provisions of Section 19.1 of this Agreement giving the Client itself a reasonable opportunity to directly inform such third parties of any such issue and further provided Client fails to do so within a reasonable time.

6.4. Client and Parexel may use the other party's Confidential Information only in connection with its rights and obligations under this Agreement. Except as expressly permitted herein, each party will maintain in confidence and will not disclose the other party's Confidential Information, using the same degree of care, but no less than reasonable care, as it uses to protect its own confidential information of a similar nature. The receiving party may disclose the disclosing party's Confidential Information only to the receiving party's Affiliates and those third parties (provided that with regard to disclosure by Client, such third parties are not Direct Competitors of Parexel) who (a) have a need to know such Confidential Information, (b) are made aware of the Confidential Information's confidential and/or proprietary nature and (c) are under an obligation to protect confidential and/or proprietary information no less restrictive than the obligations set forth herein. To the extent necessary to discharge a party's obligations under this Agreement, that party may disclose the other party's Confidential Information to Regulatory Authorities, ethics committees, and institutional review boards. To the extent that Confidential Information contains the disclosing party's SOPs (defined above), such Confidential Information may only be viewed by the receiving party on the disclosing party's premises or remotely in case of Client's review of Parexel SOPs (e.g. electronically, online or similar, as set forth by Parexel's SOPs and policies and no portion thereof may be photocopied or replicated in any way.

6.5. The terms and conditions of this Agreement shall also apply to any Confidential Information made available to either party (or its Affiliates) by the other party (or its Affiliates) during the term of this Agreement and for a period of [***] thereafter, including Confidential Information exchanged by the parties or their Affiliates before, during or after a bid defense or a request for a proposal.

6.6. Parexel and Client will comply with Data Protection Law in connection with the Services. With respect to the Covered Data relating to a study subject, Site investigators and research site staff, which is collected in connection with a Project, together with any other data subject whose Personal Data is Processed by Parexel on Client's behalf in connection with the performance of the Services (the "**Data Subjects**"), the parties acknowledge and agree that the Client and/or its Affiliates will be the "controller" and Parexel a "processor". If and to the extent that Parexel Processes Covered Data on behalf of Client and applicable Data Protection Law requires, the parties agree that the terms of **Attachment E** attached hereto shall also apply in respect of such Covered Data.

6.7. The parties acknowledge that, as long as Parexel has obtained any required consent(s) and/or is otherwise permitted to Process Personal Data relating to investigators and/or statistics relating to study subjects' participation in a Study, (a) Parexel may use Personal Data that is collected in the course of providing the Services to evaluate investigator performance and improve future clinical trials, and (b) such usage shall not constitute the Processing of Covered Data for the purpose of this Agreement.

7. OWNERSHIP

7.1. Client shall retain and have full ownership right, title and interest in all information, reports, products, designs, methodologies, programs, systems, and other proprietary property that were owned, developed, or licensed by, or on behalf of, Client or its Affiliates prior, or independent of, this Agreement (**"Client Pre-Existing Intellectual Property**"). Client will retain and have full ownership rights in the Study Drug and/or Study Device and their applications. Client will own all inventions, discoveries, know how, idea, copyrights, trademarks relating to the Study Drug or Study Device under a Protocol or Project made by Client, Parexel, its Affiliates or Subcontractors, or Client-Designated Vendors, or its or their respective agents or employees, either solely or jointly with others (**"Client Inventions**"). Parexel hereby assigns all such Client Inventions to Client and will cause all of its Affiliates, employees and Subcontractors to do the same. In addition, Client shall own all data (and all intellectual property rights thereto) in any form generated in the performance of this Agreement, any Work Order, any Protocol or any Project (**"Study Data"**) as a work made for hire. Parexel and its employees, agents, Subcontractors, Affiliates and its and their related personnel, shall upon Client's request and at Client's reasonable expense, execute such documents and take such other actions as Client Intellectual Property. Parexel shall require that each of its directors, officers, employees and Subcontractors performing any part of the Services shall have a contractual obligation to assign to Client all Client Inventions so that Parexel can comply with its obligations hereunder, and Parexel shall enforce such agreements to provide Client with the benefits thereof.

7.2. Parexel understands and agrees that all materials, data, information, reports, records documentation and/or results (including, without limitation, Study Data, deliverables under the applicable Work Order ("**Deliverables**"), project management documentation, documents submitted to and received from regulatory authorities, case report forms, project databases, site regulatory documentation related to a Study, etc.) generated, prepared or obtained by Parexel as a result of conducting a Project under this Agreement (collectively, the "**Service Records**") shall be the sole and exclusive property of Client. To the extent any Parexel Intellectual Property is included in the Deliverable, Parexel hereby grants to Client a non-exclusive, irrevocable, worldwide, fully paid-up license to use such intellectual property rights as they are contained in the Deliverables as reasonably necessary to use the Deliverables for the regulatory approval or commercial exploitation of the Study Drug or Study Data. Parexel shall provide any or all Deliverables and Service Records (including originals thereof) to Client upon Client's written request, unless the applicable Work Order provides for an alternate disposition thereof. Client shall have the right to use Deliverables and Service Records for any lawful purpose without additional compensation to Parexel beyond the agreed budget amount set forth in the applicable Work Order for Services actually performed by Parexel. All Deliverables are works made for hire.

7.3. Parexel will retain all Client Intellectual Property, Deliverables, Study Data and Service Records in confidence and in accordance with all Applicable Laws. In particular, and without limitation, Parexel will ensure that all electronic records, as defined in 21 C.F.R. §11.3(a)(6), as amended, are maintained consistent with the requirements of 21 C.F.R. Part 11, as amended.

7.4. Notwithstanding anything to the contrary contained in this Agreement or any Work Order, Parexel retains exclusive ownership of all rights, title and interest in and to all intellectual property (including without limitation, patents, copyrights, trademarks, trade secrets, know-how, software, inventions, designs, utilities, tools, models, methodologies, programs, systems, databases, and specifications) that is owned, developed, or licensed by, and/or on behalf of, Parexel or its Affiliates prior to, or independent of, Parexel's performance under this Agreement or any Work Order, even if

utilized to provide the Services (the "**Parexel Pre-Existing Intellectual Property**"), as well as all improvements, modifications or enhancements to such intellectual property developed in the course of performing the Services (each an "**Improvement**") provided in no event shall Parexel Pre Existing Intellectual Property or Improvement include or incorporate any Client Pre-Existing Intellectual Property, Client Confidential Information or including Client Inventions or Study Data. Client hereby assigns to Parexel's at Parexel's expense, all right, title, and interest it may have or obtain in any such Improvements, including, without limitation, any and all intellectual property rights arising therefrom or related thereto. The Parexel Pre-Existing Intellectual Property, together with any Improvements, shall collectively be referred to as "**Parexel Intellectual Property**."

7.5. Unless otherwise set forth in a Work Order, Client will be responsible for archiving of Project documents according to Applicable Law. Parexel will return to Client for archiving all documents relating to the Services performed (according to the Applicable Law of the participating countries) upon completion of the Services under any Work Order (or at any earlier point in time when requested to do so by Client in writing) at Client's reasonable expense, and thereafter Client will be responsible for the archiving of such documents. Parexel may retain one copy of the Project documents, including Confidential Information, if any, to satisfy regulatory and audit requirements as well as for feasibility purposes solely related to the general design and management of clinical studies without reference to or disclosure of Client's Confidential Information.

7.6. As between Client and Parexel or its Affiliates or any Subcontractor, Client shall exclusively and solely own all Specimens. "**Specimens**" means any biological samples or specimens provided by or taken from any human subject in connection with participating in a Project, including, without limitation, any tissue samples, biopsies, and blood samples. By-products and derivatives of any such samples, specimens, or biopsies shall also be considered Specimens. Parexel shall not use Specimens except to the extent specifically set forth in a Work Order. If and to the extent that Parexel has agreed in a Work Order to do so, Parexel shall [***]. If and to the extent that Parexel has agreed in a Work Order to do so, Parexel shall [***].

8. INSURANCE

8.1. Each of Client and Parexel shall bind and maintain, at its sole expense, with financially sound and reputable insurers, insurance coverage at the following minimum limits covering the conduct of its business during the term of this Agreement and any Work Order, and for a period of [***] following the termination of this Agreement or any Work Order (whichever is longer) provided that [***]. The limits below are in United States dollars and may be satisfied when in currencies other than United States dollars equivalent to the limits stated below.

- (a) Commercial General Liability: [***] per occurrence and [***] in the aggregate.
- (b) Errors and Omissions: [***] per claim and in the aggregate. (Parexel only)
- (c) When Client has marketed products, Products Liability: [***] per occurrence (Client only). Client hereby warrants that, the policy shall include clinical trials coverage and does not exclude coverage for any product or compound subject to any Project.
- (d) Client and Parexel shall bind and maintain all other statutory insurance coverage as required by local laws in each country of operation.

8.2. In addition, to the fullest extent required under Applicable Law, Client will maintain in full force and effect during the term of this Agreement and any Work Order when a human clinical trial is being conducted under a Protocol, insurance coverage for all subjects who have been enrolled into any Project and/or in whom Project-related procedures are undertaken as specified in the applicable Protocol. Client hereby warrants that the policy does not exclude coverage for any product or compound subject to any Project.

8.3. Client shall be responsible for insuring the Study Materials against loss or damage.

8.4. Client and Parexel will, upon written request from the other party, provide certificates of insurance evidencing the above required coverage, and showing the expiration date of each such policy.

8.5. All such Study Materials are and shall remain the sole property of Client, and Parexel will use Study Materials only in connection with the applicable Protocol and for no other purpose unless otherwise approved in writing by Client. Parexel will require that Study Materials in its possession and control (or in the control or possession of Affiliates or Subcontractors) are at all times handled, stored, and administered in full compliance with Applicable Laws.

8.6. Parexel shall maintain Warehouseman's legal liability insurance or similar for loss, destruction, adulteration or misbranding of any Study Materials in its possession [***] in the amount of at least [***] per occurrence and in the aggregate.

9. AUDIT

9.1. Subject to Section 9.2 below, during the term of this Agreement, upon reasonable advance written notice (which, at a minimum, must include, at least [***] prior to Client's proposed audit commencement date, reasonably sufficient details of Client's proposed audit agenda, timing, and scope) and at times reasonably agreed upon by the parties during Parexel's normal business hours, but no more frequently than [***] (except that one additional permitted "follow-on" audit shall be permitted in the event of material negative findings in the initial annual audit), Client may, without material disruption to Parexel's normal business operations, audit Parexel's facilities or those of its Affiliates used to perform the Services, Project documentation and Pass-Through Expenses that relate exclusively to the Services for the purpose of determining Parexel's or those of its Affiliates compliance with this Agreement and the applicable Work Order(s). Any underlying Parexel Confidential Information disclosed or incorporated into the audit results shall remain the Confidential Information of Parexel. Within [***] after the completion of each audit, Client will provide a written report detailing the results of such audit to Parexel. As permitted by Applicable Law and if related directly to Services, Parexel and its Affiliates will provide all information and records reasonably requested by Client to permit Client to conduct the audit to Client's reasonable satisfaction, including, without limitation: [***]. If Parexel or its Affiliates receives any regulatory findings or citations, including but not limited to U.S. FDA Form 483 notices or observations; or any refusal to file, rejection or warning letters, or similar notices, affecting or relating to a Project or the Services and/or the facilities in which the Services are or were conducted, Client shall be entitled conduct a for-cause audit and inspection of Parexel and the applicable Affiliate. Upon Client's reasonable written notice, [***].

9.2. Notwithstanding anything to the contrary contained in this Agreement, no third party auditor used by Client to conduct an audit under this Agreement ("**Third Party Auditor**") will be (a) a Direct Competitor of Parexel or any of its Affiliates, or (b) permitted to access or to examine any information, materials or facilities, until such Third Party Auditor has entered into a non-disclosure agreement with Parexel on terms no more burdensome than those contained in Section 6 of this Agreement. Affiliates of Client shall not be considered Third Party Auditors. If the audit is to be conducted by an Affiliate of Client, Client shall obligate such Affiliate to comply with confidentiality obligations with respect to such audit that are no less restrictive than the confidentiality obligations set forth in Section 6 of this Agreement, and shall be liable for any breach by its Affiliate of those obligations. Client, its Affiliates, and its Third Party Auditors will have the right to conduct audits having the scope of, and according to the process set forth in Section 9.1. Parexel will not be required to provide access to (a) the confidential information of any other third party, except as set forth in Section 9.1, or (b) its internal QA programs.

9.3. If any Regulatory Authority conducts, or gives notice of its intent to conduct, an inspection at Parexel's facility (or that of an Affiliate or Subcontractor) or any Site or facility relating to a Study, or takes any other regulatory action (of which it provides actual notice to Parexel) with respect to Services provided by Parexel pursuant to this Agreement, Parexel will promptly give Client notice thereof, supply to Client all information pertinent thereto which Parexel is permitted to disclose subject to Applicable Laws, and cooperate with such inspection and provide timely access for such Regulatory Authority to the requested documentation and facilities. Parexel will permit any Regulatory Authority advising of its intent to audit Parexel related to the Services performed hereunder to (a) inspect any facilities where the Services have been or are being performed or those of its Affiliates or

Subcontractors; (b) monitor and/or audit the conduct of the Project; or (c) inspect, audit and/or copy any and all Project documents, source documents, work product and required licenses, certificates and accreditations. Parexel shall, and shall cause its Affiliates, Subcontractors, and its and their employees to, cooperate with any of the foregoing activities and shall provide timely access to requested documentation and facilities, and will promptly provide a detailed written summary of any such inspection visit directly related to a Study or the Services, including, without limitation any regulatory findings or citations such as U.S. FDA Form 483 notices, and any refusal to file, rejection or warning letters, and the basis therefor, and any corrective actions to be implemented by Parexel in response to such findings or citations. Client will have the right to be present at the opening and closing meeting of any inspection, audit or visit by a Regulatory Authority that pertains to any Study or Services conducted by Parexel on behalf of Client. Client will not [***]. Should Client request that Parexel [***].

9.4. Parexel Service fees and Pass-Through Expenses associated with audits performed by Client or on behalf of Client, except for Followon Audits, are considered outside the scope of Services, unless specifically defined otherwise in a Work Order. Any Service fees or Pass-Through Expenses with respect to Client audits will be billed [***].

10. REPRESENTATIONS AND WARRANTIES

10.1. Parexel represents that, consistent with Section 306(a) and Section 306(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 335a (a) and 335a (b)), neither it nor any of its Affiliates or Subcontractor's, nor its or its Affiliates' employees engaged in the performance of Services, is debarred and Parexel will not knowingly hire any debarred individual to perform Services. If Parexel, any of its Affiliates, or Subcontractors, or Parexel's, its Affiliates' or Subcontractors' employees or any individuals contracted thereby to perform Services, is debarred or, to Parexel's knowledge, receives notice of an action or threat of action of debarment, Parexel shall promptly notify Client. [***].

10.2. Each Party represents that it is not constrained by any existing agreement from performing its obligations under this Agreement.

10.3. Each Party represents that (a) it has full power and authority to enter into this Agreement, (b) this Agreement has been duly authorized, and (c) this Agreement is binding upon it

- **10.4.** Parexel represents, warrants and covenants that [***].
- **10.5.** Client and Parexel shall comply with all Applicable Law relating to the Projects and Services.
- **10.6.** Parexel represents and warrants that, during the performance of the Services, Parexel shall not [***].

11. INDEMNIFICATION

11.1. Parexel will defend, indemnify and hold harmless Client, its Affiliates and their respective directors, officers, and employees ("**Client Indemnitees**") from and against all damages, liabilities, judgments, settlements, penalties, and costs and expenses (including without limitation, reasonable fees and disbursements of counsel and costs and expenses associated with subpoenas, document production and testimony) (collectively, "**Costs**") as incurred by Client Indemnitees arising out of or in connection with any third party (including without limitation, government agencies) claims, suits, actions, proceedings, investigations and/or demands ("**Third Party Claims**") arising out of: (a) the material breach of this Agreement or the applicable Work Order(s) by Parexel, its Affiliates or Subcontractors and/or (b) any negligence, breach of Applicable Law or willful misconduct on the part of Parexel or its Affiliates or Subcontractors with respect to the Services or (c) [***]; provided, however, that Parexel shall have no obligation of indemnity hereunder with respect to any Third Party Claim to the extent Client is required to indemnify any Parexel Indemnitee (as defined below) for such Third Party Claim as set forth in Section 11.2 below. If Client is required [***], Parexel agrees [***].

11.2. Client will defend, indemnify and hold harmless Parexel, its Affiliates, and their respective directors, officers, and employees ("**Parexel Indemnitees**") from and against all Costs as incurred by

Parexel Indemnitees arising out of or in connection with any Third Party Claims arising out of: (a) [***], (b) the material breach of this Agreement or the applicable Work Order(s) by Client, (c) Client's negligence and/or willful misconduct, and/or (d) [***]; provided, however, that Client shall have no obligation of indemnity hereunder with respect to any Third Party Claim to the extent Parexel is required to indemnify any Client Indemnitee for such Third Party Claim as set forth in Section 11.1 above.

11.3. The party seeking indemnification for any Third Party Claim covered by this Section ("**Covered Claim**") will promptly notify the indemnifying party in writing of such Covered Claim. The indemnifying party will have sole control of the defense, settlement or compromise of the Covered Claim and the indemnified party will cooperate with the indemnifying party, at the indemnifying party's expense, in the defense, settlement or compromise of the Covered Claim. Neither party will settle any Covered Claim without the other party's prior written consent, which consent will not be unreasonably withheld, conditioned or delayed. The failure of an indemnified party to promptly notify the indemnifying party of any Covered Claim will not relieve the indemnifying party of its obligations under this Section unless and to the extent the indemnifying party is materially prejudiced by such failure to provide notice.

11.4. Notwithstanding anything to the contrary contained in this Agreement, if a conflict of interest exists between the parties with respect to the Third Party Claim, or if the assumption and conduct of the defense by the indemnifying party would adversely affect the indemnified party in any manner or prejudice its ability to conduct a successful defense, then the indemnified party may be separately represented with respect to such Third Party Claim by legal counsel reasonably acceptable to the indemnifying party and at the indemnifying party's expense.

11.5. In the event that Parexel is [***], Client agrees [***].

12. DISCLAIMER AND LIMITATION OF LIABILITY

12.1.

- (a) TO THE EXTENT PERMITTED BY APPLICABLE LAW, UNLESS SET FORTH HEREIN OR A WORK ORDER, PAREXEL DOES NOT MAKE ANY, AND HEREBY DISCLAIMS ALL, REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, WRITTEN OR ORAL, INCLUDING WITHOUT LIMITATION, [***]. WITHOUT IN ANY WAY LIMITING THE GENERALITY OF THE IMMEDIATELY PRECEDING SENTENCE, PAREXEL MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO [***].
- (b) TO THE EXTENT PERMITTED BY APPLICABLE LAW, UNLESS SET FORTH HEREIN OR A WORK ORDER, [***].

12.2. The aggregate liability of each party and its Affiliates to the other party, regardless of the theory of liability, for any claim, breach or default under this Agreement, will be limited to [***] and, except as set forth in Section 12.3, shall not exceed [***]. In no event will either party or its Affiliates be liable for any lost profits, or for any special, incidental, punitive, exemplary, consequential or other indirect damages (collectively, "**Indirect Damages**"), regardless of whether a party has been advised of the possibility of such damages. The aforementioned limitations shall not apply to (i) Client's payment obligations hereunder for Services performed in accordance with the terms of this Agreement and the applicable Work Order, (ii) to the extent such limitations are prohibited by Applicable Law, (iii) in connection with either party's indemnification obligations under this Agreement, or (iv) in connection with claims [***]. In addition, the limitation on Indirect Damages will not apply to [***].

12.3 Parexel's liability to Client for damage, destruction or loss to Study Materials caused by Parexel's (or Parexel's Affiliates or Subcontractors) negligence shall be limited to [***]. Unless otherwise agreed in a Work Order, [***]. In no event shall Parexel or its Affiliates have any liability to Client for loss, destruction or damage to Study Materials caused by any third party [***].

13. DELAYS

13.1. Parexel's performance under this Agreement or any Work Order may be contingent upon the performance of obligations by Client itself and Client-Designated Vendors and other third parties who are not Parexel Affiliates or Subcontractors. To the extent that Parexel is delayed or unable to perform its obligations under this Agreement or any Work Order as solely a result of Client's or a Client-Designated Vendor's or another third party's (who is not a Parexel Affiliate or Subcontractor) failure to perform its obligations, in a timely manner or otherwise, such delay or failure to perform by Parexel will not be deemed a breach by Parexel and the parties to the Work Order will promptly cooperate in good faith to either update a CIS Log or negotiate and enter into a Change Order, as the case may be, pursuant to Section 2 above with respect to any required changes or additions to the description of Services, budget, estimated timelines, or payment schedule or Client may terminate this Agreement or any Work Order pursuant to Section 5.4.

13.2. Neither party to this Agreement and/or any Work Order will be responsible for any default or delay under this Agreement or such Work Order by reason of strikes, riots, wars, acts of terrorism, fire, acts of God, epidemic or pandemic, or any other cause beyond its reasonable control. The affected party shall promptly give notice of such default or delay to the other party. The affected party's default or delay in performance shall be excused for the duration of such event. The parties may mutually agree in writing to modify the Services to address the effect of such event.

13.3. If Client delays or suspends the Services to be provided for a period of [***] or longer, the parties to the Work Order may agree in writing that certain Parexel staff will continue to be assigned to perform such Services. In such event, during the period of delay or suspension, and if agreed to in a Work Order or Change Order Client will pay a monthly maintenance fee in an amount to be mutually agreed by the parties as set out in the Work Order or Change Order. If such delay or suspension lasts [***], then either party will have the right to terminate or discuss amending the respective Work Order on [***] prior written notice.

14. PUBLICITY

14.1. Except as permitted under Section 6 or as necessary to perform the Services hereunder (including without limitation for purposes of recruitment of study subjects, using materials approved by Client or registration of clinical trials approved by Client), Client and Parexel agree that they will obtain the other party's prior written approval before using each other's name, symbols and/or marks in any form of publicity.

15. INDEPENDENT CONTRACTOR

15.1. The relationship of the Client and Parexel to each other is that of independent contractors, and nothing contained herein will be construed to constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind. Except as expressly provided for in this Agreement, under no circumstances will the employees or agents of one party be considered employees or agents of the other party. In that respect, and subject to the terms of Section 3.2, neither Party shall have the authority to execute any agreement on behalf of the other Party, nor shall either Party have any authority to negotiate any agreement, except as the other Party may expressly direct in writing.

16. NON-SOLICITATION

16.1. During the term of this Agreement and for a period of [***] following any termination or expiration of this Agreement, Client agrees, on behalf of itself and its Affiliates, not to solicit for employment, employ or otherwise retain any employee or consultant of Parexel or its Affiliates providing (or who has provided) Services under any Work Order; provided that it will not be a violation of this Section if an employee or consultant of Parexel responds to an indirect solicitation (e.g., advertisements in media of general circulation).

17. ASSIGNMENT

17.1. Client may assign this Agreement without the other party's prior written consent to a successor in interest by reason of merger, acquisition, partnership, license agreement or otherwise; provided that, in the case of assignment by Client, no assignment to a Direct Competitor of Parexel will be permitted without Parexel's prior written consent; and further provided that the assigning party shall [***]. Except as expressly provided in this Section, neither party will have the right to assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other party. Any attempt at assignment in violation of this Section shall be null and void.

18. DISPUTE RESOLUTION

18.1. If a dispute arises between the parties relating to this Agreement or any Work Order, the parties to this Agreement or such Work Order will meet and attempt to resolve the dispute in good faith. In the event the dispute is not resolved through negotiation within [***] after said meeting, the parties will submit to confidential, non-binding mediation before a mutually acceptable mediator. Each party will designate at least one corporate officer with full authority to resolve the dispute who will attend and participate in the mediation. If the dispute remains unresolved after mediation, then each party will be free to pursue any available remedy at law or in equity. Each party will bear its own legal fees and any costs incurred under this Section. Notwithstanding the foregoing, either party may seek injunctive relief through a court of competent jurisdiction with respect to any dispute arising in connection with Section 6 or 7.

19. GENERAL

19.1. Notice. Any notice or communication required or permitted hereunder shall be in writing and shall be deemed received (a) on the date received if delivered by a reputable overnight delivery service, or (b) three (3) days after the date postmarked if sent by first class, registered or certified mail, with return receipt requested, or (c) one (1) business day following the date of the email if sent electronically. Notice given under this Section shall be sent to the parties at the following addresses (or such other address as the applicable party may provide by written notice):

To Parexel:	To Client:
Parexel International (IRL) Limited	Savara Inc.
One Kilmainham Square	6836 Bee Cave Road
Inchicore Road	Building III, Suite 200
Kilmainham	Austin, TX 78746
Dublin 8, Ireland	ATTN: [***]
ATTN: Legal Department	[***]
	[***]
With copy to:	
	[***]
Parexel International	[***]
notices@parexel.com	
[Subject line should read as follows: Savara Inc.	. – Attn. General
Counsel]	

Failure to give notice in accordance with the terms set forth in this Section shall result in such notice being deemed null and void.

19.2. Entire Agreement. This Agreement, including any Work Order(s) and attachments hereto, constitutes the entire understanding of Client and Parexel with respect to the subject matter hereof and supersedes and replaces all prior contracts, agreements, and understandings relating to the same subject matter, whether written or oral, including without limitation that certain Mutual Confidentiality Agreement dated November 11, 2020 and that certain Start-up Agreement dated January 6, 2021 between Client and Parexel. No waiver, consent, change or modification to this Agreement will be binding, unless in writing and signed by duly authorized representatives of Parexel and Client.

19.3. Severability. If any term of this Agreement is declared unenforceable, then the unenforceability thereof will not affect the remaining terms of this Agreement.

19.4. Waiver. Failure to enforce any of the terms or conditions of this Agreement will not constitute a waiver of any such terms or conditions, then or in the future, or of any other terms or conditions.

19.5. Governing Law and Forum. This Agreement will be governed by and construed in accordance with the laws of the State of New York without regard to its conflict of laws provisions. For all disputes arising out of or related to the Agreement, Client and Parexel submit to the jurisdiction and venue of the United States District Court for the Southern District of New York. If there is no jurisdiction in the United States District Court for the Southern District of New York, located in the borough of Manhattan.

19.6. Good Faith and Parties. Both parties shall act only in good faith in the performance of their respective obligations and the exercise of their respective rights under this Agreement. Client and Parexel are the parties to this Agreement and there are no third party beneficiaries hereto.

19.7. Survival. The following Sections of this Agreement shall survive the expiration or termination of this Agreement: 4, 5, 6, 7, 8 (with respect to tail coverage), 11, 12, 14, 15, 16 and 19, as well as any other provision that, in order to give proper effect to its intent, should survive such expiration or termination.

19.8. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one agreement. The parties agree that execution of this Agreement by industry standard electronic signature software and /or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

[Signatures on following page]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement through their duly authorized representatives effective as of the Effective Date.

Savara Inc.	Parexel International (IRL) Limited
By: /s/ Matthew Pauls	By: /s/ Ciarán Troy
Name: Matthew Pauls	Name: Ciarán Troy
Title: Chief Executive Officer	Title: Finance Director, Transformation
Date: 03/05/2021	Date: Mar 3, 2021

ATTACHMENT A FORM OF WORK ORDER

ATTACHMENT B FORM OF CHANGE IN SCOPE LOG

ATTACHMENT C FORM OF CHANGE ORDER

ATTACHMENT D ADDITIONAL TERMS FOR CTSL SERVICES

The parties hereto agree that in those cases where Parexel is to provide clinical trial supplies and logistics services ("**CTSL Services**") to Client, the provision of such CTSL Services shall be governed by the applicable provisions of the Agreement and also governed by the additional provisions as set forth in this **Attachment D**.

1. **DEFINITIONS**

The defined terms used in the Agreement apply to this **Attachment D** and in addition:

"Facility" means Parexel's designated facility(ies) used for the storage and distribution of Study Materials. Parexel will identify by name and location all such Facilities in the applicable Work Order.

"Label/Labelling" of the Study Materials means labelling of the Study Materials. All Label/Labelling specifications are set forth in the CTSL Quality Agreement (defined below) and in any Work Order.

"**Logistics**" means Services related to the shipping, storage and transport of the Study Materials. All Logistics specifications are set forth in the CTSL Quality Agreement and in any Work Order.

"**Package/Packaging**" means the packaging of the Study Materials. All Package/Packaging specifications are set forth in the CTSL Quality Agreement and in any Work Order.

"Territory" means the country(ies) set out in the applicable Work Order.

"Waste" means Pharmaceutical Waste as defined in Section 2 of the World Health Organization Handbook on Safe management of wastes from health-care activities.

2. SERVICES

2.1. Parexel will provide to Client the CTSL Services set forth in the applicable Work Order under the heading "CTSL Services" in accordance with this Agreement, the CTSL Quality Agreement, the Work Order and all specifications for such Packaging, Labelling and Logistics (such specifications, the "**Specifications**"). All CTSL Services are Services under the Agreement. The parties do not intend this **Attachment D** to supersede the terms of the Agreement, and in the absence of conflict the Agreement is presumed to control In the event of any conflict or inconsistency between the documents comprising this Agreement, this **Attachment D** shall take precedence in respect of the CTSL Services but this Agreement shall take precedence in respect of any other Service.

2.2. Parexel and Client will enter into a quality agreement documenting each parties' obligations with respect to quality matters in connection with the CTSL Services (the "**CTSL Quality Agreement**"). The CTSL Quality Agreement shall be governed by the Agreement.

2.3. All right, title and interest in and to all of Client's Study Materials in the possession of Parexel shall at all times remain the sole property of Client. Parexel shall hold such Study Materials on a fiduciary basis as Client's bailee. In particular, Parexel shall ensure that all the Study Materials are clearly distinguished from other stocks and supplies held by Parexel on behalf of itself or other customers. Unless required by Applicable Law to perform the CTSL Services hereunder, Parexel shall not destroy, deface or obscure any identifying mark or packaging on or relating to the Study Materials without Client's prior written consent.

2.4 Client and Parexel agree that in those cases where Parexel serves as importer of record or exporter of record on behalf of Client, the terms of **Exhibit 1** attached hereto shall also apply.

2.5 In the event that Client requires that Parexel use a Client-Designated Vendor in connection with any CTSL Service, and as a consequence, Parexel is required to qualify such Client-Designated Vendor, then Client will [***].

2.6 Parexel will receive Study Materials from Client or its designee so that Parexel may Package, Label and provide Logistics Services.

2.7 Packaging. If provided for in the Work Order, Parexel may procure material for the Study Materials provided by Client or Client's designee for use in Packaging. As between Client and Parexel, all Packaging and Study Materials, and all intellectual property rights thereto, shall be owned exclusively by Client. In addition, if set forth in the applicable Work Order, Parexel may Package (including, for example, placing or sealing the Client supplied Study Materials into tamper resistant Packaging). Parexel will Package all Study Materials in accordance with this Agreement, the applicable Work Order, the CTSL Quality Agreement and the Specifications.

2.8 Labelling. Parexel will provide Labelling services as set forth in the Work Order in accordance with this Agreement and the Specifications and the CTSL Quality Agreement.

2.9 Logistics. Parexel will provide the Logistics services as set forth in the Work Order in accordance with this Agreement and the Specifications and the CTSL Quality Agreement.

3. DELIVERY, ACCEPTANCE AND STORAGE OF PRODUCTS

3.1. Unless otherwise specified in a Work Order, Client shall deliver Study Materials to the relevant Facility identified by Parexel and DDP (Delivery Duty Paid) Incoterms ("**Incoterms 2020**"). In the event the CTSL Services involve Parexel purchasing Study Materials on behalf of Client, Parexel shall be responsible for shipment of such Study Materials and Client shall reimburse Parexel for the Pass-Through Expense of such Study Materials and shipment [***]. Client acknowledges and agrees [***]. The scope of Study Materials subject to Parexel's obligations hereunder shall be mutually agreed to in the applicable Work Order.

3.2. In the event Parexel or any Parexel Affiliate procures Study Materials on behalf of the Client, legal and economic ownership of said Study Materials shall transfer to Client upon Parexel's allocation of such Study Materials to the Client in accordance with the applicable Work Order. For clarification, Client responsibility shall include, without limitation, responsibility for all costs, including insurance and risk of loss associated with shipment of such items to their final destination. Parexel (a) shall bear no responsibility in the event of any defects in any Study Materials procured by Parexel on Client's behalf, and (b) makes no representations or warranties, as to the merchantability or fitness for use of any Study Materials procured on behalf of Client.

3.3. Each delivery of Study Materials shall be supported by delivery receipts provided by Client detailing without limitation the following:

- (a) a complete and comprehensive description of the Study Materials and the quantity of such Study Materials;
- (b) if applicable, manufacturer information, customs value, applicable import/ export codes, quantities, batch numbers, and expiration dates of the Study Materials as well as identification of whether the Study Materials are classified as dangerous goods; and
- (c) all other information, instructions and documents requested by Parexel as may be necessary for Parexel to perform its CTSL Services with respect to the Study Materials under the applicable Work Order. Parexel will [***].

3.4. Client shall provide written notice to Parexel prior to any delivery of Study Materials from Client or any Client-Designated Vendor to Parexel to the relevant Facility under the applicable Work Order. The notice shall state the proposed date and time at which the Study Materials will be delivered to such Facility.

3.5. Parexel will visually inspect all Study Materials for damage or loss in transit, ascertain the quantities received, stop temperature monitoring devices and download readings and check the packaging of physical Study Materials against Specifications in order to verify that the Study Materials appear to meet the Specifications, all such inspections to be done in accordance the timing and in the manner set forth in the CTSL Quality Agreement. In the event that any of the Study Materials do not appear to comply with the Specifications, Parexel will notify Client in writing thereof and provide any other information reasonably requested by Client with respect to such rejected Study Materials. Upon receipt of notice, Client will respond promptly (but in no event more than [***] to Parexel with instructions as to any follow-up measures to be taken in connection with any non-compliant Study Materials.

3.6. Parexel understands and accepts that some Study Materials may subsequently be sent to designated Sites for the performance of clinical trials. As part of the Logistics Services, at such time as requested by Client, Parexel shall ship the Study Materials as designated by Client in writing to the relevant location and Parexel shall require that such shipment of the Study Materials shall be in accordance with Applicable Laws, the CTSL Quality Agreement and this Agreement. Parexel shall ensure that the Study Materials are properly prepared for shipment and shall select the best mode of transport for such Study Materials Client shall [***].

- **3.7.** During the term of the applicable Work Order, Parexel shall:
 - (a) keep all Study Materials properly stored at its Facility in accordance with Applicable Laws and applicable cGXPs and the conditions specified in the Work Order;
 - (b) be responsible for all the costs associated with maintaining and occupying the Facility;
 - (c) if required by the Work Order, collect Study Materials from Sites and return them to the Facility or other location as may be advised in writing by Client for storage until a request is received for their subsequent destruction as Waste as per Section 4.1 of this **Attachment D**; and

4. **PRODUCT SECURITY**

- **4.1. Waste.** To the extent set forth in a Work Order, Parexel will handle or dispose of Waste in accordance with the following terms:
 - (a) Waste shall be destroyed by Parexel within a reasonable time and in accordance with Applicable Law. Until destruction of the Waste has taken place, the Waste shall be stored and handled by Parexel in a manner designed to prevent unauthorized access and possible misuse. If Client requires specific measures to be taken in relation to the disposal or handling of Waste, such measures shall be mutually agreed to in a Work Order or the CTSL Quality Agreement.
 - (b) All records and certificates concerning Waste shall be kept by Parexel for a period of at least [***] following completion of the CTSL Services, or such longer period as required by Applicable Law, and shall be made available to Client upon request.
 - (c) If Parexel requests, in writing, Client's permission to dispose of any Study Materials, and Client does not respond to such request within [***] after receiving such request from Parexel, then Parexel shall be entitled, in its sole discretion, to dispose of all such items and Client will be responsible for the reasonable direct cost of such disposal.

4.2. Security.

- (a) During the term of the applicable Work Order, Parexel shall employ all reasonable and necessary security measures and policies to safeguard the integrity, accessibility and confidentiality of the Study Materials and establish and maintain all necessary disaster and emergency recovery plans to avoid any disruption to the CTSL Services.
- (b) Parexel may only deliver the Study Materials to such persons who are authorized to receive the relevant Study Materials, as designated in writing by Client to Parexel. Parexel may, in its discretion, transfer Study Materials to Logistics suppliers with whom it has contracted to facilitate the CTSL Services and delivery of Study Materials. Client may request that Parexel [***].

4.3. **Rejected and Returned Study Materials.**

- (a) Any Study Materials that Parexel is considering rejecting and any rejected, surplus, obsolete or out of date Study Materials or those returned to Parexel shall be appropriately identified and kept physically separate in quarantine in a dedicated area or under other equivalent (e.g., electronic) segregation, so as to avoid confusion with other goods and prevent the Study Materials being sent to any other person.
- (b) Where any doubt arises over the quality of Study Materials it should not be considered suitable for distribution by Parexel. Obsolete or out of date Study Materials shall, if not returned to Client by Parexel, be destroyed in accordance with this Agreement and in such way that eliminates the possibility of re-use and be kept in a secure manner until they have been destroyed.
- (c) Parexel shall have in place and comply with a system that meets the requirements of Applicable Laws and including a written procedure to recall promptly and effectively Study Materials known or suspected to be defective, with a designated person(s) responsible for recalls. Parexel shall cooperate with Client, at Client's expense and direction, in conducting any recall, and Client shall provide Parexel with written authorization to recall any Study Material. In the event of a recall, Parexel shall ensure that all recalled Study Materials at a Parexel-controlled site, or supplied by a Facility, are reconciled and shall provide Client with all requested information regarding the storage and warehousing of recalled Study Materials. Parexel shall ensure that recalled Study Materials under Parexel's control are secured and are subsequently destroyed if required or otherwise handled in accordance with Client's written instructions.

5. TERM AND TERMINATION

5.1. Within [***] of termination of or expiration of the applicable Work Order, Parexel shall return to or transport to a location designated by Client all Study Materials and this shall be at Parexel's expense unless set forth in the Work Order. Any Study Materials returned or destroyed due to the expiration or termination of the applicable Work Order shall be returned or destroyed at Client's reasonable cost and reasonable expense.

6. **REPRESENTATIONS AND WARRANTIES**

- **6.1.** Client represents and warrants to Parexel that, with regard to Study Materials supplied by Client:
 - (a) Prior to delivery, it has, to the extent available, provided all safe handling instructions, health and environmental information and material safety data sheets applicable to the Study Materials as well as to any Study Materials that Client has applicable information;

- (b) It has produced the Study Materials in compliance with all Applicable Laws, and it shall comply with all applicable specifications, and Study Materials shall not be adulterated, misbranded or mislabeled within the meaning of any Applicable Law; and
- (c) it has provided accurate and complete information for all Study Materials to facilitate import/export activities, including but not limited to product description, customs values, manufacturer information and applicable import/export codes (collectively, "Trade Compliance Information"). Client acknowledges and agrees that Parexel will rely on such Trade Compliance Information in its communications with Regulatory Authorities.

EXHIBIT 1 IMPORTER/ EXPORTER OF RECORD

ATTACHMENT E ADDITIONAL TERMS FOR PROCESSING OF PERSONAL DATA

If and to the extent that Parexel Processes Covered Data on behalf of Client and applicable Data Protection Law requires, the parties agree that, in addition to the applicable provisions of the Agreement, the terms set out in this **Attachment E** will also apply in respect of such Covered Data.

- 1. Parexel agrees that:
 - (a) Parexel Processes the Covered Data on behalf of Client in the context of providing the Services under this Agreement, for the duration of the Agreement and/or any applicable Work Order. The obligations and rights of Client are as set out in this Agreement;
 - (b) Parexel will only Process the Covered Data in accordance with this Agreement and any other documented written instructions of Client;
 - (c) Parexel shall ensure that the persons authorised by Parexel to Process the Covered Data are bound by appropriate statutory confidentiality obligations;
 - (d) Parexel shall implement such technical and organisational security measures as are required to comply with its data security obligations under Data Protection Law;
 - (e) Parexel shall, taking into account the nature of the Processing, assist Client by implementing appropriate technical and organisational measures (insofar as this is possible) to assist Client to comply with requests from Data Subjects to exercise their rights under Data Protection Law and any such assistance may incur additional reasonable fees as mutually agreed by the parties in writing;
 - (f) Parexel shall assist Client in ensuring compliance with its obligations in respect of security of Covered Data under Data Protection Law and any such assistance may incur additional reasonable fees as mutually agreed by the parties in writing;
 - (g) Parexel shall: (i) at the written election of Client, delete or return the Covered Data to Client when Parexel ceases to provide Services relating to Covered Data processing and (ii) not retain any copies of such Covered Data unless EU law or the laws of an EU Member State require storage of the Personal Data or unless such Personal Data is retained in system-wide backup media, in which case it will be deleted in accordance with Parexel's standard back-up policy;
 - (h) Parexel shall make available to Client all information necessary to demonstrate compliance with and enable Client to audit the obligations laid down in this Section 1 (subject to and in accordance with Section 9 of the Agreement) provided that Parexel shall inform Client immediately if, in its opinion, it receives an instruction from Client or any Client Designated-Vendor which infringes Data Protection Law; and
 - (i) taking into account the nature of the Processing and the information available to Parexel, Parexel shall notify Client via email to <u>dataprivacy@savara.com</u> and <u>dave.lowrance@savarapharma.com</u> without undue delay, and no longer than [****], after becoming aware of any breach of Parexel security leading to the accidental or unlawful destruction, loss, alteration, breach, unauthorised disclosure of, or access to, Covered Data transmitted, stored or otherwise processed and provide Client with such reasonable co-operation and assistance as may be required to mitigate against the effects of, and comply with any reporting obligations which may apply in respect of, any such breach.

- 2. Subject to Section 3 below, Parexel shall be entitled to engage sub-processors to Process Covered Data in connection with the provision of the Services, and Client hereby consents to such appointments provided that:
 - (a) Parexel shall ensure that a written contract exists between Parexel and the sub-processor containing clauses equivalent to those imposed on Parexel in this **Attachment E** and Parexel is liable for the acts, omissions, breaches and duties of such sub-processor as if performed by Parexel itself; and
 - (b) Parexel shall inform Client if it intends to replace a sub-processor or engage additional sub-processors and shall provide Client with an opportunity to object to such changes, in circumstances where Client objects to the change of a sub-processor in writing within [***] of receipt of the notice, the parties shall discuss the matter in good faith, it being understood that if Client fails to object within this [***] period, the sub-processor shall be deemed approved.
- 3. No Covered Data shall be transferred outside of the European Economic Area by Parexel or any of its agents or sub-processors without the prior written consent of Client unless Parexel ensures that any such transfer is effected in a manner which is compliant with Data Protection Law Client hereby consents to the transfer of Covered Data to Parexel, Client, their respective Affiliates and subprocessors, and to Sites, in any country. Client hereby appoints Parexel as its agent to enter into EU Commission standard contractual clauses (in such form as they exist from time to time) on Client's behalf for the transfer of Covered Data outside the EEA in connection with the processing of such data by Parexel as contemplated by this Agreement.

Certain identified information in this document has been excluded because it is both (i) not material and (ii) is the type of information the issuer both customarily and actually treats as private and confidential. [***] indicates where such information has been omitted.

Parexel Project # [***]

WORK ORDER

This Work Order #1 (this "Work Order") is by and between Savara Inc. ("Client") and Parexel International (IRL) Limited ("Parexel").

Governing Agreement. This Work Order incorporates the terms and conditions of the Master Services Agreement dated January 6, 2021, as may be amended from time to time, between Client and Parexel (the "**Agreement**"). Capitalized terms used in this Work Order and not defined herein shall have the same meanings ascribed to them in the Agreement. If any term in this Work Order conflicts with the Agreement, the Agreement will control except to the extent that this Work Order expressly states that such conflicting term prevails over the Agreement. To the extent that any Services relate to scientific matters, the Protocol will control the performance of such Services, and will take precedence over all other Study documents for such Services.

Term. This Work Order is made effective as of January 6, 2021 (the "**Effective Date**") and terminates upon the completion of Services described herein unless otherwise terminated as provided in the Agreement.

Study. The "**Study**" is Client's Protocol number [***]; entitled: "A randomized, double-blind, placebo-controlled clinical trial of once-daily inhaled molgramostim nebulizer solution in adult subjects with autoimmune pulmonary alveolar proteinosis (a PAP)". For purposes of this Work Order, wherever the term "Project" is used in the Agreement, it shall be read to mean "Study."

Prior Agreements. This Work Order once executed will supersede and replace in its entirety the Start-Up Agreement dated January 6, 2021 (the **"SUA"**) between Client and Parexel related to the Study.

Services. This Work Order details the full scope of Services Parexel will provide for Client based on the specifications and assumptions, tasks and responsibilities, and estimated timelines (collectively, the "**Key Specifications**") contained herein. **Exhibit D** to this Work Order sets forth the CTSL Services to be provided by Parexel.

Budget. The budget is based upon the Key Specifications. Any changes to the Key Specifications may require that the parties amend the budget and if such amendment is required, they will to so pursuant to the procedures set forth in Section 2 of the Agreement.

	Service Fees	Pass-Through Expenses (Excluding Investigator Grants)	Investigator Grants	[****]	Totals
Start-Up Agreement	[***]	[***]	-	[***]	[***]
Work Order	[***]	[***]	[***]	[***]	[***]
Total Budget	[***]	[***]	[***]	[***]	\$30,978,447

The Exhibits attached hereto more fully describe this Work Order's Key Specifications, budget, and payment terms, and are hereby incorporated into this Work Order.

In the event that any Services will be performed at Sites located in the United Kingdom (including but not limited to Parexel's Clinical Pharmacology Unit), then the terms and conditions set forth in **Exhibit E** shall apply to those Services at those Sites.

Designated Savara Representatives. The following persons are Savara Representatives, as defined in Section 2.2(a) of the Agreement, for purposes of this Work Order:

Title	Name	Telephone Number	Email
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Pursuant to Section 2.2(a) of the Agreement, Client may change Savara Representatives by written update in its sole discretion.

PAREXEL Key Personnel. The following Parexel Key Personnel, as defined in Section 7 of the Agreement, are assigned to the Project covered by this Work Order:

Title	Name	Telephone Number	Email
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Subcontractors, Client-Designated Vendors:

As set out in the Agreement, Parexel may use Affiliates, Subcontractors and Client-Designated Vendors to perform the Services, as each is defined in the Agreement, and in accordance with the terms thereunder.

The following Subcontractors and Client-Designated Vendors will be used in the Study. Additional Vendors may be added

Subcontractors:

• [*]

Client-Designated Vendors:

• [***]

Upon Client's request, Parexel [***].

Data Privacy. In accordance with the Data Security and Privacy Addendum set forth in **Attachment E** to the Agreement, the Details of Processing under this Work Order are contained in **Exhibit H** to this Work Order. In the event of any data breach (as described in Section 1(i) of **Attachment E** to the Agreement), notice shall be given to Client in accordance with the notice provisions of Section 19 of the Agreement, and by email to [***].

Exhibits A through H attached hereto more fully describe this Work Order's Key Specifications, budget and payment terms, and are hereby incorporated in their entirety by reference into this Work Order

Remainder of this page is intentionally left blank.

IN WITNESS WHEREOF, the parties have executed this Work Order through their duly authorized representatives effective as of the Effective Date.

Savara Inc.	Parexel International (IRL) Limited
By: /s/ Matthew Pauls	By: /s/ Maria King
Name: Matthew Pauls	Name: Maria King
Title: Chief Executive Officer	Title: Senior Director
Date: 03/05/2021	Date: March 8, 2021

EXHIBIT A SPECIFICATIONS AND ASSUMPTIONS

[***] (6 pages omitted)

EXHIBIT B TASKS & RESPONSIBILITIES

Standard Operating Procedures ("**SOPs**"). Parexel will perform the Services in accordance with Parexel's standard operating procedures ("**SOPs**"), report and file templates, personnel training curriculum, and systems, unless specifically stated otherwise in this Work Order. Parexel's SOPs shall follow applicable regulatory authority requirements.

EXHIBIT C ESTIMATED TIMELINES

[***]

EXHIBIT D CTSL SERVICES

[***] (3 pages omitted)

EXHIBIT E ADDITIONAL TERMS WITH RESPECT TO SITES LOCATED IN THE UNITED KINGDOM

The parties acknowledge and agree that, notwithstanding anything in the Agreement to the contrary, the terms and conditions set forth below will apply with respect to the Services being performed in the United Kingdom. The parties do not intend this **Exhibit E** to supersede the terms of the Agreement, and in the absence of conflict the Agreement is presumed to control. In the event of a conflict between the terms set forth in this **Exhibit E** and the Agreement or any other terms set forth in this Work Order, then solely with respect to those Services being performed in the United Kingdom, the terms of this **Exhibit E** will control. Capitalized terms not defined herein shall have the meaning set forth in the Agreement.

- 1. In addition to Client's obligations set forth in Section 2.8 of the Agreement, Client agrees it will promptly provide Parexel with any and all updates made to applicable Regulatory Authorities, and if no such updates are made, it will [***]. Client agrees it will promptly provide Parexel with any and all updates made to applicable Regulatory Authorities, and if no such updates, and if no such updates are made, it will [***]. Client further represents that [***].
- 2. Except to the extent that Parexel is responsible under this Work Order for supplying Study Materials as part of the scope of Services, Client shall provide Parexel or a Site, as applicable, with a Protocol required quantity of the Study Drug to conduct the Study, as well as any other compounds, materials and information, which the Protocol specifies Client shall deliver or which Client deems necessary to conduct the Study. All such Study Drug, compounds, materials and other information are and shall remain the sole property of Client.
- 3. To the extent applicable, Client will be responsible for the:
 - [***]
 - [***]
 - [***]
 - [***]
 - [***]
 - [***]
 - [***]
 - [***]
 - [***]
- 4. Client will inform Parexel promptly of any potential decision to recall the Study Drug that has been supplied to Parexel for conduct of a Study under this Agreement. Parexel will provide all reasonable assistance to Client to investigate or implement a recall. Parexel will inform Client, as a matter of urgency, of any issue relating to the Study Drug that has been supplied by Client, which might result in the need to consider a potential recall of the Study Drug.

EXHIBIT F BUDGET

Payments: The Work Order Currency, as defined by Section 6.4 of the Agreement, shall be United States Dollars for this Work Order

Change in Scope Process. As provided under Section 2.2 of the Agreement, Parexel will generate and maintain a Change in Scope Log ("**CIS Log**") in accordance with the form attached as Attachment B to the Agreement, capturing the cost impact of changes to Key Specifications under this Work Order. The parties will follow the CIS Log approval and Change Order preparation process as provided under Section 2.2 of the Agreement. The CIS Log monetary threshold at which a Change Order will be prepared for this Work Order is \$[***].

Inflation. Parexel's Service fees herein incorporate [***] inflationary adjustments to account for labor cost inflation during the estimated timeline. The budget may be amended for inflation adjustments if timelines change, such changes to be reflected in a CIS Log/Change Order.

Clinical Trial Supply & Logistics (CTSL). Pass-Through Expenses related to CTSL Services are estimates based on currently available project information and general assumptions (based on previous project experiences).

- [***]
- [***]
- [***]
- [***]

Table 1 – Budget Grid begins on the next page.

Table 1 - Budget Grid

[***] (18 pages omitted)

EXHIBIT G PAYMENT TERMS

Service Fees. Parexel will invoice Client each month for Service fee units completed per the unit prices in **Exhibit F**. Upon execution of this Work Order, Parexel will invoice an advance payment of \$[***] for Service fees. This advance payment will be reconciled against the final invoices for Service fees. Parexel will [***]. The advance payment for Service fees made under the SUA shall be applied to the advance payment due under this Work Order

Pass-Through Expenses (excluding Investigator Grants). Parexel will invoice Client each month for Pass-Through Expenses incurred following receipt of invoice from the third party for such Pass-Through Expenses, except in cases where Parexel does not require invoices from third parties in order to administer payments. Upon execution of this Work Order, Parexel will invoice an advance payment of \$[***] for Pass-Through Expenses. This advance payment will be reconciled against the final invoices for Pass-Through Expenses. The advance payment for Pass-Through Expenses made under the SUA shall be applied to the advance payment due under this Work Order. In the event this advance payment is insufficient to cover anticipated pass through expenses, Parexel will invoice, and Client shall pay, any additional amounts required to meet the shortfall in accordance with the payment terms set forth in the Agreement.

Investigator Grants. Parexel will invoice Client on a monthly basis for Investigator Grant payments incurred. To ensure Parexel has funds in hand to make such payments, upon execution of this Work Order, Parexel will invoice an advance amount of \$[***] ("**Investigator Grant Advance**"). When the Investigator Grant Advance balance is forecasted to be depleted in the next calendar quarter and for each quarter thereafter, Parexel will invoice Client an amount equal to the estimated Investigator Grants to be incurred by Parexel over the current and/or following quarter. Parexel agrees to issue invoices for quarterly advances 30 days prior to the start of each quarter, and such invoices shall be paid in accordance with the payment terms set forth in the Agreement. If the amounts invoiced are not depleted in the following quarter, they shall be applied toward the next quarter's activity.

INVOICE INSTRUCTIONS. PAREXEL WILL EMAIL INVOICES TO CLIENT AT [***]. CLIENT WILL PAY PAREXEL'S INVOICES IN ACCORDANCE WITH THE TERMS OF THE AGREEMENT AND WILL REMIT PAYMENTS

Check Remittance Address:	For Wires/Electronic Funds Transfers (in USD)
[***]	Bank Account Name: [***] Bank Account Number: [***] SWIF/BIC code: [***] Branch Name: [***] Branch Address: [***]

Client shall send the remittance advice information to the following email alias: [***]

EXHIBIT H

Details of Processing Activities

This Exhibit H includes certain details of the Processing of Subject Personal Data as required by Article 28(3) GDPR.

Nature and Purpose of Processing: Parexel will Process Subject Personal Data as necessary to perform the Services pursuant to the MSA and the applicable Work Order.

Subject Matter and Duration of Processing: The subject matter and duration of the Processing of the Subject Personal Data are set out in the MSA, the applicable Work Order and this Addendum.

1. LOCATION(S) OF PROCESSING:

Categories of Data: In providing Services to Savara, Parexel may Process one or more of the following categories of data Study Subject Personal Data:

- A. Study Subject Personal Data: [***]
- **B.** Special categories of data: [***].

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 procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2021

/s/ Matthew Pauls Matthew Pauls Chief Executive Officer and Chairman (Principal Executive Officer)

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 procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2021

/s/ David Lowrance David Lowrance Chief Financial Officer (Principal Financial and Accounting Officer)

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 March 31, 2021, 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 of 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.

May 13, 2021

/s/ Matthew Pauls

Matthew Pauls Chief Executive Officer and Chairman (Principal Executive Officer)

In connection with the Quarterly Report of Savara Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2021, 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 of 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.

May 13, 2021

/s/ David Lowrance

David Lowrance Chief Financial Officer (Principal Financial and Accounting Officer)