UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from _____ to _____

Commission File Number 001-32157

Savara Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
6836 Bee Cave Road, Building III, Suite 200 Austin, TX	**78746**
(Address of principal executive offices)	**(Zip Code)**

(512) 961-1891
(Registrant's telephone number, including area code)

N/A

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of May 9, 2019, the registrant had 37,721,138 shares of common stock, $0.001 par value per share, outstanding.

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	SVRA	The Nasdaq Global Select Market

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 25,671	$ 24,301
Short-term investments	79,508	86,529
Prepaid expenses and other current assets	2,339	2,514
Total current assets	107,518	113,344
Property and equipment, net	474	522
In-process R&D	11,135	11,372
Goodwill	26,849	26,918
Other non-current assets	2,287	131
Total assets	$ 148,263	$ 152,287
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,503	$ 3,879
Accrued expenses and other current liabilities	5,417	3,375
Total current liabilities	8,920	7,254
Long-term liabilities:		
Debt facility	24,677	24,530
Contingent consideration	12,347	12,214
Other long-term liabilities	515	70
Total liabilities	46,459	44,068
Stockholders' equity:		
Common stock, $0.001 par value, 200,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 35,830,240 and 35,146,096 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	36	36
Additional paid-in capital	243,598	237,702
Accumulated other comprehensive income	1	200
Accumulated deficit	(141,831)	(129,719)
Total stockholders' equity	101,804	108,219
Total liabilities and stockholders' equity	$ 148,263	$ 152,287

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

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

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 10,019	$ 8,539
General and administrative	2,763	1,769
Impairment of acquired IPR&D	—	21,692
Depreciation and amortization	138	107
Total operating expenses	12,920	32,107
Loss from operations	(12,920)	(32,107)
Other income, net:		
Interest expense, net	(20)	(104)
Foreign currency exchange loss	(59)	(61)
Tax credit income	964	924
Change in fair value of financial instruments	(77)	(56)
Total other income	808	703
Loss before income taxes	(12,112)	(31,404)
Income tax benefit	—	4,555
Net loss	$ (12,112)	$ (26,849)
Net loss per share:		
Basic and diluted	$ (0.34)	$ (0.86)
Weighted average common shares outstanding:		
Basic and diluted	36,016,406	31,318,746
Other comprehensive loss:		
Gain (loss) on foreign currency translation	(225)	341
Unrealized gain (loss) on short-term investments	26	(24)
Total comprehensive loss	$ (12,311)	$ (26,532)

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

Savara Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity
Periods Ended March 31, 2019 and 2018
(In thousands, except share amounts)
(Unaudited)

	Stockholders' Equity					
	Common Stock				Accumulated	
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Income	Total
Balance on December 31, 2018	**35,146,096**	**$ 36**	**$ 237,702**	**$ (129,719)**	**$ 200**	**$ 108,219**
Issuance of common stock upon at the market offerings, net	647,426	—	4,890	—	—	4,890
Issuance of common stock for settlement of RSUs	13,125	—	—	—	—	—
Issuance of common stock upon exercise of stock options	23,593	—	6	—	—	6
Stock-based compensation	—	—	1,000	—	—	1,000
Foreign exchange translation adjustment	—	—	—	—	(225)	(225)
Unrealized gain on short-term investments	—	—	—	—	26	26
Net loss incurred	—	—	—	(12,112)	—	(12,112)
Balance on March 31, 2019	**35,830,240**	**$ 36**	**$ 243,598**	**$ (141,831)**	**$ 1**	**$ 101,804**

	Stockholders' Equity					
	Common Stock				Accumulated	
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Income	Total
Balance on December 31, 2017	**30,509,522**	**$ 32**	**$ 186,522**	**$ (68,203)**	**$ 958**	**$ 119,309**
Issuance of common stock upon at the market offerings, net	46,900	—	493	—	—	493
Issuance of common stock for settlement of RSUs	11,250	—	—	—	—	—
Net issuance of common stock upon cashless exercise of stock options	28,655	—	—	—	—	—
Issuance of common stock upon exercise of stock options	6,000	—	3	—	—	3
Issuance of common stock upon exercise of warrants	2,039	—	18	—	—	18
Stock-based compensation	—	—	412	—	—	412
Foreign exchange translation adjustment	—	—	—	—	341	341
Unrealized loss on short-term investments	—	—	—	—	(24)	(24)
Net loss incurred	—	—	—	(26,849)	—	(26,849)
Balance on March 31, 2018	**30,604,366**	**$ 32**	**$ 187,448**	**$ (95,052)**	**$ 1,275**	**$ 93,703**

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

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

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (12,112)	$ (26,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization including right-of-use assets	307	107
Impairment of acquired IPR&D	—	21,692
Changes in fair value of financial instruments	77	96
Change in fair value of contingent consideration	133	(134)
Noncash interest (income) / expense	(4)	35
Foreign currency loss	59	61
Amortization of debt issuance costs	147	109
Accretion on discount to short-term investments	(342)	(138)
Stock-based compensation	1,000	412
Benefit for deferred taxes	—	(4,555)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	69	54
Non-current assets	(953)	—
Accounts payable and accrued expenses and other current liabilities	953	(554)
Long-term liabilities	(193)	(7)
Net cash used in operating activities	$ (10,859)	$ (9,671)
Cash flows from investing activities:		
Purchase of property and equipment	(96)	(19)
Purchase of available-for-sale securities, net	(46,035)	(15,891)
Maturities of available-for-sale securities	42,800	25,300
Sale of available-for-sale securities, net	10,651	—
Net cash provided by investing activities	$ 7,320	$ 9,390
Cash flows from financing activities:		
Issuance of common stock upon exercise of warrants	$ -	$ 18
Issuance of common stock upon at the market offerings, net	4,890	493
Proceeds from exercise of stock options	6	3
Capital lease obligation principal payments	—	(243)
Net cash provided by financing activities	$ 4,896	$ 271
Effect of exchange rate changes on cash and cash equivalents	13	11
Increase in cash and cash equivalents	$ 1,370	$ 1
Cash and cash equivalents beginning of period	24,301	22,121
Cash and cash equivalents end of period	$ 25,671	$ 22,122
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 528	$ 334

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

1. Description of Business and Basis of Presentation

Description of Business

Savara Inc. ("Savara," the "Company," or as used in the context of "we" or "us") is an orphan lung disease company. The Company's pipeline comprises of Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"), in Phase 2a development for nontuberculous mycobacterial ("NTM") lung infection, and in Phase 2a development for the treatment of NTM lung infection in people living with cystic fibrosis ("CF"), and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of persistent methicillin-resistant Staphylococcus aureus, or MRSA, lung infection in individuals living with CF. 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.

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"). These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2018. Certain prior period amounts have been reclassified for consistency with current period presentation.

Unaudited Interim Financial Information

The interim condensed consolidated financial statements included in this document are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of March 31, 2019, and its results of operations for the three months ended March 31, 2019 and 2018, and cash flows for the three months ended March 31, 2019 and 2018. 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, 2019 or for any other future annual or interim period. The December 31, 2018 consolidated balance sheet was derived from audited financial statements but does not include all disclosures required by U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2018.

2. Summary of Significant Accounting Policies

Liquidity

As of March 31, 2019, the Company had an accumulated deficit of approximately $141.8 million. The Company also had negative cash flow from operations of approximately $10.9 million during the three months ended March 31, 2019. 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. Accordingly, the Company will need additional capital to further fund the development of, and seek regulatory approvals for, its product candidates and begin to commercialize any approved products.

Currently, the Company is primarily focused on the development of respiratory drugs and believes such activities will result in the Company's continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of the Company's product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of the Company's product candidates, if approved, fail 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 and through a combination of equity offerings, debt financings, government or other third-party funding, and other collaborations and strategic alliances. 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.

While the Company had cash and cash equivalents of $25.7 million and short-term investments of $79.5 million as of March 31, 2019, the Company intends to continue to raise additional capital as needed through the issuance of additional equity and potentially through borrowings, and strategic alliances with partner companies. However, if such financings are not available timely and at adequate levels, the Company will need to reevaluate its operating plans. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Principles of Consolidation

The interim condensed consolidated financial statements of the Company are stated in U.S. dollars and are prepared using U.S. GAAP. These 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." All intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Management's estimates include those related to the accrual of research and development costs, certain financial instruments recorded at fair value, stock-based compensation, contingent consideration, 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 candidates being developed by the Company require approvals 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 candidates will receive the necessary approvals. If the Company is denied regulatory approval of its product candidates, 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.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash, institutional bank money market accounts, commercial paper, and corporate securities with original maturities of three months or less when acquired and are stated at cost, which approximates fair value.

Short-term Investments

The Company has classified its investments in debt securities with readily determinable fair value 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" within stockholders' equity.

The fair value of the investments is based on the specific quoted market price of the securities or comparable securities at the balance sheet dates. Investments in debt securities are considered to be impaired when a decline in fair value is judged to be other than temporary because the Company either intends to sell or it is more-likely-than not that it will have to sell the impaired security before recovery. Once a decline in fair value is determined to be other than temporary, an impairment charge is recorded and a new cost basis in the investment is established.

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. 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.

Accrued Research and Development Costs

The Company records the costs associated with research, nonclinical studies, clinical trials, and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's on-going research and development activities conducted by third-party service providers, including contract research and manufacturing organizations.

The Company accrues for expenses resulting from obligations under agreements with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be amortized or expensed as the contracted services are performed. As actual costs become known, the Company adjusts its prepaids and accruals. Inputs, such as the services performed, the number of patients enrolled, or the study duration, may vary from the Company's estimates resulting in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. To date, the Company has not experienced any material deviations between accrued and actual research and development expenses.

Business Combinations

Assets acquired and liabilities assumed as part of a business acquisition are recorded at their estimated fair value at the date of acquisition. The excess of purchase price over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Determining fair value of identifiable assets, particularly intangibles, and liabilities acquired also requires management to make estimates, which are based on available information and, in some cases, assumptions with respect to the timing and amount of future revenue and expenses associated with an asset.

Goodwill, Acquired In-Process Research and Development, and Deferred Tax Liability

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized, but assessed for impairment on an annual basis or more frequently if impairment indicators exist. Recent guidance issued by the FASB, as previously adopted by the Company, provides an impairment model whereby the Company has the option to implement a one-step method for determining impairment of goodwill, simplifying the subsequent measurement of goodwill by eliminating Step 2 (measuring a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill) from the goodwill impairment test. Under the amendments in this guidance, an entity should perform its annual goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.

Acquired in-process research and development ("IPR&D") is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. The Company adopted accounting guidance related to its annual acquired IPR&D impairment test, a two-step method, which allows the Company to first assess qualitative factors before performing a quantitative assessment of the fair value of a reporting unit. If it is determined on the basis of qualitative factors that the fair value of the IPR&D is more likely than not less than the carrying amount, a quantitative impairment test is required.

If the associated research and development effort is abandoned, the related asset will be written-off, and the Company will record a noncash impairment loss on its consolidated statements of operations and comprehensive loss. For those products that reach commercialization, the IPR&D asset will be amortized over its estimated useful life.

The Company performs its annual goodwill impairment test and IPR&D impairment test, as described above, as of June 30th and September 30th, respectively, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of those assets. During the three months ended March 31, 2019, the Company experienced approximately a $0.1 million and $0.2 million decrease in the carrying value of goodwill and IPR&D, respectively, related to its acquisition of the assets of its Danish subsidiary, which was due to foreign currency translation.

Tax Credit Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS, for the three months ended March 31, 2019. 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. As of March 31, 2019, credits totaling $1.6 million had been generated but not yet received. Of this Danish tax credit of approximately $1.6 million, $0.8 million is related to research and development activities incurred during the year ended December 31, 2018 and is recorded in "Prepaid expenses and other current assets" and expected to be received in the fourth quarter of 2019. The remaining portion of the Danish tax credit of $0.8 million, which was generated during the three months ended March 31, 2019, is recorded in "Other non-current assets" and is expected to be received in the fourth quarter of 2020.

The Company also recognized tax credit income for the three months ended March 31, 2019 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. As of March 31, 2019, credits totaling $0.6 million had been generated but not yet received. This Australian tax credit of approximately $0.6 million includes approximately $0.5 million in tax credits generated during the year ended December 31, 2018 and is recorded in "Prepaid expenses and other current assets" as receipt is expected to occur in the fourth quarter of 2019. The remaining portion of the Australian tax credit of $0.1 million, which was generated during the three months ended March 31, 2019, is recorded in "Other non-current assets" and is expected to be received in the fourth quarter of 2020.

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.

Change in Accounting Principle

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02") as codified in Accounting Standards Codification ("ASC") No. 842 ("ASC 842"). ASU 2016-02 and ASC 842 are intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases that extend more than twelve months. This accounting update also requires additional disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. The Company adopted ASU 2016-02 as of January 1, 2019 using the effective date transition method of implementation offered under ASU 2018-11, "Leases (Topic 842) – Targeted Improvements" issued in July 2018 ("ASU 2018-11"), under which entities may change their date of initial application of ASU 2016-02 to the beginning of the period of adoption, or January 1, 2019, in the case of Savara. Accordingly, the Company is required to apply the prior lease guidance pursuant to ASC Topic 840 in the comparative periods, provide the disclosures required by ASC Topic 840 for all periods that continue to be presented in accordance with ASC Topic 840, recognize the effects of applying ASC 842 as a cumulative-effect adjustment to retained earnings as of January 1, 2019, if any, and provide certain disclosures under ASC 842 (see Note 10). The Company has also elected the package of practical expedients, applied by class of underlying asset, permitted in ASU 2018-11. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC 842, (b) whether classification of the operating leases would be different in accordance with ASC 842, and (c) whether the unamortized initial direct costs before transition adjustments (as of the period of adoption) would have met the definition of initial direct costs in ASC 842 at lease commencement, and the Company did not separate lease and non-lease components.

As a result of the adoption of the new lease accounting guidance using the effective date transition method, on January 1, 2019, the Company recognized (a) a lease liability of approximately $1.4 million, which represents the present value of the remaining lease payments, as of the date of adoption, of approximately $1.5 million, discounted using the Company's incremental borrowing rate of 8.5%, and (b) a right-of-use asset of approximately $1.4 million. The adoption of the new standard did not result in any adjustment to the Company's retained earnings as of January 1, 2019. The adoption of this standard did not have a material impact on the Company's condensed consolidated balance sheets, cash used/provided from operating, investing, or financing in the condensed consolidated statements of cash flows, or on the Company's operating results. The most significant impact was the recognition of right-of-use assets for operating leases which are reflected in "Other non-current assets" and lease liabilities for operating leases which are reflected in "Accrued expenses and other current liabilities," for the current portion of the lease liabilities, and in "Other long-term liabilities" for the non-current portion of the lease liabilities, respectively.

Fair Value of Financial Instruments

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

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.

Financial instruments carried at fair value include cash and cash equivalents, short-term investments, contingent consideration related to the acquisition of certain assets, liabilities, and subsidiaries of Serendex A/S through the Company's Danish subsidiary, Savara ApS, (see Note 7) for which any change is reflected in "General and administrative" expense, and foreign exchange derivatives not designated as hedging instruments.

Financial instruments not carried at fair value include accounts payable and accrued liabilities. The carrying amounts of these financial instruments approximate fair value due to the highly liquid nature of these short-term instruments.

Revenue Recognition

The Company will record revenue based on a five-step model in accordance with ASC 606, "Revenue from Contracts with Customers." To date, the Company has not generated any product revenue from its drug candidates. The Company's ability to generate product revenues, which the Company does not expect will occur in the near term, if ever, will depend heavily on the successful development, regulatory approval, and eventual commercialization of the Company's product candidates.

Milestone Revenue

The Company is subject to a license agreement related to its Molgradex product candidate (see Note 12) which includes certain milestone payments to be remunerated by the licensee to Savara. Pursuant to the license agreement, the Company identifies the performance obligations, determines the transaction price, allocates the contract transaction price to the performance obligations, and recognizes the revenue when (or as) the performance obligation is satisfied. The Company identifies the performance obligations included within the license agreement and evaluates which performance obligations are distinct.

The milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. The milestone payments are estimated and included in the transaction price when the Company determines, under the variable consideration constraint, that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price.

Net Loss per Share

Basic net loss attributable to common stockholders per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period without consideration of common stock equivalents. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods presented as the inclusion of all potential dilutive securities would have been antidilutive.

Stock-Based Compensation

The Company recognizes the cost of stock-based awards granted to employees based on the estimated grant-date fair value of the awards. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The Company recognizes the compensation costs for awards that vest over several years on a straight-line basis over the vesting period (see Note 11). Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise.

Manufacturing and Other Commitments and Contingencies

The Company is subject to various manufacturing royalties and payments related to its product candidate, Molgradex. Under an agreement, as amended, with the active pharmaceutical ingredients ("API") manufacturer, no signing fee or milestones are included in the royalty payments, and there is no minimum royalty. Upon the successful development, registration and attainment of approval by the proper health authorities, such as the FDA, in any territory except Latin America, Central America and Mexico, the Company must pay a royalty of three percent (3%) on annual net sales and certain milestones to the manufacturer of its API.

On April 26, 2019, the Company entered into a new manufacture and supply agreement ("New Supply Agreement") with this vendor that supersedes the aforementioned original agreement, as amended. The terms of the royalties and milestones under the New Supply Agreement are disclosed in Note 14. Although the effective date of the New Supply Agreement was subsequent to March 31, 2019, conditions of certain milestones under the New Supply Agreement existed and were incurred during the three months ended March 31, 2019. Accordingly, the Company has recognized research and development expense and recorded an accrued liability for this activity of approximately $1.4 million as of and for the three months ended March 31, 2019. Savara must make certain payments to the API manufacturer upon achievement of the milestones outlined in the table set forth below.

Pursuant to a license agreement (see Note 12) between the Company and a Japanese licensee regarding the development and commercialization of Molgradex for the treatment of aPAP in Japan, the Company shall fund the licensee fifty percent (50%), up to a maximum of approximately $0.8 million, of the external costs associated with specific research, regulatory, and filing activities to be conducted by the licensee. As of the March 31, 2019, no costs have been incurred.

Under an agreement with a medical education and research foundation entered into on October 8, 2018, the Company is subject to a milestone payment for the use of proprietary information and material in intellectual property filings related to the application of Molgradex in the treatment of NTM. The Company will owe royalties to the foundation based on net sales of Molgradex for the treatment of NTM equal to one half of one percent (0.5%) after publication of the intellectual property filings and one quarter of one percent (0.25%) prior to the publication or in the event publication does not occur, with respect to the specified intellectual property filings.

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 Molgradex. In addition to these milestones, the Company will owe a royalty to the manufacturer of the nebulizer based on net sales. The royalty rate ranges from three and one half percent (3.5%) to five percent (5%) depending on the device technology used by the Company to administer the product.

Manufacturing and Other Contingent Milestone and Co-Development Payments (in thousands):

	March 31, 2019
Molgradex API manufacturer:	
Achievement of certain milestones related to validation of API and regulatory approval of Molgradex	$ 3,650
Molgradex nebulizer manufacturer:	
Achievement of various development activities and regulatory approval of nebulizer utilized to administer Molgradex	7,635
Molgradex Japanese licensee:	
Co-development and regulatory costs	750
Medical education and research foundation:	
First commercial sale in the U.S. of Molgradex in treatment of NTM	500
Total manufacturing and other commitments	**$ 12,535**

The milestones and co-developement commitments disclosed above reflect the activities that have (i) not been met or incurred; (ii) not remunerated; and (iii) not accrued, as the activities are not deemed probable or resonably estimable, as of March 31, 2019.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities will be recognized in the period that includes the enactment date. A valuation allowance is established against the deferred tax assets to reduce their carrying value to an amount that is more likely than not to be realized.

Recent Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, “Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” The update aims at simplifying the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees. The standard is effective for fiscal years beginning after December 15, 2018 with early adoption permitted. The adoption of ASU 2018-07 did not have a material impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework- Changes to the Disclosure Requirements for Fair Value Measurement.” The update eliminates, adds, and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years, with early adoption permitted. The Company has not adopted ASU 2018-013 and is currently evaluating its impact on our condensed consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, “Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606.” The update clarifies that certain transactions between collaborative partners should be accounted for as revenue under the new revenue standard ASC 606 when the collaborative partner is a customer, specifies the unit of account for determining whether a transaction with a customer is a distinct good or service under ASC 606, and precludes a company from presenting transactions with a collaborative partner that are not in the scope of ASC 606 together with revenue from contracts with customers. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years, with early adoption permitted. The Company has not yet adopted ASU 2018-18 and is currently evaluating its impact on our financial statements.

In March 2019, the FASB issued ASU 2019-01, “Leases (Topic 842): Codification Improvements,” which aims to clarify and revise guidance for certain lessors and clarify interim transition disclosure requirements for ASC 842. ASU 2019-01 is effective for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years, with early adoption permitted. The Company has not yet adopted ASU 2019-01 and is currently evaluating its impact on our financial statements.

3. Prepaid expenses and other current assets

Prepaid expenses consisted of (in thousands):

	March 31, 2019	December 31, 2018
R&D tax credit receivable	$ 1,236	$ 1,263
Prepaid clinical trial costs	510	561
VAT receivable	311	421
Prepaid insurance	121	162
Deposits and other	161	107
Total prepaid expenses and other current assets	**$ 2,339**	**$ 2,514**

4. Accrued expenses and other current liabilities

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

	March 31, 2019	December 31, 2018
Accrued contracted research and development costs	$ 3,580	$ 2,044
Accrued general and administrative costs	368	371
Accrued compensation	392	643
Foreign currency exchange derivative	85	26
Deferred revenue	242	250
Lease liability	709	—
Other	41	41
Total accrued expenses and other current liabilities	**$ 5,417**	**$ 3,375**

5. Short-term Investments

Short-term Investments in Available-for-Sale Securities

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

As of March 31, 2019:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 6,974	$ 3	$ —	$ 6,977
Asset backed securities	6,235	3	—	6,238
Corporate securities	36,065	14	(2)	36,077
Commercial paper	30,216	—	—	30,216
Total short-term investments	**$ 79,490**	**$ 20**	**$ (2)**	**$ 79,508**

As of December 31, 2018:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 15,967	$ —	$ (2)	$ 15,965
Asset backed securities	8,595	—	(7)	8,588
Corporate securities	19,975	—	(21)	19,954
Commercial paper	42,022	—	—	42,022
Total short-term investments	**$ 86,559**	**$ —**	**$ (30)**	**$ 86,529**

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 sheets. 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, 2019 and March 31, 2018.

6. Debt Facility

On April 28, 2017, the Company entered into a loan and security agreement with Silicon Valley Bank, as amended on October 31, 2017, (the "Loan Agreement"), which provided for a $15.0 million credit facility that was made available in two equal tranches. In December 2018, the Company entered into an amendment to the Loan Agreement (the "Loan Amendment") to increase the amount of the term loan facility from $15.0 million to $45.0 million and make certain other changes. The Loan Agreement, as amended, provides that the funds are available in two tranches: (i) $25.0 million became available upon the effectiveness of the Loan Amendment, of which $15.0 million was used to refinance the existing amount outstanding under the loan facility, and (ii) $20.0 million is to be made available upon the Company's request prior to September 30, 2019, subject to certain conditions. However, if the Company draws the second tranche, it will be required to provide cash collateral for $20.0 million if the Company's market capitalization falls below $200 million, until certain market capitalization requirements and thresholds are met.

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 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.

Pursuant to the Loan Amendment, the loans bear interest at the prime rate reported in The Wall Street Journal, plus a spread of 3.0%. Interest only payments are due through October 2020 followed by monthly payments of principal plus interest over the following twenty-five (25) months and a maturity date of November 1, 2022. The Loan Amendment includes (i) a prepayment fee (3.0% of funded amounts in months 1-12, 2.0% of funded amounts in months 13-24, and 1.0% thereafter); and (ii) an end of term charge equal to 6.0% of the amount of principal borrowed. Savara paid minimal legal costs directly attributable to the Loan Amendment and previously paid $0.1 million in legal costs directly attributable to the original issuance of the debt instrument. 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.

The end of term charge equal to 6.0% of the amount of principal borrowed will be due on the scheduled maturity date and is being recognized as an increase to the principal with a corresponding charge to interest expense over the term of the facility using the effective interest method.

Upon the funding of each tranche, as described above, under the Loan Agreement, the Company was obligated to issue warrants to purchase shares of its common stock, as described below.

Upon funding the first tranche of the Loan Agreement, the Company issued warrants to purchase 24,725 shares of the Company's common stock at an exercise price of $9.10 per share, with a ten-year life, expiring April 28, 2027 ("April 2017 Warrants"). Upon funding the second tranche of the Loan Agreement, the Company issued warrants to purchase 41,736 shares of the Company's common stock at an exercise price of $5.39 per share with a ten-year life, expiring June 15, 2027 ("June 2017 Warrants"). The April 2017 Warrants and June 2017 Warrants issued were valued using the Black-Scholes option pricing model with the following assumptions: volatility of 71.42% and 71.57%, respectively, expected term of ten years, risk-free interest rate of 2.33% and 2.16%, respectively, and a zero-dividend yield. The collective warrant fair value of $0.4 million has been recorded as a debt discount and is being amortized through interest expense using the effective interest method through the scheduled maturity date.

Upon the funding of the tranche in connection with the Loan Amendment, the Company was obligated to issue warrants to purchase 11,332 shares of the Company's common stock at an exercise price of $8.824 per share with a ten-year life, expiring December 4, 2028 ("December 2018 Warrants"). The December 2018 Warrants issued were valued using the Black-Scholes option pricing model with the following assumptions: volatility of 80.09%, expected term of ten years, risk-free interest rate of 2.98%, and a zero-dividend yield. The collective warrant fair value of approximately $0.1 million has been recorded as a debt discount and is being amortized through interest expense using the effective interest method through the scheduled maturity date, as amended and described above.

Summary of Carrying Value

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

	As of March 31, 2019	
	Short-term	Long-term
Principal payments to lender and end of term charge	$ —	$ 25,132
Debt Issuance costs	—	(243)
Debt discount related to warrants	—	(212)
Carrying Value	$ —	$ 24,677

The carrying value of the debt facility approximates fair value.

7. Fair Value Measurements

The Company measures and reports certain financial instruments at fair value on a recurring basis and evaluates its financial instruments subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them in each reporting period.

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 Company also determined that the contingent consideration, described further below, was a Level 3 financial instrument.

The fair value of these instruments as of March 31, 2019 and December 31, 2018 was as follows (in thousands):

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of March 31, 2019:			
Cash equivalents:			
U.S. Treasury money market funds	$ 20,193	$ —	$ —
Short-term investments:			
U.S. government securities	$ 6,977	$ —	$ —
Asset backed securities	$ —	$ 6,238	$ —
Corporate securities	$ —	$ 36,077	$ —
Commercial paper	$ —	$ 30,216	$ —
Liabilities:			
Contingent consideration	$ —	$ —	$ 12,347
Foreign exchange derivatives not designated as hedging instruments	$ —	$ 85	$ —
As of December 31, 2018:			
Cash equivalents:			
U.S. Treasury money market funds	$ 14,710	$ —	$ —
Commercial paper	$ —	$ 4,411	$ —
Corporate securities	$ —	$ 2,371	$ —
Short-term investments:			
U.S. government securities	$ 15,965	$ —	$ —
Asset backed securities		$ 8,588	
Corporate securities	$ —	$ 19,954	$ —
Commercial paper	$ —	$ 42,022	$ —
Liabilities:			
Contingent consideration	$ —	$ —	$ 12,214
Foreign exchange derivatives not designated as hedging instruments	$ —	$ 26	$ —

Pursuant to the acquisition of certain assets, liabilities, and subsidiaries of Serendex A/S through its wholly-owned Danish subsidiary, Savara ApS, on July 15, 2016, Savara agreed to pay the seller, in addition to a set amount of shares of Savara's common stock, (i) $5.0 million upon receipt of marketing approval of Molgradex by the European Medicines Agency, (ii) $15.0 million upon receipt of marketing approval of Molgradex by the FDA, and (iii) $1.5 million upon receipt of marketing approval of Molgradex by the Japanese Pharmaceuticals and Medical Devices Agency (the "Contingent Milestone Payments"). The Company estimates the likelihood of approval in each region, separately, based on the product candidate's current phase of development and utilizing published studies of clinical development success rates for comparable non-oncology orphan drugs. The present value of the potential cash outflows from the probability weighted Contingent Milestone Payments is then estimated by taking into consideration that the Contingent Milestone Payments are similar to a business expense of the Company and would be senior to any Company debt obligations. The resulting weighted average present value factor is then applied to discount the probability adjusted Contingent Milestone Payments for each region to derive the fair value of the Contingent Milestone Payments.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands) for the three months ended March 31, 2019 and year ended December 31, 2018:

	Contingent Consideration
As of December 31, 2017	**$ 11,948**
Change in fair value	266
Balance at December 31, 2018	**$ 12,214**
Change in fair value	133
Balance at March 31, 2019	**$ 12,347**

The Company records changes in fair value of the contingent consideration in general and administrative expense. In requisite quarters prior to the three months ended March 31, 2019, the Company has adjusted the value of the contingent consideration due to changes in the Molgradex program based upon guidance and revisions provided by regulatory authorities.

The Company also accounted for the time value of money related to the Contingent Milestone Payments from December 31, 2018 to March 31, 2019 in its assessment. Accordingly, the related contingent consideration liability was remeasured to $12.3 million as of March 31, 2019.

The Company did not transfer any assets measured at fair value on a recurring basis to or from Level 1, Level 2, and Level 3 during the three months ended March 31, 2019 and year ended December 31, 2018.

8. 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, 2019, there was an asset of approximately $3.0 million consisting of unsettled forward exchange contracts to purchase foreign currency and a corresponding liability of approximately $3.1 million consisting of forward exchange contract obligations, resulting in $0.1 million net derivative financial instruments, recorded at their estimated fair value in "Accrued expenses and other current liabilities."

9. Shareholders' Equity

Common Stock Sales Agreement

On April 28, 2017, the Company entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC ("Wainwright"), as sales agent, which was amended by Amendment No. 1 to the Common Stock Sales Agreement (the "Amendment") on June 29, 2018 (the "Sales Agreement"), pursuant to which the Company may offer and sell, from time to time, through Wainwright, shares of Savara's common stock, par value $0.001 per share (the "Shares"), having an aggregate offering price of not more than $60.0 million, in addition to the $2.3 million in shares sold prior to the Amendment. The Amendment was effective on July 13, 2018, the date the Company's new shelf registration agreement on Form S-3, as filed with the Securities and Exchange Commission on June 29, 2018, was declared effective ("New Registration Statement") by the Securities and Exchange Commission. The Shares will be offered and sold pursuant to the New Registration Statement. Subject to the terms and conditions of the Sales Agreement, Wainwright will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions. The Company has provided Wainwright with customary indemnification rights, and Wainwright will be entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per Share sold. Sales of the Shares, if any, under the Sales Agreement may be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. The Company has no obligation to sell any of the Shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement.

During the three months ended March 31, 2019, the Company sold 647,426 shares of common stock under the Sales Agreement, for net proceeds of approximately $4.9 million.

Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue 201 million shares of common and preferred stock, consisting of 200 million shares of common stock with $0.001 par value and one million shares of preferred stock with $0.001 par value. The following is a summary of the Company's common stock at March 31, 2019 and December 31, 2018.

	March 31, 2019	December 31, 2018
Common stock authorized	200,000,000	200,000,000
Common stock outstanding	35,830,240	35,146,096

The Company's shares of common stock reserved for issuance as of March 31, 2019 and December 31, 2018 were as follows:

	March 31, 2019	December 31, 2018
Warrants acquired in merger	750,840	750,840
Warrants converted pursuant to merger	72,869	72,869
April 2017 SVB Warrants	24,725	24,725
June 2017 SVB Warrants	41,736	41,736
December 2018 SVB Warrants	11,332	11,332
Pre-funded warrants	775,000	775,000
Stock options outstanding	3,133,827	3,077,264
Issued and nonvested RSU's	143,125	156,250
Total shares reserved	**4,953,454**	**4,910,016**

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of March 31, 2019:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
314,446	$	52.50	November 2019
32,467	$	7.00	August 2020
403,927	$	29.40	February 2021
72,869	$	8.98	June 2021
775,000	$	0.01	October 2024
24,725	$	9.10	April 2027
41,736	$	5.39	June 2027
11,332	$	8.824	December 2028
1,676,502			

10. Commitments

Operating Leases

We are obligated under operating leases and subleases for office space. On November 29, 2017, we entered into a sublease agreement for new office space for our corporate headquarters in Austin, Texas. The term of the sublease for the new space commenced on January 1, 2018 and will continue until July 31, 2021, with annual rental payments of approximately $0.2 million, paid over monthly installments, subject to increases of approximately 2% annually on the anniversary of the commencement date of the sublease term. However, monthly base rent for the first month of the sublease term was abated.

We leased new office space in Copenhagen, Denmark with an effective date of November 1, 2018 and expiring on September 30, 2022. The lease in Copenhagen can be terminated by the lessee and lessor no earlier than March 31, 2022 for vacating the premises by September 30, 2022 and contains an option to extend the lease term to remain in force until it is terminated in writing by either the lessee or lessor with a six month notice period from the first day of the month following September 30, 2022. For the three months ended March 31, 2019, it is not reasonably certain the Company will exercise the extension options inherent in the lease. Our annual rent is approximately $0.1 million, paid over monthly installments, subject to annual increases equal to the Danish consumer price index, or approximately 2% annually.

On March 23, 2017, we sublet office space located in San Diego, California with rentable office space of approximately 13,707 square feet, which previously served as a predecessor's corporate headquarters, to a third party as the Company no longer had an ongoing need for this facility. The term of the sub-sublease commenced on July 1, 2017 and expires on May 31, 2020, coterminous with a sublease agreement dated June 19, 2014 with the sublessor. As of March 31, 2019, annual rent under the sub-sublease is approximately $0.5 million, payable in monthly installments.

We previously leased office space for our corporate headquarters, prior to our relocation on January 1, 2018, discussed herein, in Austin, Texas, pursuant to an operating lease dated November 19, 2012, as amended May 22, 2015, under which we are obligated to remit annual rental payments of approximately $0.1 million payable in monthly installments for the period January 1, 2018 through November 30, 2019. On November 29, 2017, we entered into a sublease agreement pursuant to which the sublessee assumed the office space and rental payments effective January 1, 2018 through November 30, 2019 except for the first month rent on January 2018.

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of March 31, 2019 (in thousands):

Year ending December 31,		
2019	$	592
2020		478
2021		184
2022		67
Total future minimum lease payments	**$**	**1,321**
Less imputed interest		(107)
Total	**$**	**1,214**

	For the three months ended March 31, 2019	
Lease cost:		
Operating lease cost	$	369
Sublease income		(153)
Total lease cost	**$**	**216**
Other information:		
Operating cash flows from operating leases	$	194
Weighted-average remaining lease term (in months) - operating leases		23.8
Weighted-average discount rate - operating leases		8.5%

As of March 31, 2019, the carrying value of the right-of-use assets for the operating leases was $1.2 million, which is reflected in "Other non-current assets," and the carrying value of the lease liabilities for operating leases was $1.2 million, of which $0.7 million related to the current portion of the lease liabilities is recorded in "Accrued expenses and other current liabilities," and $0.5 million related to the non-current portion of the lease liabilities is recorded in "Other long-term liabilities."

Cardeas

In June 2018, the Company entered into an asset purchase agreement with Cardeas Pharma Corporation ("Cardeas") under which Savara acquired substantially all of the assets, including intellectual property, of Cardeas for a purchase price comprised of (i) an upfront payment of shares of the Company's common stock and (ii) certain contingent payments due upon the achievement of distinct development milestones. As of the measurement date of the acquisition and at March 31, 2019, the Company has deemed that the contingent payments are not probable and as such has not recorded an associated liability but will continue to assess at each period.

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.

Employment Agreements

Certain executive officers are entitled to payments if they are terminated without cause or resign for good reason (each as defined in the employment agreements). Upon termination without cause, and not as a result of death or disability or resignation for good reason, each of such officers is entitled to receive a payment of base salary for twelve months and a pro-rated portion of their unpaid bonus following termination of employment, and such officer will be entitled to continue to receive coverage under medical and dental benefit plans for twelve months or until such officer is covered under a separate plan from another employer. Upon a termination other than for cause or resignation for good reason within twelve months following a change in control, each of such officers is entitled to receive a payment of base salary for eighteen months and one-hundred percent of their unpaid bonus following termination of employment and such officer will be entitled to continue to receive coverage under medical and dental benefit plans for twelve months or until such officer is covered under a separate plan from another employer and will also be entitled to certain acceleration of such officer's outstanding nonvested options at the time of such termination.

11. Stock-Based Compensation

A. Equity Incentive Plan

2008 Stock Option Plan

The Company adopted the Savara Inc. Stock Option Plan (the "2008 Plan"), pursuant to which the Company had reserved shares for issuance to employees, directors, and consultants. The 2008 Plan includes (i) the option grant program providing for both incentive and non-qualified stock options, as defined by the Internal Revenue Code, and (ii) the stock issuance program providing for the issuance of awards that are valued based upon common stock, including restricted stock, dividend equivalents, stock appreciation rights, phantom stock, and performance units. The 2008 Plan also allows eligible persons to purchase shares of common stock at an amount determined by the plan administrator. Upon a participant's termination, the Company retains the right to repurchase nonvested shares issued in conjunction with the stock issuance program at the fair market value per share as of the date of termination.

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

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"), which was amended and approved by stockholders in June 2018. 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, 2019, the number of shares of our common stock available for grant under the 2015 Plan was 1,508,362 shares.

B. Stock Option and Restricted Stock Units

The Company values stock options using the Black-Scholes 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 near 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. Stock option awards generally have ten-year contractual terms and vest over four years for issuances to employees based on continuous service; however, the 2015 Plan allows for other vesting periods.

C. Stock-Based Award Activity

The following table provides a summary of stock-based awards for the 2008 Plan and 2015 Plan for the three months ended March 31, 2019 and 2018:

	Three months ended March 31, 2019			Three months ended March 31, 2018		
	Stock Options	RSUs	Total	Stock Options	RSUs	Total
Outstanding as of December 31	**3,077,264**	**156,250**	**3,233,514**	**1,916,832**	**86,875**	**2,003,707**
Granted	90,000	—	90,000	10,000	120,000	130,000
Exercised	(23,593)	(13,125)	(36,718)	(37,894)	(11,250)	(49,144)
Forfeited	(9,844)	—	(9,844)	(102,500)	—	(102,500)
Outstanding as of March 31	**3,133,827**	**143,125**	**3,276,952**	**1,786,438**	**195,625**	**1,982,063**

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, 2019 and 2018 (in thousands):

	Three Months Ended	
	March 31, 2019	March 31, 2018
Research and development	$ 452	$ 228
General and administrative	548	184
Total stock-based compensation	**$ 1,000**	**$ 412**

12. License Agreement

The Company entered into a license agreement on May 12, 2016, as amended on June 4, 2018 (the "License Agreement"), with a licensee under which the licensee received an exclusive right to import, market, sell, distribute and promote Molgradex in Japan for the treatment of aPAP. In return, the licensee will pay the Company marketing and regulatory-based milestone payments and sales-based royalties. In October 2018, the Company achieved a milestone payment pursuant to the License Agreement resulting in the receipt of $0.3 million from the licensee. As of March 31, 2019, the Company has determined that it has not met all of the performance obligations under the License Agreement and, accordingly, has recorded the milestone payment as deferred revenue in "Accrued expenses and other current liabilities" in the Company's condensed consolidated balance sheet until such time the performance obligations are met.

13. Net Loss per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding during the period. 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 weighted-average 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 Ended	
	March 31, 2019	March 31, 2018
Awards under equity incentive plan	3,133,827	1,786,438
Nonvested restricted shares and restricted stock units	143,125	207,768
Warrants to purchase common stock	901,502	1,291,645
Total	**4,178,454**	**3,285,851**

The following table reconciles basic earnings per share of common stock for the three months ended March 31, 2019 and 2018:

	Three Months Ended	
	March 31, 2019	March 31, 2018
Net loss	$ (12,112)	$ (26,849)
Net loss attributable to common stockholders	(12,112)	(26,849)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	(12,112)	(26,849)
Weighted average common shares outstanding, basic and diluted	36,016,406	31,318,746
Basic and diluted EPS	**$ (0.34)**	**$ (0.86)**

14. Subsequent Events

On April 26, 2019 (“Effective Date”), the Company, through its wholly-owned subsidiary Savara ApS, entered into the New Supply Agreement (See Note 2) with a vendor pursuant to which the vendor will supply API of Molgradex, which supersedes the original supply agreement, as amended, and all other agreements with the vendor. Under the New Supply Agreement, the Company shall remit up to $5.0 million in various milestone payments related to the vendor’s completion of requirements related to the commercial process and regulatory approvals, as well as Molgradex’s marketing approval in specified jurisdictions.

Additionally, upon first receipt of marketing approval by Savara from a regulatory authority in such country for a product containing the API for therapeutic use in humans and ending the earlier of (i) ten (10) years thereafter or (ii) the date a biological product that is licensed and/or approved by a regulatory authority based on a showing that it is highly similar to the product containing the API and has no clinically meaningful differences in safety and efficacy is first sold in such country, Savara shall pay vendor a royalty equal to low-single digits of the net sales in such country.

Under the New Supply Agreement, Savara shall provide vendor with a good-faith written forecast of the estimated required quantities of API on a rolling quarterly basis as well as related purchase orders, the vendor shall use commercially reasonable efforts to accept and fulfill all purchase orders, and Savara shall be monetarily responsible for such purchases, which are subject to commercially reasonable price increases from time to time.

The New Supply Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to certain provisions, shall continue in full force and effect, until the twentieth (20th) anniversary of the date of receipt of approval by a regulatory authority of the first regulatory filing for the marketing and first sale involving the Molgradex API in any country and may be subsequently extended for additional twelve (12) month periods by the written consent of both parties.

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

This Quarterly Report on Form 10-Q 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 and those discussed in the section entitled "Risk Factors" in this Quarterly Report on pages 30 through 51.

Overview

We are an orphan lung disease company. Our current pipeline comprises Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor ("GM-CSF") in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"), in Phase 2a development for nontuberculous mycobacterial ("NTM") lung infection, and in Phase 2a development for the treatment of NTM lung infection in people living with cystic fibrosis ("CF"), and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of persistent methicillin-resistant Staphylococcus aureus ("MRSA") lung infection in individuals living with CF. Our strategy involves expanding our pipeline of potentially best-in-class products through indication expansion, strategic development partnerships and product acquisitions, with the goal of becoming a leading company in our field. Our management team has significant experience in orphan drug development and pulmonary medicine, in identifying unmet needs, developing and acquiring new product candidates, and effectively advancing them to approvals and commercialization.

Together with our wholly-owned subsidiaries, including Aravas Inc., Savara ApS, Drugrecure A/S, and Savara Australia Pty. Limited, we operate in one segment with our principal offices 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 material product revenue from inception to date as we have not yet commenced commercial operations. From our inception to March 31, 2019, we have raised net cash proceeds of approximately $214.2 million from public offerings of 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 were $12.1 million for the three months ended March 31, 2019 and $61.5 million for the year ended December 31, 2018, which included an impairment charge of $21.7 million on certain acquired in-process research and development ("IPR&D"). As of March 31, 2019, we had an accumulated deficit of $141.8 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative ("G&A") 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 increase our operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, our product candidates and add necessary personnel accordingly. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

As of March 31, 2019, we had cash of $25.7 million and short-term investments of $79.5 million. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. 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

ENCORE Study

During the first quarter of 2019, we initiated a Phase 2a clinical study of Molgradex for the treatment of NTM lung infection in people living with CF, named ENCORE. ENCORE is an open-label, non-controlled, multi-center, Phase 2a clinical study of Molgradex in patients living with CF who have persistent pulmonary NTM lung infection. ENCORE will enroll approximately 30 patients (≥18 years of age) with chronic Mycobacterium avium complex or Mycobacterium abscessus infection, with all patients either having antibiotic refractory infection, experiencing intolerance to standard NTM antibiotics, or not currently meeting recommendations for antibiotic treatment. The study comprises a 48-week treatment period of 300µg of Molgradex once daily and a 24-week follow up period.

The primary endpoint in the study is sputum culture conversion, defined as at least three consecutive negative NTM sputum samples with a four-week interval between each. Secondary endpoints include: (i) the number of patients with sputum smear conversion to negative, defined as at least three consecutive negative acid-fast bacilli stained sputum smears on microscopy among patients who were smear positive at baseline, (ii) the reduction of bacterial load in sputum, and (iii) other microbiological indicators, pulmonary measures, and patient reported outcomes.

GEMA

On April 26, 2019 ("Effective Date"), the Company, through its wholly-owned subsidiary Savara ApS, entered into the New Supply Agreement (See Note 2 of the condensed consolidated financial statements in this report) with a vendor pursuant to which the vendor will supply API of Molgradex, which supersedes the original supply agreement, as amended, and all other agreements with the vendor. Under the New Supply Agreement, the Company shall remit up to $5.0 million in various milestone payments related to the vendor's completion of requirements related to the commercial process and regulatory approvals, as well as Mogradex's marketing approval in specified jurisdictions.

Additionally, upon first receipt of marketing approval by Savara from a regulatory authority in such country for a product containing the API for therapeutic use in humans and ending the earlier of (i) ten (10) years thereafter or (ii) the date a biological product that is licensed and/or approved by a regulatory authority based on a showing that it is highly similar to the product containing the API and has no clinically meaningful differences in safety and efficacy is first sold in such country, Savara shall pay vendor a royalty equal to low-single digits of the net sales in such country.

Under the New Supply Agreement, Savara shall provide vendor with a good-faith written forecast of the estimated required quantities of API on a rolling quarterly basis as well as related purchase orders, the vendor shall use commercially reasonable efforts to accept and fulfill all purchase orders, and Savara shall be monetarily responsible for such purchases, which are subject to commercially reasonable price increases from time to time.

The New Supply Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to certain provisions, shall continue in full force and effect, until the twentieth (20th) anniversary of the date of receipt of approval by a regulatory authority of the first regulatory filing for the marketing and first sale involving the Molgradex API in any country and may be subsequently extended for additional twelve (12) month periods by the written consent of both parties.

Common Stock Sales Agreement

During the three months ended March 31, 2019, we sold 647,426 shares of our common stock under our Common Stock Sales Agreement, as amended, with H.C. Wainwright & Co., LLC, as sales agent, (the "Sales Agreement") resulting in net proceeds of $4.9 million.

Financial Operations Overview

Research and Development Expenses

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 consultants and clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of 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. Any unallocated internal research and development costs consist primarily of:

- personnel costs, which include salaries, benefits, and stock-based compensation expense;
- allocated facilities and other expenses, which include expenses for rent and maintenance of facilities and depreciation expense; and
- regulatory expenses and technology license fees related to development activities.

The largest component of our operating expenses has historically been our investment in research and development activities. The following table shows our research and development expenses for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Product candidates:		
AeroVanc	$ 3,304	$ 3,039
Molgradex	6,685	4,781
Other	30	719
Total research and development expenses	**$ 10,019**	**$ 8,539**

We expect research and development expenses will increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing and inventory build-up related costs. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to license fee and/or milestone payments.

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 any of our product candidates.

General and Administrative Expenses

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development Expenses

We record accrued expenses for estimated costs of our research and development activities conducted by external service providers, which include the conduct of clinical trials and contract formulation and manufacturing activities. We record the estimated costs of development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued liabilities in the consolidated balance sheet and within research and development expense in the consolidated statement of operations and comprehensive loss. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these external service providers.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Goodwill and Acquired IPR&D

In accordance with Accounting Standards Codification ("ASC") Topic 350, "Intangibles – Goodwill and Other," our goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired.

Accounting Standards Update ("ASU") 2017-04, "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment," outlines an impairment model providing the Company the option to implement a one-step method for determining impairment of goodwill, thereby simplifying the subsequent measurement of goodwill by eliminating Step 2 (measuring a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill) from the goodwill impairment test. Under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.

With respect to the impairment testing of acquired IPR&D, ASU 2011-08, "Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment," and ASU 2012-02, "Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment," provides us a two-step impairment process with the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more-likely-than not (that is, a likelihood of more than 50%) that our acquired IPR&D is impaired. If we choose to first assess qualitative factors and we determine that it is more-likely-than not acquired IPR&D is not impaired, we are not required to take further action to test for impairment.

If we perform a quantitative assessment of acquired IPR&D, we compare its carrying value to its estimated fair value to determine whether an impairment exists. In previous years, due to a lack of Level 1 or Level 2 inputs, the Multi-Period Excess Earnings Method ("MPEEM"), which is a form of the income approach, was used to estimate the fair value of acquired IPR&D when performing a quantitative assessment. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset's projected incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life. We evaluate potential impairment of our acquired IPR&D annually on September 30th utilizing a qualitative approach and determining if it was more-likely-than not that the fair value was not impaired. We evaluate potential impairment of our acquired goodwill annually on June 30th performing the quantitative analysis based upon market capitalization. While we continue to evaluate opportunities to monetize our acquired assets, we can provide no assurances that we will be able to do so. However, we believe that our approach is a more appropriate method for assessing fair value in the context of our current business.

Our determinations as to whether, and if so, the extent to which, goodwill and acquired IPR&D become impaired are highly judgmental and, in the case of applying the MPEEM approach to estimate fair value, are based on significant assumptions regarding our projected future financial condition and operating results, changes in the manner of our use of the acquired assets, development of our acquired assets or our overall business strategy, and regulatory, market, and economic environment and trends.

Share-based Compensation Expenses

We recognize the cost of stock-based awards granted to employees based on the estimated grant-date fair value of the awards. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. We recognize the compensation costs for awards that vest over several years on a straight-line basis over the vesting period. Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise.

We estimate the grant-date fair value of a stock option award using the Black-Scholes option pricing model ("Black-Scholes model"). In determining the grant-date fair value of a stock option award under the Black-Scholes model, we must make a number of assumptions, including the term of the award, the volatility of the price of our common stock over the term of the award, and the risk-free interest rate. Changes in these or other assumptions could have a material impact on the compensation expense we recognize.

Revenue

We record revenue based on a five-step model in accordance with ASC 606, "Revenue from Contracts with Customers." To date, we have not generated any product revenue from our product candidates.

Milestone Revenue

With respect to our license agreement (see Note 12 of the condensed financial statements in this report), which includes certain milestone payments to be remunerated to us by the licensee, we identify the performance obligations, determine the transaction price, allocate the contract transaction price to the performance obligations, and recognize the revenue when (or as) the performance obligation is satisfied. We identify the performance obligations included within the license agreement and evaluate which performance obligations are distinct.

The milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. The milestone payments are estimated and included in the transaction price when we determine, under the variable consideration constraint, that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust the estimate of the overall transaction price.

Results of Operations — Comparison of Three Months Ended March 31, 2019 and 2018

	Three Months Ended March 31,		Dollar Change
	2019	2018	
		(in thousands)	
Operating expenses:			
Research and development	$ 10,019	$ 8,539	$ 1,480
General and administrative	2,763	1,769	994
Impairment of IPR&D	—	21,692	(21,692)
Depreciation	138	107	31
Total operating expenses	12,920	32,107	(19,187)
Loss from operations	(12,920)	(32,107)	19,187
Other income, net	808	703	105
Net loss before income taxes	(12,112)	(31,404)	19,292
Income tax benefit	—	4,555	(4,555)
Net loss	**$ (12,112)**	**$ (26,849)**	**$ 14,737**

Research and development

Research and development expenses increased by $1.5 million, or 17.3% to $10.0 million for the three months ended March 31, 2019 from $8.5 million for the three months ended March 31, 2018. The increase was primarily due to approximately $0.3 million in increased AeroVanc study costs related to Phase 3 activities and $1.9 million in increased development costs associated with the development of Molgradex. Conversely, other program cost for the three months ended March 31, 2019 was minimal and decreased by approximately $0.7 million from the three months ended March 31, 2018. This decrease is related to costs incurred for a Phase 2 study of an acquired product candidate. This study was abandoned in the first quarter of 2018 due to the product candidate's inability to meet its primary endpoints for the related Phase 2 study.

General and administrative

G&A expenses increased by $1.0 million, or 56.2%, to $2.8 million for the three months ended March 31, 2019 from $1.8 million for the three months ended March 31, 2018. The increase was primarily due to increased personnel costs and other legal, accounting, insurance, and other operating activities.

Impairment of IPR&D

During the quarter ended March 31, 2018, we recognized a $21.7 million impairment charge to the carrying value of acquired IPR&D related to a drug candidate previously assumed by us. Due to unfavorable results from the Phase 2 study that demonstrated a failure of this drug candidate to meet the endpoints of the study and limited effectiveness of the compound in patients, we recognized an impairment charge equal to the full carrying value of the related IPR&D. We are no longer supporting or pursuing this drug candidate**.**

Other income, net

Other income, net of other expense, increased by $0.1 million to $0.8 million for the three months ended March 31, 2019 from $0.7 million for the three months ended March 31, 2018 and was primarily related to a reduction of net interest expense.

Income tax benefit

Income tax benefit decreased by $4.5 million for the three months ended March 31, 2019 from the three months ended March 31, 2018 primarily due to the reversal of a deferred tax liability resulting from the impairment of certain acquired IPR&D during the first quarter of 2018.

Liquidity and Capital Resources

As of March 31, 2019, we had $25.7 million in cash, $79.5 million in short-term investments and an accumulated deficit of $141.8 million. We entered into a loan and security agreement with Silicon Valley Bank during the year ended December 31, 2017, which was amended December 2018 through which we have drawn a total of $25.0 million and which $20.0 million is available upon the Company's request prior to September 30, 2019, subject to certain conditions. We continue to sell our common stock through "at the market offerings" under the Sales Agreement and have raised net proceeds of $7.2 million under the sales agreement since April 2017. Since April 2017, we have completed three public offerings with combined net proceeds from the offerings, after deducting the underwriting discounts and commissions and offering expenses, of approximately $135.3 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, the initiation of Molgradex pre-commercialization activities, and G&A expenses.

Cash Flows

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

	Three Months Ended March 31,	
	2019	**2018**
	(in thousands)	
Cash used in operating activities	$ (10,859)	$ (9,671)
Cash provided by investing activities	7,320	9,390
Cash provided by financing activities	4,896	271
Effect of exchange rate changes	13	11
Net increase in cash	**$ 1,370**	**$ 1**

Cash flows from operating activities

Cash used in operating activities for the three months ended March 31, 2019 was $10.9 million, consisting of a net loss of $12.1 million, which was partially offset by noncash charges of $1.4 million, mainly comprised of depreciation and amortization including right-of-use assets, noncash interest, fair value changes, accretion on discount to short-term investments, amortization of debt issuance costs, and stock-based compensation, and increased by a net increase in assets and liabilities of approximately $0.2 million. The change in our net operating assets and liabilities was primarily due to an increase in accrued liabilities primarily related to research and development costs for both AeroVanc and Molgradex.

Cash flows from investing activities

Cash provided by investing activities for the three months ended March 31, 2019 and was primarily the result of the net sales and maturities of short-term investments.

Cash flows from financing activities

Cash provided by financing activities for the three months ended March 31, 2019 was primarily related to net proceeds of $4.9 million from the "at the market offerings" under the Sales Agreement.

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 any of our product candidates. 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 of regulatory approval for, our product candidates. In addition, subject to obtaining regulatory approval of any of our product candidates, we anticipate that we will need substantial additional funding in connection with our continuing operations.

As of March 31, 2019, we had cash, cash equivalents, and short-term investments of $105.2 million. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. 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.

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 and potentially through borrowings, grants and strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. 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.

Contractual Obligations

There were no other material changes outside of the ordinary course of business in our contractual obligations during the three months ended March 31, 2019 from those disclosed in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations - Contractual Obligations and Other Commitments" of our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 13, 2018.

For a summary of the contingent milestone payments, see Note 2 "Summary of Significant Accounting Policies - Manufacturing Commitments and Contingencies" of the condensed consolidated financial statements in this report.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Recent Accounting Pronouncements

See Note 2, "Summary of Significant Accounting Policies – Recent Accounting Pronouncements," of the condensed consolidated financial statements in this 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 had a material impact on our 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 as a result of our loan and security agreement with Silicon Valley Bank. As of March 31, 2019, the outstanding gross principal amount of the secured term loan was $25.0 million. The loan agreement bears interest at the prime rate reported in The Wall Street Journal, plus a spread of 3.0%. 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, 2019 were to have occurred, this change would not have had a material effect on our interest expense obligations with respect to outstanding borrowed amounts.

We have ongoing operations in Denmark and pay those vendors in local currency (Danish Krone) or Euros. We seek to limit the impact of foreign currency fluctuations through the use of derivative instruments, short-term foreign currency forward exchange contracts not designated as hedging instruments. We also have ongoing operations in Australia as a result of the expansion of Molgradex for the treatment of NTM lung infection and pay our respective vendors in Australian Dollars. We did not recognize any significant exchange rate losses during the three months ended March 31, 2019 and 2018. A 10% change in the Krone-to-dollar, Euro-to-dollar, Australian dollar-to-dollar, or Krone-to-Australian dollar exchange rate on March 31, 2019 would not have had a material effect on our results of operations or financial condition.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2019. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of March 31, 2019 these disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarterly period covered by this report that has materially affected, or is 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.

Investment in our common stock involves a high degree of risk and uncertainty. Our business, operating results, growth prospects, and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with all of the information in this report and our other public filings, before making investment decisions regarding our securities. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects, or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment.

Risks Related to Our Capital Requirements and Financial Condition

We have a limited operating history and have incurred significant losses since inception and expect that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

We are a clinical development-stage biopharmaceutical company with a limited operating history upon which to evaluate our business and prospects. We have not been profitable since we commenced operations and may not ever achieve profitability. In addition, we have limited history as an organization and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates, or generated any product revenue. We have devoted significant resources to research and development and other expenses related to our ongoing clinical trials and operations, in addition to acquiring product candidates.

For the three months ended March 31, 2019, we incurred a net loss of $12.1 million, and net cash used in operating activities was $10.9 million. At March 31, 2019, our cash, cash equivalents and short-term investment securities were $105.2 million, and working capital was $98.6 million. At March 31, 2019, we had an accumulated deficit of $141.8 million. We expect to continue to incur substantial operating losses for the next several years as we seek to advance our product candidates through clinical development, global regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, one of our product candidates is approved by the Food and Drug Administration ("FDA") or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve.

We will require additional financing to obtain regulatory approval for Molgradex and AeroVanc, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our product development efforts or other operations.

Since our Aravas subsidiary was formed in 2007, most of our resources have been dedicated to the development and acquisition of our product candidates, Molgradex and AeroVanc. Under our current operating plan, we believe that our existing capital resources will be sufficient to fund our planned operations into 2020. However, we may raise additional capital, including through our "at the market offering" program to fund new studies, programs, or acquisitions, or to address changes in our existing development programs. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidates and there is no certainty that we will be able to raise the necessary capital on reasonable terms or at all.

Our capital requirements for the foreseeable future will depend in large part on, and could increase significantly as a result of, our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties, and will depend on, and could increase significantly as a result of, many factors, including:

- the number, size, complexity, results, and timing of our drug development programs;
- the timing and terms of any collaborative or other strategic arrangement that we may establish;

- the number of clinical and nonclinical studies necessary to demonstrate acceptable evidence of the safety and efficacy of our product candidates;
- changes in standards of care which could increase the size and complexity of our clinical studies;
- the number of patients who participate, the rate of enrollment, and the ratio of randomized to evaluable patients in each clinical study;
- the ability to locate patients to participate in a study given the limited number of patients available for orphan or ultra-orphan indications;
- the number and location of sites and the rate of site initiation in each study;
- the duration of patient treatment and follow-up;
- the potential for additional safety monitoring or other post-marketing studies that may be requested by regulatory agencies;
- the time and cost to manufacture clinical trial material and commercial product, including process development and scale-up activities, and to conduct stability studies, which can last several years;
- the degree of difficulty and cost involved in securing alternate manufacturers or suppliers of drug product, components, or delivery devices, as necessary to meet FDA requirements and/or commercial demand;
- the costs, requirements, timing of, and the ability to, secure regulatory approvals;
- the extent to which we increase our workforce and the costs involved in recruiting, training, and incentivizing new employees;
- the costs related to developing, acquiring, and/or contracting for sales, marketing, and distribution capabilities, supply chain management capabilities, and regulatory compliance capabilities, if we obtain regulatory approval for a product candidate and commercialize it without a partner;
- the costs involved in evaluating competing technologies and market developments or the loss in sales in case of such competition; and
- the costs involved in establishing, enforcing, or defending patent claims and other proprietary rights.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we will be required to delay, limit, reduce, or terminate our establishment of sales and marketing, manufacturing or distribution capabilities, development activities, or other activities that may be necessary to commercialize our product candidates, or conduct preclinical or clinical studies.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams, or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our stockholders will be diluted and the terms of any new equity securities may have preferential rights over our common stock. If we raise additional capital through debt financing, it may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures, or subject to specified financial ratios, any of which could restrict our ability to develop and commercialize our product candidates or operate as a business.

Our loan agreement contains covenants which may adversely impact our business; the failure to comply with such covenants could cause our outstanding debt to become immediately payable.

On April 28, 2017, we entered into a Loan and Security Agreement, as subsequently amended on December 4, 2018 to increase the committed facility amount, between us and Aravas, as co-borrowers, and Silicon Valley Bank (the "Amended Loan Agreement"). The Amended Loan Agreement includes a number of restrictive covenants, including restrictions on incurring additional debt, making investments, granting liens, disposing of assets, paying dividends, and redeeming or repurchasing capital stock, subject to certain exceptions. Collectively, these covenants could constrain our ability to grow our business through acquisitions or engage in other transactions. In addition, the Amended Loan Agreement includes covenants requiring, among other things, that we provide financial statements, comply with all laws, pay all taxes, and maintain insurance. If we are not able to comply with these covenants, the loans under the Loan Agreement could become immediately due and payable and would have a material adverse effect on our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

We have significant goodwill and IPR&D and impairment of goodwill and IPR&D may have a significant adverse impact on our future financial condition and results of operations.

As of March 31, 2019, we had goodwill and IPR&D of approximately $38.0 million. These intangible assets are subject to an impairment analysis whenever an event or change in circumstances indicates the carrying amount of such an asset may not be recoverable. We test our goodwill and IPR&D for impairment annually, or more frequently if an event or change in circumstances indicates that the asset may be impaired. If an impairment is identified, we would be required to record an impairment charge with respect to the impaired asset to our condensed statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations. We will continue to evaluate our intangible assets for potential impairment in accordance with our accounting policies.

Events giving rise to impairment are difficult to predict and are an inherent risk in the pharmaceutical industry. Some of the potential risks that could result in impairment of our goodwill and IPR&D include negative clinical study results, adverse regulatory developments, delay or failure to obtain regulatory approval, additional development costs, changes in the manner of our use or development of our product candidates, competition, earlier than expected loss of exclusivity, pricing pressures, higher operating costs, changes in tax laws, prices that third parties are willing to pay for our IPR&D or similar assets in an arm's-length transaction being less than the carrying value of our IPR&D, and other market and economic environment changes or trends. Events or changes in circumstances may lead to significant impairment charges on our goodwill and/or IPR&D in the future, which could materially adversely affect our financial condition and results of operations.

Risks Related to Our Business Strategy and Operations

We are substantially dependent upon the clinical, regulatory, and commercial success of our product candidates, Molgradex and AeroVanc. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate to the satisfaction of regulatory authorities the safety and efficacy of our product candidates.

The success of our business is dependent on our ability to advance the clinical development of Molgradex for the treatment of patients with aPAP, treatment of patients with NTM lung infection, and its expansion into NTM lung infection with people living with CF, and AeroVanc for the treatment of MRSA infection in the lungs of CF patients. The Molgradex Phase 3 clinical study, for the treatment of aPAP, designated as IMPALA, is ongoing in Europe, Japan, and the U.S. We expect to announce top-line results from the Phase 3 study of Molgradex in the second quarter of 2019. The Molgradex studies for (i) the treatment of NTM lung infections, designated as OPTIMA, and the treatment of NTM lung infection in people living with CF, designated ENCORE, are in Phase 2a development. The AeroVanc Phase 3 study, designated as AVAIL, started in the U.S. and Canada in the third quarter of 2017. We expect to announce top-line results from the Phase 3 study of AeroVanc in the second quarter of 2020.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

Given the developmental nature of our product candidates, we are subject to risks associated with initiating, completing, and achieving positive outcomes from our current and future clinical trials, including:

- slow implementation, enrollment, and completion of the clinical trials;
- inability to enroll enough patients in the clinical trials;
- low patient compliance and adherence to dosing and reporting requirements, for example incomplete reporting of patient reported outcomes in the clinical trials or missed doses;
- lack of safety and efficacy in the clinical trials;
- delays in manufacture of supplies for both drug and device components due to delays in formulation, process development, or manufacturing activities;
- requirements for additional nonclinical or clinical studies based on changes to formulation and/or changes to regulatory requirements; and
- requirements for additional clinical studies based on inconclusive clinical results or changes in market, standard of care, and/or regulatory requirements.

If we successfully complete the necessary clinical trials for our product candidates, our success will be subject to the risks associated with obtaining regulatory approvals, product launch, and commercialization, including:

- FDA rejection of our New Drug Application ("NDA") and Biologics License Application ("BLA") submissions for our product candidates;
- regulatory rejection in the EU, Japan, and other markets;
- delays during regulatory review and/or requirements of additional Chemistry, Manufacturing, and Controls, nonclinical, or clinical studies, resulting in increased costs and/or delays in marketing approval and subsequent commercialization of the product candidates in the U.S. and other markets;
- inability to consistently manufacture commercial supplies of drug and delivery devices resulting in slowed market development and lower revenue;
- poor commercial sales due to:
    - the inability of our future sales organization or our potential commercialization partners to effectively sell the product candidates;
    - our lack of success in educating physicians and patients about the benefits, administration, and use of our product candidates;
    - the availability, perceived advantages, relative cost, relative safety, and relative efficacy of other products or treatments for the targeted indications of the product candidates;
    - low patient demand for the product candidates; and
    - poor prescription coverage and inadequate reimbursement for our product candidates;
- our inability to enforce our intellectual property rights in our product candidates; and
- reduction in the safety profile of our product candidates following approval.

Many of these clinical, regulatory, and commercial matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure that we will be able to advance our product candidates further through final clinical development, or obtain regulatory approval of, commercialize, or generate significant revenue from them. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.

We have historically operated with a limited number of employees that manage third parties for most development activities. Institutional knowledge is concentrated within a small number of employees. Our success depends on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel. Our future success is highly dependent upon the contributions of our senior management, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals, who all have at-will employment arrangements with us, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, or the commercialization of our product candidates.

Replacing key employees may be a difficult, costly, and protracted process, and we may not have other personnel with the capacity to assume all the responsibilities of a key employee upon his/her departure. Transition periods can be difficult to manage and may cause disruption to our business. In addition, there may be intense competition from other companies and organizations for qualified personnel. Other companies and organizations with which we compete for personnel may have greater financial and other resources and different risk profiles than us, and a history of successful development and commercialization. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals.

In addition, the success of our business will depend on our ability to develop and maintain relationships with respected service providers and industry-leading consultants and advisers. If we cannot develop and maintain such relationships as needed, the rate and success at which we can develop and commercialize product candidates may be limited. In addition, our outsourcing strategy, which has included engaging consultants that spend considerable time to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

We do not have, and do not have plans to establish commercial manufacturing facilities. We completely rely on third parties for the manufacture and supply of our clinical trial drug and delivery device supplies and, if approved, commercial product materials. The loss of any of these vendors or a vendor's failure to provide us with an adequate supply of clinical trial or commercial product material in a timely manner and on commercially acceptable terms, or at all, could harm our business.

We outsource the manufacture of our product candidates and do not plan to establish our own manufacturing facilities. To manufacture our product candidates, we have made numerous custom modifications at contract manufacturing organizations ("CMOs"), making us highly dependent on these CMOs. For clinical and commercial supplies, if approved, we have supply agreements with third party CMOs for drug substance, finished drug product, drug delivery devices and other necessary components of our product candidates. While we have secured long-term commercial supply agreements with many of the third party CMOs, we would need to negotiate agreements for commercial supply with several important CMOs, and we may not be able to reach agreement on acceptable terms. In addition, we rely on these third parties to conduct or assist us in key manufacturing development activities, including qualification of equipment, developing, and validating methods, defining critical process parameters, releasing component materials, and conducting stability testing, among other things. If these third parties are unable to perform their tasks successfully in a timely manner, whether for technical, financial, or other reasons, we may be unable to secure clinical trial material, or commercial supply material if approved, which likely would delay the initiation, conduct, or completion of our clinical studies or prevent us from having enough commercial supply material for sale, which would have a material and adverse effect on our business.

All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with current good manufacturing practices ("cGMP") requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our clinical trial material may be unable to comply with these cGMP requirements and with other FDA, state, and foreign regulatory requirements. While we and our representatives generally monitor and audit our manufacturers' systems, we do not have full control over their ongoing compliance with these regulations. And while the responsibility to maintain cGMP compliance is shared between us and the third-party manufacturer, we bear ultimate responsibility for our supply chain and compliance with regulatory standards. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval.

Currently, we do not have alternative vendors to back up our primary vendors of clinical trial material or, if approved, commercial supply material. Identification of and discussions with other vendors may be protracted and/or unsuccessful, or these new vendors may be unsuccessful in producing the same results as the current primary vendors producing the material. Therefore, if our primary vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which would materially and adversely affect our development programs, commercial activities, operating results, and financial condition. In addition, the FDA or regulatory authorities outside of the U.S. may require that we have an alternate manufacturer of a drug product before approving it for marketing and sale in the U.S. or abroad and securing such alternate manufacturer before approval of an NDA or BLA could result in considerable additional time and cost prior to NDA or BLA approval.

Any new manufacturer or supplier of finished drug product or its component materials, including drug substance and delivery devices, would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing of such product or ingredients required by us. The FDA or foreign regulatory agency may require us to conduct additional clinical studies, collect stability data, and provide additional information concerning any new supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that manufacturer or supplier or revised process. For example, if we were to engage a third party other than our current CMOs to supply the drug substance or drug product for future clinical trial or commercial product, the FDA or regulatory authorities outside of the U.S. may require us to conduct additional clinical and nonclinical studies to ensure comparability of the drug substance or drug product manufactured by our current CMOs to that manufactured by the new supplier. Changing of suppliers or equipment is particularly challenging for companies like us, with inhalation products, because any change could alter the performance of the drug product.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling-up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, and shortages of qualified personnel. Some of our product candidates have not been manufactured at the scale we believe will be necessary to maximize its commercial value and, accordingly, we may encounter difficulties in attempting to scale-up production and may not succeed in that effort on a timely basis or at all. In addition, the FDA or other regulatory authorities may impose additional requirements as we scale up initial production capabilities, which may delay our scale-up activities and/or add expense.

If our manufacturers encounter any of the aforementioned difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements due to capital constraints, we may have insufficient quantities of material to support ongoing and/or planned clinical studies or to meet commercial demand, if approved. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidates could delay the completion of our clinical studies, increase the costs associated with our development programs, and depending upon the period of delay, require us to commence new clinical studies at significant additional expense or terminate the studies completely. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. We cannot provide assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our clinical trial material or commercial product, if approved, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such clinical trial material or commercial product, as applicable. In addition, Molgradex and AeroVanc are currently manufactured entirely or partially outside the U.S. and, as a result, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, changes in currency fluctuations, shipping costs, or import tariffs could adversely affect cost of goods sold. Any of the above factors could cause us to delay or suspend anticipated or ongoing trials, regulatory submissions or commercialization of our product candidates, entail higher costs, or result in being unable to effectively commercialize our products. Our dependence upon third parties for the manufacture of our clinical trial material may adversely affect our future costs and our ability to develop and commercialize our product candidates on a timely and competitive basis.

We rely significantly on third parties to conduct our nonclinical testing and clinical studies and other aspects of our development programs and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our product candidates could be adversely affected.

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, contract research organizations ("CROs"), CMOs, and others to assist in the design and conduct of nonclinical and clinical studies of our product candidates, with interpretation of the results of those studies and with regulatory activities, and we expect to continue to outsource all or a significant amount of such activities. As a result, many important aspects of our development programs are and will continue to be outside our direct control, and our third-party service providers may not perform their activities as required or expected, including the maintenance of good clinical practice ("GCP"), good laboratories practice ("GLP"), and cGMP compliance, which are ultimately our responsibility to ensure. Further, such third parties may not be as committed to the success of our programs as our own employees and, therefore, may not devote the same time, thoughtfulness, or creativity to completing projects or problem-solving as our own employees would. To the extent we are unable to successfully manage the performance of third-party service providers, our business may be adversely affected.

The CROs that we engage to execute our clinical studies play a significant role in the conduct of the studies, including the collection and analysis of study data, and we likely will depend on CROs and clinical investigators to conduct future clinical studies and to assist in analyzing data from completed studies and developing regulatory strategies for our product candidates. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we have limited control over the amount or timing of resources that they devote to their programs. If our CROs, study investigators, and/or third-party sponsors fail to devote sufficient time and resources to studies of our product candidates, if we and/or our CROs do not comply with all GLP and GCP regulatory and contractual requirements, or if their performance is substandard, we may delay commencement and/or completion of these studies, submission of applications for regulatory approval, regulatory approval, and commercialization of our product candidates. Failure of CROs to meet their obligations to us could adversely affect development of our product candidates.

In addition, CROs we engage may have relationships with other commercial entities, some of which may compete with us. Through intentional or unintentional means, our competitors may benefit from lessons learned on our projects that could ultimately harm our competitive position. Moreover, if a CRO fails to properly, or at all, perform our activities during a clinical study, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs may increase costs and divert management time and attention. In addition, there likely would be a transition period before a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical studies, which could materially impact our ability to meet our desired and/or announced development timelines and have a material adverse impact on our business and financial condition.

We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our products, if approved, or generate product revenue.

To commercialize our products, if approved, in the U.S. and other jurisdictions we seek to enter, we must build our marketing, sales, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our products receive regulatory approval, we expect to market such products in the U.S. through a focused, specialized sales force, which will be costly and time consuming. Institutionally, we have no prior experience in the marketing and sale of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Outside of the U.S., we may consider collaboration arrangements. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products in certain markets. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our products. If we are not successful in commercializing our products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

To establish a sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization, and we may experience difficulties in managing this growth.

As of May 9, 2019, we had 39 full-time employees, including 28 employees engaged in research and development. As we advance our product candidates through the development process and to commercialization, we will need to continue to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance, and other resources to manage our operations and clinical trials, continue our development activities, and commercialize our product candidates, if approved. As our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers, and other organizations.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the physical expansion of our operations may lead to significant costs and may divert our management attention and resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue, and operating results.

Any future acquisitions that we make could disrupt our business and harm our financial condition.

We expect to evaluate, from time to time, potential strategic acquisitions of complementary businesses, products, or technologies. In addition, we expect to evaluate joint ventures, licensing opportunities, and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance, or integrate acquisitions of any businesses, products, or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert our management's time and resources from our core business and disrupt our operations. Any cash acquisition we pursue would diminish the funds otherwise available to us for other uses. Any acquisition using our stock would dilute our stockholders' ownership interests.

Our product candidates may cause undesirable side effects or adverse events or have other properties that could delay or prevent our clinical development, regulatory approval, or commercialization.

Undesirable side effects or adverse events caused by our product candidates could interrupt, delay, or halt clinical studies and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidates. A significant challenge in clinical development is that the patient population in early studies, where small numbers of patients are required, is different from the patient population observed in later stage studies, where larger groups of patients are required. For example, patients in earlier stage studies may be more sick, compliant, or otherwise motivated than patients in larger studies. As such, efficacy or safety results may differ significantly between studies. Side-effects seen at high doses in earlier studies of AeroVanc, such as bronchoconstriction or other airway irritation, may be seen in significant numbers at the lower doses selected for later studies. Also, for AeroVanc, while not observed in the Phase 2 clinical study, the emergence of vancomycin-resistant MRSA could occur during the longer dosing period of AeroVanc that is currently implemented in the Phase 3 clinical study. If this or other undesirable side effects occur, they could possibly prevent approval, which would have a material and adverse effect on our business.

If any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way the product is administered, conduct additional clinical studies, or change the labeling of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenue from its sale.

We may not achieve our projected development goals in the time frames we have announced.

We have set goals for accomplishing certain objectives material to the successful development of our product candidates. The actual timing of these events may vary due to many factors, including delays or failures in our nonclinical testing, clinical studies, and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. From time to time we create estimates for the completion of enrollment of or announcement of data from clinical studies of our product candidates. However, predicting the rate of enrollment or the time from completion of enrollment to announcement of data for any clinical study requires us to make significant assumptions that may prove to be incorrect. Our estimated enrollment rates and the actual rates may differ materially and the time required to complete enrollment of any clinical study may be considerably longer than we estimate. Such delays may adversely affect our financial condition and results of operations.

Even if we complete a clinical study with successful results, we may not achieve our projected development goals in the time frames we initially anticipate or announce. If a development plan for a product candidate becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, may discontinue development in a particular indication or of the product candidate as a whole. In addition, even if a study did complete with successful results, changes may occur in regulatory requirements or policy during the period of product development and/or regulatory review of an NDA or BLA that relate to the data required to be included in NDAs or BLAs which may require additional studies that may be costly and time consuming. Any of these actions may be viewed negatively, which could adversely impact our financial condition.

Further, throughout development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently develop and produce our product candidates in conformance with GLP, GCP, cGMP, and other regulatory standards. As discussed above, we rely on CMOs for the manufacture of clinical, and future commercial, quantities of our product candidates. If future FDA or other regulatory authority inspections identify cGMP compliance deficiencies at these third-party facilities, production of our clinical trial material or, in the future, commercial product, could be disrupted, causing potentially substantial delay in or failure of development or commercialization of our product candidates.

Our employees, independent contractors and consultants, principal investigators, CROs, CMOs and other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors and consultants, principal investigators, CROs, CMOs and other vendors, and any future commercial partners may engage in fraudulent conduct or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards required by cGMP or our standards, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to them. The misconduct of our employees and other service providers could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against them, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. For example, if one of our manufacturing partners was placed under a consent decree, we may be hampered in our ability to manufacture clinical or commercial supplies.

Our business and operations would suffer in the event of third-party computer system failures, cyber-attacks on third-party systems, or deficiency in our cyber-security.

We rely on information technology systems, including third-party "cloud based" service providers, to keep financial records, maintain laboratory, clinical data and corporate records, communicate with staff and external parties and operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories, and archives. If any of these third-party information technology ("IT") providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber-attacks, or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion by computer hackers, foreign governments, or cyber-terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider's operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in loss or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed or could fail. We have experienced and may continue to experience attempts to breach our security and attempts to introduce malicious software into our information technology systems; however, to date and to our knowledge, such attacks have not resulted in any material damage to us.

We are continually working to maintain reliable systems to control costs and improve our operations. Our efforts include, but are not limited to, the following: firewalls, antivirus protection, patches, log monitors, routine backups with offsite retention of storage media, system audits, data partitioning, and routine password modifications. Our internal information technology systems environment continues to evolve and our business policies and internal security controls may not keep pace as new threats emerge. No assurance can be given that our efforts to continue to enhance our systems will be successful.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

A number of state, national, and foreign laws and regulations apply to the collection, use, retention, protection, disclosure, transfer, and other processing of personal data. Due to our Danish subsidiary, Savara ApS, our clinical trial activities and operations in Europe, we are subject to data protection laws in the EU, including the General Data Protection Regulation ("GDPR"). The GDPR, which became effective on May 25, 2018, has caused the EU requirements for the protection of personal data to become more stringent and increased the penalties for noncompliance. Penalties can consist of fines up to €20 million or 4% of global annual revenues, whichever is higher. As a result, we have been required to implement additional mechanisms to ensure compliance with the new EU data protection rules, which may cause us to incur additional costs.

If we or our vendors fail to comply with applicable data privacy laws, including the GDPR, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our corporate headquarters is located in a single commercial facility in Austin, Texas, USA. We maintain a second office in a single commercial facility in Denmark where many of our product development staff are located. Important documents and records, including copies of our regulatory documents and other records for our product candidates, are located both at a secure offsite document storage facility as well at our own facilities and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, terrorist attacks, or severe weather conditions could significantly disrupt our operations and result in additional, unplanned expense. As a small company with limited resources, we have not prepared or implemented a formal business continuity or disaster recovery plan and any natural disaster or catastrophic event could disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that are not covered by or exceed the coverage available under these insurance policies.

Risks Related to Drug Development and Commercialization

We depend on the successful completion of clinical studies of our product candidates, and any positive results in prior clinical studies do not ensure that ongoing or future clinical studies will be successful.

Pharmaceutical products are subject to stringent regulatory requirements covering quality, safety, and efficacy. The burden of proof is on the manufacturer, such as Savara, to show with substantial clinical data that the risk/benefit profile for any new drug is favorable. Only after successfully completing extensive pharmaceutical development, nonclinical testing, and clinical studies may a product be considered for regulatory approval.

Clinical studies are expensive, difficult to design and implement, they can take many years to complete, and outcomes are inherently uncertain. A drug product may fail to demonstrate positive results at any stage of testing despite having progressed satisfactorily through nonclinical testing and initial clinical studies. There is significant risk in clinical development where later stage clinical studies are designed and powered based on the analysis of data from earlier studies, with these earlier studies involving a smaller number of patients, and the results of the earlier studies being driven primarily by a subset of responsive patients. In addition, interim results of a clinical study do not necessarily predict final results. Further, clinical study data frequently are susceptible to varying interpretations. Medical professionals and/or regulatory authorities may analyze or weigh study data differently than the sponsor company, resulting in delay or failure to obtain marketing approval for a product candidate. Additionally, the possible lack of standardization across multiple investigative sites may induce variability in the results which can interfere with the evaluation of treatment effects.

If we license rights to develop our product candidates to independent third parties or otherwise permit such third parties to evaluate our product candidates in clinical studies, we may have limited control over those clinical studies. Any safety or efficacy concern identified in a third-party sponsored study could adversely affect our or another licensee's development of our product candidate and prospects for its regulatory approval, even if the data from that study are subject to varying interpretations and analyses.

There is significant risk that ongoing and future clinical studies of our product candidates are unsuccessful. Negative or inconclusive results could cause the FDA and other regulatory authorities to require us to repeat or conduct additional clinical studies, which could significantly increase the time and expense associated with development of that product candidate or cause us to elect to discontinue one or more clinical programs. Failure to complete a clinical study of a product candidate or an unsuccessful result of a clinical study could have a material adverse effect on our business.

Molgradex and AeroVanc have received Orphan Drug Designation by the FDA and Molgradex has received Orphan Drug Designation also in Europe. While orphan designation provides certain benefits there are also associated risks.

Molgradex has received Orphan Drug Designation in the U.S. by the FDA and in Europe by the European Medicines Agency ("EMA") for the treatment of aPAP, and AeroVanc has been granted Orphan Drug Designation in the U.S. by the FDA for the treatment of MRSA lung infection in patients with CF. Orphan Drug Designation will not shorten the regulatory review or reduce the clinical data requirements needed to obtain approval. If approval is received to market either Molgradex or AeroVanc for the respective indications, the FDA will not approve a similar product, with the same active ingredient, to Molgradex or AeroVanc for seven years and the EMA will not approve a similar product to Molgradex for ten years, unless we are unable to produce enough supply to meet demand in the marketplace or another similar product, with the same active ingredient, is deemed clinically superior. Similar product candidates, with the same active ingredient and route of delivery, may be granted Orphan Drug Designation during the development of the respective products, but the Orphan Drug exclusivity is granted only to the first of such products approved, which means there is risk that a competitor product candidate may receive approval and Orphan Drug exclusivity before us, thus preventing us from marketing one or more of our product candidates until the exclusivity of the competing product expires. Also, the Orphan Drug status will not prevent a competitor with a different active ingredient from competing with our product candidates. If we are prevented from marketing one or more product candidates due to a competitor's Orphan Drug exclusivity, this would have a material adverse effect on our business.

Delays in commencement and completion of clinical studies are common and have many causes. Delays in clinical studies of our product candidates would likely increase overall development costs and jeopardize our ability to obtain regulatory approval and successfully commercialize any approved products.

Clinical testing typically is expensive, can take many years to complete, and its outcome is inherently uncertain. Clinical studies may not commence on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a variety of reasons, including:

- inability to raise sufficient funding to initiate or continue a clinical study;
- delays in obtaining regulatory approval to commence a clinical study;
- delays in identifying and reaching agreement on acceptable terms with prospective CROs, clinical study sites, and investigators, which agreements can be subject to extensive negotiation and may vary significantly among study sites;
- delays in obtaining regulatory approval in a prospective country;
- delays in obtaining ethics committee approval to conduct a clinical study at a prospective site;

- delays in reaching agreements on acceptable terms with prospective CMOs or other vendors for the production and supply of clinical trial material and, if necessary, drug administration devices, which agreements can be subject to extensive negotiation;
- delays in the production or delivery of sufficient quantities of clinical trial material or drug delivery devices from our CMOs and other vendors to initiate or continue a clinical study;
- delays due to product candidate recalls as the result of stability failure, excessive product complaints, or other failures of the product candidate during its use or testing;
- invalidation of clinical data caused by premature unblinding or integrity issues;
- invalidation of clinical data caused by mixing up of the active drug and placebo through randomization or manufacturing errors;
- delays on the part of our CROs, CMOs, and other third-party contractors in developing procedures and protocols or otherwise conducting activities in accordance with applicable policies and procedures and in accordance with agreed upon timelines;
- delays in identifying and hiring or engaging, as applicable, additional employees or consultants to assist in managing clinical study-related activities;
- delays in recruiting and enrolling individuals to participate in a clinical study, which historically can be challenging in orphan diseases;
- delays caused by patients dropping out of a clinical study due to side effects, concurrent disorders, difficulties in adhering to the study protocol, unknown issues related to different patient profiles than in previous studies, such as the reduced age limit required for inclusion into the AeroVanc Phase 3 study, or otherwise;
- delays in having patients complete participation in a clinical study, including returning for post-treatment follow-up;
- delays resulting from study sites dropping out of a trial, providing inadequate staff support for the study, problems with shipment of study supplies to clinical sites, or focusing its staff's efforts on enrolling studies that compete for the same patient population;
- suspension of enrollment at a study site or the imposition of a clinical hold by the FDA or other regulatory authority following an inspection of clinical study operations at study sites or finding of a drug-related serious adverse event; and
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

Patient enrollment, a critical component to successful completion of a clinical study, is affected by many factors, including the size and nature of the study population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, ongoing studies competing for the same patient population and clinicians, patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including therapies being investigated by other companies which may be viewed as more beneficial or important to study, fear of being randomized to the placebo arm, and changes in standard of care. Challenges to complete enrollment can be exacerbated in orphan indications, like those being pursued by us, with a limited number of qualifying patients and the lack of clinical sites with the necessary expertise and experience to conduct our studies. Further, completion of a clinical study and/or its results may be adversely affected by failure to retain patients who enroll in a study but withdraw due to adverse side effects, perceived lack of efficacy, belief that they are on placebo, improvement in condition before treatment has been completed, or for personal reasons, or without reason, or by patients who fail to return for or complete post-treatment follow-up.

Clinical studies may not begin on time or be completed in the time frames we anticipate and may be costlier than we anticipate for a variety of reasons, including one or more of those described above. The length of time necessary to successfully complete clinical studies varies significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and/or availability of results from our clinical studies, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons, including patient enrollment rates, length of time needed to prepare raw study data for analysis and then to review and analyze it, and other factors described above. If we experience delays in the completion of a clinical study, if a clinical study is terminated, or if failure to conduct a study in accordance with regulatory requirements or the study's protocol leads to deficient safety and/or efficacy data, the regulatory approval and/or commercial prospects for our product candidates may be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical studies likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize our product candidates, the standard of care may have changed or other therapies for the same indications may have been introduced to the market in the interim and may establish a competitive threat to us or diminish the need for our products.

Clinical studies are very expensive, difficult to design and implement, often take many years to complete, and the outcome is inherently uncertain.

Clinical development of pharmaceutical products for humans is generally very expensive, takes many years to complete, and failures can occur at any stage of clinical testing. We estimate that clinical development of our product candidates will take several additional years to complete, but because of the variety of factors that can affect the design, timing and outcome of clinical studies, we are unable to estimate the exact funds required to complete research and development, obtain regulatory approval, and commercialize all of our product candidates. We will need significant additional capital to continue to advance our products as per current business plans.

Failure at any stage of clinical testing is not uncommon and we may encounter problems that would require additional, unplanned studies or cause us to abandon a clinical development program.

In addition, a clinical study may be suspended or terminated by us, an Independent Review Board ("IRB"), a data safety monitoring board, the FDA, or other regulatory authorities due to a number of factors, including:

- lack of adequate funding to continue the study;
- failure to conduct the study in accordance with regulatory requirements or the study's protocol;
- inspection of clinical study operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues, including adverse side effects; or
- changes in governmental regulations or administrative actions.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes, or we may amend study protocols for other reasons. Amendments may require us to resubmit protocols to IRBs for re-examination and approval or renegotiate terms with CROs, study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

There is significant uncertainty regarding the regulatory approval process for any investigational new drug, substantial further testing and validation of our product candidates and related manufacturing processes may be required, and regulatory approval may be conditioned, delayed, or denied, any of which could delay or prevent us from successfully marketing our product candidates and substantially harm our business.

Pharmaceutical products generally are subject to rigorous nonclinical testing and clinical studies and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or materially influence the manufacturing, safety, labeling, storage, record keeping, and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources.

Molgradex is currently undergoing a Phase 3 clinical study in the U.S., Europe, and Japan. The product (formulation, process, packaging, and device) used in this Phase 3 study will be submitted in marketing applications to regulatory authorities unchanged. However, the product submitted may result in regulatory delays and/or non-acceptance for a variety of reasons including but not limited to: justification for inclusion of one or more excipients; safety qualification of one or more excipients; acceptability of commercial manufacturing site; ease of presenting the dose to the nebulizer; and, reproducibility of delivered dose from the nebulizer. Concurrently, we are exploring formulation, process, packaging, and device improvements that could simplify the composition of the drug product by eliminating one or more potentially unnecessary or harmful excipients, improve the ease of use of the product, and/or reduce the overall product variability. While we expect these changes to improve the product quality and possibly reduce other documentation requirements, the regulatory agencies may require additional clinical or nonclinical studies prior to approval of such changes, including conducting an additional Phase 3 clinical study that would significantly extend the timeline for clinical development of Molgradex in aPAP.

The manufacturing process and site for the drug product may change post-Phase 3. Changes in the manufacturing process have a potential to result in untoward changes in drug product characteristics. If the commercial drug product differs significantly from the product studied in Phase 3, then regulatory agencies may require additional clinical or nonclinical studies prior to approval of such changes, including conducting an additional Phase 3 clinical study that would significantly extend the timeline for clinical development of Molgradex in aPAP.

We received guidance from the FDA on the requirements to initiate clinical studies in the U.S. and on the clinical study requirements to achieve BLA approval for Molgradex. Based on the guidance, we amended our ongoing Phase 3 clinical study to include more patients, and amended our endpoint hierarchy and statistical analyses to be used for U.S. approval purposes. Even if the clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results to provide persuasive evidence of efficacy across multiple clinical endpoints. Instead, they may require additional clinical studies and/or other costly studies, including an additional Phase 3 study, which would require us to expend substantial additional resources and would significantly extend the timeline for clinical development prior to market approval, or result in failure to complete the clinical development of Molgradex.

We have commenced the Phase 3 trial of AeroVanc, the success of which will be needed for FDA approval to market AeroVanc in the U.S. to treat persistent MRSA lung infection in individuals living with CF. While significant communication with the FDA on the Phase 3 study design has occurred, even if the Phase 3 clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results as robust and convincing. They may require additional clinical studies and/or other costly studies, which could require us to expend substantial additional resources and could significantly extend the timeline for clinical development prior to market approval. Additionally, we are conducting a two-year nonclinical carcinogenicity study on the AeroVanc powder, required by the FDA. The results of this study will not be known until a short time prior to potential submission of an NDA or BLA for AeroVanc. If the carcinogenicity study cannot be completed for technical or other reasons, or provides results that the FDA determines to be concerning, this may cause a delay or failure in obtaining approval for AeroVanc.

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including Molgradex and AeroVanc. Regardless of any guidance the FDA or foreign regulatory agencies may provide a drug's sponsor during its development, the FDA or foreign regulatory agencies retain complete discretion in deciding whether to accept an NDA or BLA or the equivalent foreign regulatory approval submission for filing or, if accepted, approve an NDA or BLA. There are many components to an NDA or BLA or marketing authorization application submission in addition to clinical study data. For example, the FDA or foreign regulatory agencies will review the sponsor's internal systems and processes, as well as those of its CROs, CMOs, and other vendors, related to development of its product candidates, including those pertaining to its clinical studies and manufacturing processes. Before accepting an NDA or BLA for review or before approving the NDA or BLA, the FDA or foreign regulatory agencies may request that we provide additional information that may require significant resources and time to generate and there is no guarantee that its product candidates will be approved for any indication for which we may apply. The FDA or foreign regulatory agencies may choose not to approve an NDA or BLA for any of a variety of reasons, including a decision related to the safety or efficacy data, manufacturing controls or systems, or for any other issues that the agency may identify related to the development of its product candidates. Even if one or more Phase 3 clinical studies are successful in providing statistically significant evidence of the efficacy and safety of the investigational drug, the FDA or foreign regulatory agencies may not consider efficacy and safety data from the submitted studies adequate scientific support for a conclusion of effectiveness and/or safety and may require one or more additional Phase 3 or other studies prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and competitors may bring products to market before us, which could impair our ability to generate revenues from the product candidates, or even seek approval, if blocked by a competitor's Orphan Drug exclusivity, which would have a material adverse effect on our business, financial condition, and results of operations.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, U.S. federal government shut-downs or budget sequestrations, such as one that occurred during January 2018 and December 2018 through January 2019, may result in significant reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

Even if the FDA or foreign regulatory agencies grant approvals for our product candidates, the conditions or scope of the approval(s) may limit successful commercialization of the product candidates and impair our ability to generate substantial sales revenue. For example, the FDA may approve label claims for AeroVanc with age restrictions and/or treatment duration limitations, or Molgradex with restrictions for use only by patients unresponsive to the current standard of care. They may limit the label of Molgradex or AeroVanc to a subset of patients based on a review of which patient groups had the greatest efficacious response in clinical studies. Such label restriction may be undesirable and may limit successful commercialization. The FDA or foreign regulatory agencies may also only grant marketing approval contingent on the performance of costly post-approval nonclinical or clinical studies, or subject to warnings or contraindications that limit commercialization. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMP, GCP, international conference on harmonization regulations, and GLP, which are regulations and guidelines that are enforced by the FDA or foreign regulatory agencies for all of its clinical development and for any clinical studies that we conduct post-approval. The FDA or foreign regulatory agencies may decide to withdraw approval, add warnings, or narrow the approved indications in the product label, or establish risk management programs that could restrict distribution of our products. These actions could result from, among other things, safety concerns, including unexpected side effects or drug interaction problems, or concerns over misuse of a product. If any of these actions were to occur following approval, we may have to discontinue commercialization of the product, limit our sales and marketing efforts, implement risk minimization procedures, and/or conduct post-approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Regulations may be changed prior to submission of a marketing application that require higher hurdles than currently anticipated. These may occur as a result of drug scandals, recalls, or a political environment unrelated to our products.

Even if we receive regulatory approval for a product candidate, we may face regulatory difficulties that could materially and adversely affect our business, financial condition, and results of operations.

Even if initial regulatory approval is obtained, as a condition to the initial approval, the FDA or a foreign regulatory agency may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or marketing surveillance programs, any of which would limit the commercial potential of the product. Our product candidates also will be subject to ongoing FDA requirements related to the manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record-keeping, and submission of safety and other post-market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post-approval clinical studies, and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers and manufacturers' facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a CMO of ours fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications;
- exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare;
- impose restrictions or affirmative obligations on our or our CMO's operations, including costly new manufacturing requirements;
- close the facilities of a CMO; or
- seize or detain products or require a product recall.

If any of our product candidates for which we receive regulatory approval fails to achieve significant market acceptance among the medical community, patients, or third-party payers, the revenue we generate from its sales will be limited and our business may never achieve profitability.

Our success will depend in substantial part on the extent to which our product candidates, if approved, are accepted by the medical community and patients and reimbursed by third-party payers, including government payers. The degree of market acceptance with respect to each of our approved products, if any, will depend upon a number of factors, including:

- the safety and efficacy of our products as demonstrated in clinical studies;
- acceptance in the medical and patient communities of our products as a safe and effective treatment;
- the product's taste, ease of use, or features associated with the delivery device;
- the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment;
- the indications for which our product is approved;
- claims or other information (including limitations or warnings) in a product's approved labeling;
- reimbursement and coverage policies of government and other third-party payers;
- pricing and cost-effectiveness of our product relative to alternative treatments;
- availability of alternative treatments;
- smaller-than-expected market size due to lack of disease awareness of a rare disease, or the patient population with a specific rare disease being smaller than anticipated;
- inappropriate diagnostic efforts due to limited knowledge and/or resources among clinicians;
- the prevalence of off-label substitution of chemically equivalent products or alternative treatments; and
- the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product.

We cannot predict with reasonable accuracy whether physicians, patients, healthcare insurers, or health maintenance organizations, or the medical community in general, will accept or utilize any of our products, if approved. If our product candidates are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or remain profitable. In addition, our efforts to educate the medical community and third-party payers regarding benefits of our products may require significant resources and may never be successful.

If we determine that a product candidate may not achieve adequate market acceptance or that the potential market size does not justify additional expenditures on the program, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of the product candidate while we evaluate whether and on what timeline to move the program forward.

Even if we receive regulatory approval to market one or more of our product candidates in the U.S., we may never receive approval or commercialize our products outside of the U.S., which would limit our ability to realize the full commercial potential of our product candidates.

In order to market products outside of the U.S., we must establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries generally differs from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S., as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies. Conversely, if the product candidates do receive approval outside the U.S. in the future, we may not meet the FDA requirements in the U.S. for approval.

We must comply with the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws.

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Other countries, such as the U.K., have similar laws with which we must comply. We face the risk that an employee or agent could be accused of violating one or more of these laws, particularly in geographies where significant overlap exists between local government and healthcare industries. Such an accusation, even if unwarranted, could prove disruptive to our developmental and commercialization efforts.

Risks Related to Our Intellectual Property

Our success will depend on obtaining and maintaining effective patent and other intellectual property protection for our product candidates and proprietary technology.

AeroVanc has received a U.S. Patent Notice of Allowance for its formulation in the U.S., AeroVanc's primary market. AeroVanc has either been issued patents or is prosecuting patent applications in numerous countries outside the U.S.. We have no patent protection for Molgradex for the treatment of aPAP, and primarily rely on the Orphan Drug exclusivity as our primary barrier to competition. Molgradex for the treatment of NTM has issued patents ex-U.S. (under prosecution in the U.S.) with an additional international patent application pending. Both Molgradex and AeroVanc utilize proprietary delivery devices with exclusive supply agreements. Molgradex receives additional protection via a proprietary cell bank used in the production of the drug substance.

Our success will depend on our ability to:

- obtain and maintain patent and other exclusivity rights with respect to our products and their uses;
- prevent third parties from infringing upon our proprietary rights;
- maintain proprietary know-how and trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, or if necessary, to secure exclusive rights to them, both in the U.S. and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies generally are highly uncertain, involve complex legal and factual questions, and have been and continue to be the subject of much litigation. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we develop or have developed or that is used by us, our CMOs, or our other service providers. In addition, any patents that are issued to us may be limited in scope or challenged, invalidated, infringed, or circumvented, including by our competitors, and rights we have under issued patents may not provide competitive advantages to us. If competitors can develop and commercialize technology and products similar to ours, our ability to successfully commercialize our technology and products may be impaired.

Patent applications in the U.S. are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned by us were the first to conceive of the inventions covered by such patents and patent applications (for U.S. patent applications filed before March 16, 2013), or that such inventors were the first to file patent applications for such inventions outside the U.S. and, after March 15, 2013, in the U.S. In addition, changes in or different interpretations of patent laws in the U.S. and foreign countries may affect our patent rights and limit the number of patents we can obtain, which could permit others to use our discoveries or to develop and commercialize our technology and products without any compensation to us.

Our AeroVanc patent is specific to the formulation of the AeroVanc powder. While this may prevent identical products from entering the market, it may not preclude someone skilled in the art from inventing an alternate formulation approach with comparable or improved characteristics.

We also rely on unpatented know-how and trade secrets and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with employees, consultants, collaborators, and others. We also have invention or patent assignment agreements with our employees and certain consultants. The steps we have taken to protect our proprietary rights, however, may not be adequate to preclude misappropriation of or otherwise protect our proprietary information or prevent infringement of our intellectual property rights, and we may not have adequate remedies for any such misappropriation or infringement. In addition, it is possible that inventions relevant to our business could be developed by a person not bound by an invention assignment agreement with us or independently discovered by a competitor.

We also intend to rely on regulatory exclusivity for protection of our product candidates, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or maintain the extent or duration of such protections that we expect for our product candidates, if approved, could affect our decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on our revenue or results of operations. For Molgradex, which is administered via nebulization, we may rely on regulatory exclusivity for the combination of Molgradex and its delivery system. However, there is no assurance that our Molgradex product and its delivery system, if approved, will benefit from this type of market protection.

We may rely on trademarks, trade names, and brand names to distinguish our products, if approved for commercial sale, from the products of our competitors. We intend to seek approval for new names for AeroVanc and Molgradex that meet the FDA's and foreign regulatory requirements. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks, in which case we may expend substantial resources to defend our proposed or approved trademarks and may enter into agreements with third parties that may limit our use of our trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. For example, we filed a trademark for the name "Savara" and were challenged. We decided to terminate its application, but we may revisit such filings at a future date. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

Our success depends on our ability to prevent competitors from duplicating or developing and commercializing equivalent versions of our product candidates, but patent protection may be difficult to obtain and any issued claims may be limited.

We have filed for patent protection in the U.S. and other countries to cover the formulation of AeroVanc and were granted a notice of allowance in the U.S., its primary market. However, this patent may not provide us with significant competitive advantages, because the validity or enforceability of the patents may be challenged and, if instituted, one or more of the challenges may be successful. Patents may be challenged in the U.S. under post-grant review proceedings, *inter partes* re-examination, *ex parte* re-examination, or challenges in district court. Any patents issued in foreign jurisdictions may be subjected to comparable proceedings lodged in various foreign patent offices, or courts. These proceedings could result in either loss of the patent or loss or reduction in the scope of one or more of the claims of the patent. Even if a patent issues and is held valid and enforceable, competitors may be able to design around our patents, such as by using pre-existing or newly developed technology, in which case competitors may not infringe our issued claims and may be able to market and sell products that compete directly with us before and after our patents expire.

We have filed for patent protection in the U.S. and other countries to cover various methods of therapeutic use of our product candidates, including the use of Molgradex for treating NTM lung infection. The potential use and potential therapeutic benefits of systemically administered GM-CSF for systemic NTM disease have been described in case reports in the literature, and therefore the use of an inhaled form of GM-CSF may be considered to lack novelty and an inventive step, and thereby to be unpatentable.

The patent prosecution process is expensive and time-consuming. We and any future licensors and licensees may not apply for or prosecute patents on certain aspects of our product candidates at a reasonable cost, in a timely fashion, or at all. We may not have the right to control the preparation, filing, and prosecution of some patent applications related to our product candidates or technologies. As a result, these patents and patent applications may not be prosecuted and enforced in a manner consistent with our best interests. It is also possible that we or any future licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, it is possible that defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, assignment, or claim scope. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. In addition, one or more parties may independently develop similar technologies or methods, duplicate our technologies or methods, or design around the patented aspects of our products, technologies, or methods. Any of these circumstances could impair our ability to protect our products, if approved, in ways which may have an adverse impact on our business, financial condition, and operating results.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in and outside of the U.S. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability use our patents to stop others from using or commercializing similar or identical products or technology, or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing, and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours once Orphan Drug and Qualified Infectious Disease Product ("QIDP") exclusivities have expired. See the section entitled "Risks Related to Our Industry" for further description of Orphan Drug and QIDP exclusivities.

Enforcement of intellectual property rights in certain countries outside the U.S. has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications are required to be paid to the United States Patent and Trademark Office ("USPTO"), and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in decreased patent term adjustment or in abandonment or lapse of the patent or patent application, leading to partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may claim that our products, if approved, infringe on their proprietary rights and may challenge the approved use or uses of a product or its patent rights through litigation or administrative proceedings, and defending such actions may be costly and time consuming, divert management attention away from our business, and result in an unfavorable outcome that could have an adverse effect on our business.

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market, and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. Because patent applications can take many years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our products, product candidates, or technologies infringe, or that the process of manufacturing our products or any of our respective component materials, or the component materials themselves, infringe, or that the use of our products, product candidates, or technologies infringe.

We or our CMOs or component material suppliers may be exposed to, or threatened with, litigation by a third party alleging that our products, product candidates, and/or technologies infringe its patents and/or other intellectual property rights, or that one or more of the processes for manufacturing our products or any of our respective component materials, or the component materials themselves, or the use of our products, product candidates, or technologies, infringe its patents and/or other intellectual property rights. If a third-party patent or other intellectual property right is found to cover our products, product candidates, technologies, or our uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, or at all. In addition, during litigation, the third-party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using, selling, or importing our products, technologies or methods.

There generally is a substantial amount of litigation involving patent and other intellectual property rights in the industries in which we operate and the cost of such litigation may be considerable. We can provide no assurance that our product candidates or technologies will not infringe patents or rights owned by others, licenses to which might not be available to us in a timely manner or on acceptable terms, or at all. If a third party claims that we or our CMOs or component material suppliers infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert management's time and attention from our business;
- substantial damages for infringement, including the potential for treble damages and attorneys' fees, which we may have to pay if it is determined that the product and/or its use at issue infringes or violates the third party's rights;
- a court prohibiting us from selling or licensing the product unless the third party licenses its intellectual property rights to us, which it may not be required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to the third party; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial expense and time.

There may be issued or filed claims covering our products, product candidates, or technology or those of our CMOs or component material suppliers or the use of our products, product candidates, or technologies. Additionally, such patents may be issued or filed in the future. Because of the large number of patents issued and patent applications filed in the industries in which we operate, there is a risk that third parties may allege they have patent rights encompassing our products, product candidates, or technologies, or those of our CMOs or component material suppliers, or uses of our products, product candidates, or technologies.

In the future, it may be necessary for us to enforce our proprietary rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, through litigation or other dispute proceedings, which may be costly, and to the extent we are unsuccessful, adversely affect our rights. In these proceedings, a court or administrative body could determine that our claims, including those related to enforcing patent rights, are not valid or that an alleged infringer has not infringed our rights. The uncertainty resulting from the mere institution and continuation of any patent or other proprietary rights-related litigation or interference proceeding could have a material and adverse effect on our business prospects, operating results, and financial condition.

Risks Related to Our Industry

We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval.

Molgradex and AeroVanc have received Orphan Drug Designation from the FDA and Molgradex has received Orphan Drug Designation from the EMA. Orphan Drug Designation will provide market exclusivity in the U.S. for 7 years and 10 years in Europe, but only if (i) Molgradex and AeroVanc receive market approval before a competitor using the same active compound for the same indication, (ii) we are able produce sufficient supply to meet demand in the marketplace, and (iii) another product with the same active ingredient is not deemed clinically superior. AeroVanc has also received QIDP status extending market exclusivity by an additional five years in addition to any other exclusivity obtained in the U.S.

The industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology, and pharmaceutical) are highly competitive and subject to rapid and significant change. Developments by others may render potential application of any of our product candidates in a particular indication obsolete or noncompetitive, even prior to completion of its development and approval for that indication. If successfully developed and approved, we expect our product candidates will face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical, and human resources than us, and may be better equipped to develop, manufacture, market, and distribute products. Many of these companies operate large, well-funded research, development, and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us and prevent us from competing due to their orphan drug protections. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, heightened awareness on the part of academic institutions, government agencies, and other public and private research organizations of the potential commercial value of their inventions have led them to actively seek to commercialize the technologies they develop, which increases competition for investment in our programs. Competitive products may be more effective, easier to dose, or more effectively marketed and sold than ours, which would have a material adverse effect on our ability to generate revenue.

We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products' commercial success, if any of our product candidates are approved.

The unavailability or inadequacy of third-party payer coverage and reimbursement could negatively affect the market acceptance of our product candidates and the future revenues we may expect to receive from those products. The commercial success of our product candidates, if approved, will depend on the extent to which the costs of such products will be covered by third-party payers, such as government health programs, commercial insurance, and other organizations. Third-party payers are increasingly challenging the prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. These challenges to prices may be problematic to us since our products are targeted for a small number of patients (those suffering from orphan diseases) thus requiring us to charge very high prices in order to recover development costs and achieve a profit on our revenue. If these third-party payers do not consider our products to be cost-effective compared to other therapies, we may not obtain coverage for our products after approval as a benefit under the third-party payers' plans or, even if we do, the level of coverage or payment may not be sufficient to allow us to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage, and payment. There is no uniform policy requirement for coverage and reimbursement for drug products among third-party payers in the U.S., therefore coverage and reimbursement for drug products can differ significantly from payer to payer. The coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payer will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use. Third-party payer reimbursement to providers of our products, if approved, may be subject to a bundled payment that also includes the procedure of administering our products or third-party payers may require providers to perform additional patient testing to justify the use of our products. To the extent there is no separate payment for our product(s), there may be further uncertainty as to the adequacy of reimbursement amounts.

The continuing efforts of governments, private insurance companies, and other organizations to contain or reduce costs of healthcare may adversely affect:

- our ability to set an appropriate price for our products;
- the rate and scope of adoption of our products by healthcare providers;
- our ability to generate revenue or achieve or maintain profitability;
- the future revenue and profitability of our potential customers, suppliers, and collaborators; and
- our access to additional capital.

Our ability to successfully commercialize our products will depend on the extent to which governmental authorities, private health insurers, and other organizations establish what we believe are appropriate coverage and reimbursement for our products. The containment of healthcare costs has become a priority of federal and state governments worldwide and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs, and President Trump has stated that reducing drug pricing is a priority for his administration. We expect that federal, state, and local governments in the U.S., as well as in other countries, will continue to consider legislation directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidates or what actions federal, state, or private payers for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability, or commercialize our product candidates, especially in light of our plans to price our product candidates at a high level.

Furthermore, we expect that healthcare reform measures that may be adopted in the future are unpredictable, and the potential impact on our operations and financial position is uncertain, but may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price we may receive for approved products. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products, if approved.

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain whether such increased or additional insurance coverage can be obtained on commercially reasonable terms, if at all.

Our business (in particular, the use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies, or others selling or involved in the use of our products. If we cannot successfully defend ourselves against any such claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products and loss of revenue;
- impairment of our business reputation;
- delays in enrolling patients to participate in our clinical studies;
- withdrawal of clinical study participants;
- a “clinical hold,” suspension or termination of a clinical study or amendments to a study design;
- significant costs of related litigation;
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our products and product candidates.

We maintain limited product liability insurance for our clinical studies, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

We expect that we will expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could consume a significant portion of our cash and adversely affect our business.

Risks Related to our Common Stock

Our stock price is expected to continue to be volatile.

The market price of our common stock has been and is expected to continue to be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure to meet or exceed any financial and development projections that we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services, or technologies by our competitors;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- failure to obtain sufficient capital to fund our business objectives;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- adverse publicity relating to the CF, aPAP, or NTM markets generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of the combined organization;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We will continue to incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We will continue to incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will also continue to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. These rules and regulations are expected to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. For example, our management team consists of certain officers who have not previously managed and operated a public company. These officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence in us and cause our business or stock price to suffer.

We do not expect to pay any cash dividends in the foreseeable future.

We expect to retain any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain, if any, for the foreseeable future.

We have completed certain transactions that likely have resulted in an ownership change under Section 382 of the Internal Revenue Code limiting the use of our net operating loss carryforwards and certain other tax attributes.

If a corporation undergoes an "ownership change" within the meaning of Sections 381, 382, and 383 of the Internal Revenue Code, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Our net operating loss carryforwards and certain other tax attributes likely will be subject to limitations on use. Additional ownership changes in the future could result in additional limitations on our net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

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
10.1*	Manufacture and Supply Agreement, dated as of April 26, 2019, between Savara ApS and GEMABIOTECH SAU.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Indicates that portions of this exhibit have been omitted due to confidentiality.

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.

Company Name

Date: May 9, 2019

By: /s/ Dave Lowrance

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

Date: May 9, 2019

By: /s/Robert Neville

Robert Neville
Chief Executive Officer
(Principal Executive Officer)

Exhibit 10.1

Certain identified information in this document has been excluded because it is both (i) not material and (ii) would likely cause competitive harm if publicly disclosed. [***] indicates where such information has been omitted.

MANUFACTURE AND SUPPLY AGREEMENT

This MASTER MANUFACTURE AND SUPPLY AGREEMENT (this "**Agreement**") is made and entered into as of April 26, 2019 ("**Effective Date**"), by and between Savara ApS, a Denmark private limited company having registered offices at Slotsmarken 17, 2.tv, DK-2970 Horsholm, Denmark ("**SAVARA**") and GEMABIOTECH SAU, a corporation organized under the laws of Argentina, having registered offices at Fray Justo Sarmiento 2350 Edificio 2B Piso 5, Olivos, Province of Buenos Aires, Argentina ("**GEMA**") (each referred herein by name, or individually, as a "**Party**" or collectively, as the "**Parties**").

BACKGROUND

SAVARA is in the business of research and development, distribution, commercialization and marketing of medicinal products;

GEMA is a highly experienced company within the area of production of biopharmaceutical products, including the API (as defined below);

SAVARA (as assignee of Serendex ApS) and GEMA (f.k.a. GEMA Biotech S.A.) entered into that certain Supply and License Agreement dated December 10, 2012, as amended by the Addendum dated February 22, 2016and the Second Addendum dated September 20, 2017 (collectively, the "**Original Supply Agreement**");

SAVARA wishes to enter into a new agreement superseding the Original Supply Agreement to engage GEMA to manufacture and supply the API (as defined below), and GEMA wishes to achieve commercial compliance and manufacture and supply the API, all on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agrees as follows:

ARTICLE 1
DEFINITIONS

Capitalized words and phrases used and not otherwise defined elsewhere in this Agreement shall have the following meanings:

1.1 "**Affiliate**" means, with respect to a Party, any person, corporation or other business entity that directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party, for so long as such control exists. For purposes of this definition, "control" means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such person, corporation or other business entity, whether through ownership or voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital in such person, corporation or other business entity.

1.2 "**Anticipated Launch Date**" means [***].

1.3 "**API**" or "**Active Pharmaceutical Ingredient**" means recombinant human Granulocyte-Macrophage Colony-Stimulating Factor (rhGM-CSF) obtained from the bacterial fermentation of E. Coli meeting all the API Specifications and having the amino acid sequence and other characteristics set forth in Exhibit 1.3.

1.4 "**API Specifications**" means the specifications set forth in Exhibit1.4.

1.5 "**Cell Line**" shall mean the cell line generated by GEMA to express the API.

1.6 "**cGMPs**" means current good manufacturing practice and standards as provided for (and as amended from time to time) in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 C.F.R. §§210 and 211) and in the European Community Directive 91/356/EEC (Principles and guidelines of good manufacturing practice for medicinal products) in relation to the manufacture of pharmaceutical products and production of finished pharmaceutical products, as interpreted by ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7a, and similar requirements of other Regulatory Authorities in jurisdictions outside the United States and the European Union, and subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.

1.7 "**FDA**" means the U.S. Food and Drug Administration, or any successor entity thereto performing similar functions.

1.8 "**Law**" means all applicable federal, state, local, national and supra-national laws, rules and regulations, including any applicable administrative order, constitution, ordinance, guideline, standard, judicial decision, statute or treaty; in each case, in effect from time to time.

1.9 "**Manufacture**" (and its correlative terms "**Manufacturing**" and "**Manufactured**") means manufacturing and related activities, including procuring Materials, processing, testing, packaging, labeling, warehousing, quality control, quality assurance, releasing, disposing, handling, shipping and all other activities undertaken or required to be undertaken in order to manufacture and supply API to SAVARA under this Agreement.

1.10 "**Manufacturing Facility**" means GEMA's facilities and equipment located at: GEMA's R&D Laboratories or manufacturing site in Buenos Aires, Olivos and Santa Fe, as upgraded to achieve compliance with the Regulatory Requirements in accordance with Section 3.1.

1.11 "**Master Cell Bank**" means the cell bank of the Cell Line from which the Working Cell Bank has been derived, propagated and maintained, as described in ICH guideline Q5B and set forth in Exhibit 1.11.

1.12 "**Materials**" means all raw materials (including the Cell Line and Working Cell Bank) and reagents as are required in connection with the Manufacture of API.

1.13 "**Product**" any pharmaceutical product containing the API to be Manufactured by GEMA.

1.14 "**Quality Technical Agreement**" or "**QTA**" means the technical agreement entered into between SAVARA and GEMA with respect to the Manufacture and supply of API and attached hereto as Exhibit 3.5, as may be amended by the Parties from time to time (including as set forth in Section 3.5 below), which specifies the Parties' respective responsibilities for storage, release, quality control and quality assurance with respect to the API. For clarity, API may be referred to as "Drug Substance" in the Quality Technical Agreement.

1.15 "**Regulatory Authority**" means the FDA or a regulatory body with similar regulatory authority in any jurisdiction outside the United States.

1.16 "**Regulatory Filing**" means all applications, filings, dossiers and the like submitted to a Regulatory Authority in a particular jurisdiction for the purpose of obtaining regulatory approval from such Regulatory Authority with respect to such jurisdiction (together with any and all supporting documentation).

1.17 "**Regulatory Requirements**" means: (a) any and all permits, licenses, filings and certifications required by the FDA or other Regulatory Authorities, and compliance with cGMPs applicable to any Manufacturing activities hereunder or Manufacturing Facilities or other facilities at which any of the Manufacturing activities hereunder are performed; and (b) any Laws of any governmental authority, whether within or outside the United States, that apply to any Manufacturing activities hereunder or the Manufacturing Facilities or other facilities at which any of the Manufacturing activities hereunder are performed.

1.18 "**Territory**" means worldwide.

1.19 "**Third Party**" means any person, corporation, partnership, joint venture or other entity other than the Parties and their respective Affiliates.

1.20 "**Validation**" means documented evidence which provides a high degree of assurance that a specific process, method, activity, piece of equipment, facility, standard operating procedure or other component required or used in the Manufacture of API will consistently meet API Specifications and expected results.

1.21 "**Working Cell Bank**" a validated cell bank of the Cell Line, prepared and characterized under cGMP and accompanied by GMP documentation, that is capable of producing the API at commercial scale.

ARTICLE 2
SUPPLY

2.1 Supply of API. GEMA shall Manufacture, and supply to SAVARA, such quantities of API as may be ordered pursuant to Article 4 below from time to time during the Term. All Product to be supplied under this Agreement shall be Manufactured by GEMA for SAVARA at the Manufacturing Facilities, in conformance with the API Specifications, cGMPs, other Regulatory Requirements, approved batch records and the applicable Quality Technical Agreement. GEMA agrees that, during the Term, GEMA and its Affiliates shall only Manufacture and supply API expressed from the Cell Line to SAVARA for use in the Territory and shall not manufacture or supply API expressed from the Cell Line to any Third Parties, nor authorize or enable any Third Parties to do so.

2.2 Approval of Subcontracting. Other than the supply arrangements with respect to the API and the Materials pursuant to Article 3 below, GEMA may not subcontract, sublicense or otherwise delegate all or any portion of its obligations under this Agreement, without SAVARA's prior written approval.

2.3 Clinical and Research Supplies. To the extent that SAVARA will conduct any clinical studies, preclinical studies and other research and development activities involving a Product, GEMA shall supply SAVARA with such quantities of API as are reasonably requested by SAVARA in order for it to conduct such clinical studies, preclinical studies and other research and development activities ("**Clinical Supplies**"). Upon SAVARA's prior written approval, the Manufacture of such Clinical Supplies may

deviate from the Regulatory Requirements or API Specifications. The Parties shall establish reasonable, mutually agreed procedures for SAVARA to forecast and submit, and GEMA to fill orders for, API for such purposes. Such procedures shall be in lieu of the forecasting and ordering procedures set forth in Section 4.2 and shall include in all events reasonable lead times (consistent with GEMA's lead time requirements in existence as of the Effective Date, unless the Parties otherwise agree) and a reasonable delivery schedule. The costs of Clinical Supplies for clinical studies, preclinical studies and other research and development activities in the Territory shall be paid for by SAVARA in accordance with Article 6below.

2.4 Affiliates. SAVARA shall have the right to have a SAVARA Affiliate exercise certain of SAVARA's rights or perform certain of SAVARA's responsibilities under this Agreement, including auditing, forecasting and ordering of API hereunder, receipt of delivery of API so ordered, payment of invoices provided by GEMA with respect to such API, and testing and acceptance or rejection of such API.

ARTICLE 3
MANUFACTURING AND PROCESSING ACTIVITIES

3.1 Commercial Compliance. GEMA shall take all actions and do all things necessary, proper or advisable to consummate, make effective, and comply with all Regulatory Requirements, including implementing the modifications to the Manufacturing Facilities set forth in Exhibit 3.1, and to obtain and maintain all governmental registrations, permits, licenses and approvals necessary for GEMA to Manufacture the API supplied under this Agreement ("**Commercial Compliance**"). SAVARA will use commercially reasonable efforts to respond to GEMA's reasonable questions with respect to obtaining and maintaining such Commercial Compliance. GEMA shall complete the activities to achieve Commercial Compliance as soon as reasonably practical but in no event later than six (6) months prior to the Anticipated Launch Date. Prior to achievement of Commercial Compliance, GEMA shall continue to supply to SAVARA API in accordance with this Agreement.

3.2 Sourcing of Materials.

3.2.1 Materials.

(a) GEMA shall be responsible for the procurement, at GEMA's own cost, of all Materials necessary for the Manufacture of API, consistent with the quantity forecasted by SAVARA in each Rolling Forecast pursuant to Section 4.1 below. GEMA may procure such Materials only from Third Party suppliers that have been approved by SAVARA in advance and any change to any such Third Party suppliers shall be approved by SAVARA in accordance with Section 3.4 and the change control procedures mutually agreed in writing by the Parties from time to time.

(b) All Materials procured by GEMA hereunder shall: (i) comply with the specifications applicable thereto as mutually agreed upon by the Parties and as set forth in the current batch records and/or other appropriate documentation (provided that such specifications may only be amended upon SAVARA's prior written approval); and (ii) be suitable (including by complying with all applicable Regulatory Requirements and the Quality Technical Agreement for the API, and in conformity to all applicable Regulatory Filings) for use in or to generate the API (including having regard to the use date of such Materials, if applicable, in accordance with the recommendations of the manufacturers thereof).

3.2.2 Testing and Inspection of Materials. GEMA shall be responsible for receiving, testing, releasing, storing and processing all Materials in accordance with all applicable Regulatory Requirements and specifications and any other requirements from SAVARA or Third Party suppliers.

3.3 Use of Materials; Inventory Reports.

3.3.1 Use. GEMA shall use the first-in first-out (FIFO) method of Material usage, subject to the prudent and appropriate usage of the first-expiring, first-out (FEFO) method. GEMA shall be responsible for, and shall bear all costs associated with, any obsolete or expired Materials, including the disposal of any such Materials.

3.3.2 Inventory Reports. Commencing no later than the first full calendar quarter after SAVARA provides the first Rolling Forecast pursuant to Section 4.1 below, within thirty (30) days after the end of each calendar quarter, GEMA shall provide to SAVARA a quarterly written report outlining the amount of its inventory of all critical Materials (as such critical Materials are identified by SAVARA from time to time).

3.4 Changes to Manufacturing Process and/or Specifications.

3.4.1 No GEMA-Initiated Changes. GEMA shall not make any changes to the API, any Materials (or suppliers thereof), formulations, processes, Manufacturing Facilities (including equipment), API Specifications, tests or any other item in any manner that would impact the Manufacturing activities related to the API to be supplied by GEMA hereunder, or affect any Regulatory Filing for API or any Product, without SAVARA's prior written approval and in compliance to the Quality Technical Agreement.

3.4.2 Required Changes. GEMA shall promptly make and implement, at its sole expense, such changes to the API Specifications or GEMA's Manufacturing activities as are required: (a) by any Regulatory Requirements that are: (i) applicable to the Manufacture of API, (ii) the result of a specific Law; and (iii) not discretionary; (b) by any concerns of SAVARA or Regulatory Authorities as to the toxicity, safety and/or efficacy of API to be Manufactured by GEMA as provided herein (or Product comprising or incorporating such API); or (c) following any amendment to the specifications for API approved by a Regulatory Authority, such that the differential between the API Specifications and such approved specifications continues to be at least equivalent to and no less stringent than any differential that may exist between the API Specifications and the specifications for API included in the first Regulatory Filing for sale of a Product ("**Required Changes**"). Prior to implementation, all Required Changes shall be subject to SAVARA's written approval, including the timelines, estimated effect on pricing and other issues regarding such implementation. GEMA shall implement such Required Changes in accordance with any applicable Regulatory Requirements for API and/or any instructions provided by SAVARA.

3.4.3 Other Changes. GEMA shall use commercially reasonable efforts to identify and develop changes to the Manufacturing process and other mechanisms for maintaining quality and lowering costs by seeking productivity improvements, by minimizing waste and improving yields, by purchasing quality materials at lower cost, by improving Manufacturing processes, by streamlining organizational processes, by achieving operational efficiencies, by reducing cycle times and lead times. GEMA shall promptly notify SAVARA regarding any such potential changes that it identifies. In addition, SAVARA may propose to GEMA certain changes to the API Specifications or the Manufacturing process for API which it reasonably believes will improve the Manufacturing process or lower costs or that SAVARA otherwise wishes to implement in connection with the Manufacture of API. Upon SAVARA's request, GEMA shall review and analyze any such change and provide a development plan, cost proposal and timeline for the implementation of such change. The Parties shall mutually agree on which changes, if any, shall be further developed or implemented in accordance with the change control procedures mutually agreed in writing by the Parties from time to time for the API. SAVARA shall bear any incremental costs to implement any improvements or other changes described in this Section 3.4.3 and any cost savings resulting from the implementation thereof shall be reflected in adjustments to the pricing for the API as mutually agreed by the Parties.

3.4.4 Deviations. Without limiting GEMA's obligations under Sections 3.1 and 3.2 above, in the event any material deviations occur during the course of the Manufacture of any batch of API under this Agreement and any subsequent corrective actions are undertaken by GEMA (including any such deviation and/or corrective action that occurs during the Manufacture, packaging, testing or shipment of any batch of API), GEMA shall immediately upon any such occurrence provide SAVARA with a detailed written description of any such deviation and/or corrective action and, to the extent known by GEMA, an explanation of the cause of such deviation and corresponding corrective actions. In addition to the provision of such notice, GEMA shall undertake those actions to investigate the cause of such deviation and to correct the same set out in the Quality Technical Agreement.

3.5 Quality Technical Agreement. Upon the request of either Party, and in any event at least six (6) months prior to the Anticipated Launch Date, the Parties shall enter into an amended Quality Technical Agreement that will cover the commercial supply of API. Upon execution, such amended Quality Technical Agreement shall be deemed to be attached to and incorporated into the Agreement as Exhibit 3.5. Without limiting the foregoing requirements, GEMA's quality assurance and quality control practices shall be at least as stringent as those practices as are standard in the pharmaceutical manufacturing industry. The Quality Technical Agreement is not intended and shall not be construed to limit any of the rights and obligations of the Parties set forth in this Agreement. Subject to the foregoing, to the extent possible, the Quality Technical Agreement will be interpreted with the terms set forth in the body of this Agreement. If there is any conflict or inconsistency between the terms of the Quality Technical Agreement and the terms set forth in this Agreement, however, the terms set forth in this Agreement shall control.

3.6 Technology Transfer.

3.6.1 Transition Assistance. Upon SAVARA's written request, GEMA shall agree to transfer all technology, methods, specifications and other know-how and information necessary for the Manufacture of API to SAVARA, and grant SAVARA all necessary licenses to use the same in connection with the Manufacture of API (and authorize the use of the same by its Affiliates and/or Third Parties for such purposes), in order for SAVARA to purchase the API from a Third Party supplier. In addition, GEMA shall, during the start-up of such Third Party supplier's supply operation: (i) provide all services to such Third Party necessary for the implementation of the manufacture of API at such Third Party supplier's facility, including without limitation, quality services and other technical services; (ii) make reasonably available GEMA's personnel with expertise in Manufacturing the API to answer over the phone or in person questions related the Manufacture of the API; provided that GEMA shall not be required to perform any additional studies, experiments or research to answer such questions; (iii) provide such Third Party with information concerning a source for raw materials; and (iv) otherwise cooperate with SAVARA and such Third Party as reasonably necessary to enable SAVARA to purchase API from such Third Party as soon as practicable.

3.6.2 Transfer of Working Cell Bank. Without limiting Section 3.6.1, GEMA shall generate and maintain complete and accurate records necessary to fully document the Working Cell Bank and Master Cell Bank, including records of each step involved in the cGMP Manufacturing process using the Cell Line within the Working Cell Bank to produce the API ("**Cell Bank Records**"). During the term and within six (6) months after termination or expiration of this Agreement, SAVARA may request from time to time a transfer of the Cell Bank Records, the Cell Line and Materials, to itself or any Third Party. In such event, GEMA shall transfer the Cell Bank Records, the Cell Line and Materials to SAVARA or to such Third Party and provide support and assistance to enable SAVARA or such Third Party to establish and perform the Manufacture of the API as soon as reasonably practicable, as requested by SAVARA. GEMA hereby transfers and assigns to SAVARA all right, title and interest in and to the Master Cell Bank, Working Cell Bank, Cell Bank Records and Cell Line.

3.6.3 Expenses. Subject to payment of the milestone payments in accordance with Section 6.2, all GEMA's activities set forth in this Section 3.6 shall be at GEMA's expense. Notwithstanding the foregoing, if GEMA personnel incur travel expenses at the request of Savara, such travel expenses shall be reimbursed in accordance with the Savara travel policy.

ARTICLE 4
ORDERS AND SHIPMENT

4.1 Commercial Supply Orders.

4.1.1 Preparation for Launch. Approximately [***] prior to the Anticipated Launch Date, GEMA shall use best efforts to make the appropriate preparations to secure sourcing of all Materials and allocate capacity and resources for the Manufacture and supply of API in accordance with any instructions, schedules, forecasts or other directions provided by SAVARA and the terms and conditions of this Agreement, including by providing the quarterly reports of the amount of its inventory in accordance with Section 3.3.2.

4.2 Forecasts. By the end of the calendar quarter in which SAVARA submits the first Regulatory Filing for sale of the first Product (and for each calendar quarter thereafter, no later than forty-five (45) days prior to the end of such calendar quarter), SAVARA shall provide GEMA with a good-faith written forecast of the quantities of API estimated to be required from GEMA during the first full calendar quarter following the date on which such forecast is provided ("**Q1**") and the next three (3) succeeding calendar quarters ("**Q2**," "**Q3**" and "**Q4**" respectively) (each such forecast, a "**Rolling Forecast**"). Each Rolling Forecast shall specify the quantity of API to be supplied. With respect to each Rolling Forecast, the forecasted quantities for Q1 shall be binding and the forecasted quantities for Q2, Q3 and Q4 shall be non-binding. Notwithstanding the provisions of this Section 4.2, the Rolling Forecasts that SAVARA is to provide hereunder need not extend beyond the Term. Each Rolling Forecast for API provided by SAVARA shall be in substantially the same form as Exhibit 4.2 attached hereto or such other form as the Parties may agree in writing from time to time.

4.3 Orders. Together with each Rolling Forecast for API, SAVARA shall provide to GEMA a purchase order (each, a "**Purchase Order**") covering the API requirements set forth in the binding portion of such Rolling Forecast. GEMA shall accept all Purchase Orders that SAVARA issues in accordance with this Article 4 and provide SAVARA with a written acceptance of each Purchase Order within ten (10) business days following GEMA's receipt thereof; provided that, if no such acceptance is provided to SAVARA within such period, such Purchase Order shall be deemed accepted by GEMA. GEMA may reject only that portion of any Purchase Order that GEMA is unable to fill due to: (a) an Event of Force Majeure; or (b) unexpected demand where the API quantity specified in such Purchase Order exceeds the API quantity specified for Q2 of the immediately preceding Rolling Forecast for API by more than twenty-five percent (25%). Accepted Purchase Orders issued by SAVARA shall constitute the binding obligation of GEMA to deliver to SAVARA the specified quantity of API by the specified delivery date and, subject to Sections 4.5.2 and 4.7 and Article 5 below, the binding obligation of SAVARA to purchase the quantity of API. Notwithstanding the foregoing, GEMA shall use commercially reasonable efforts to accept and fulfill all Purchase Orders under this Agreement.

4.4 Purchase Orders. Each Purchase Order shall specify the delivery date(s), shipping instructions, delivery location(s) and amount of API to be delivered in accordance with reasonable delivery schedules and lead times as may be agreed upon from time to time by the Parties. No terms or conditions of contained in any Purchase Order, order acknowledgement or similar standardized form given or received pursuant to this Agreement shall be construed to amend or modify the terms of this Agreement and, in the event of any conflict, this Agreement shall control, unless the Parties otherwise expressly agree in writing.

4.5 Packaging and Delivery.

4.5.1 Packaging. All API to be delivered hereunder will be packaged in containers in accordance with the applicable API Specifications or as otherwise agreed by the Parties in writing. Each such container will be individually labeled with description of its contents, batch or lot number, quantity, manufacturer and, if necessary, date of Manufacture, and any other information as may be required in order to trace the history of each batch or lot. Each batch delivered hereunder will include two (2) satellite samples per bottle of API, unless otherwise agreed by the Parties in writing.

4.5.2 Delivery. GEMA shall arrange for the delivery of all API to the location as stated on the applicable Purchase Order and in a manner consistent with good commercial practices, validated shipping procedures that comply with Regulatory Requirements for API (including shipment in approved containers), labeled storage conditions (including during shipment) and any agreed-upon shipping specifications. Each shipment of API shall be delivered by GEMA in accordance with the Quality Technical Agreement, via a pharmaceutical carrier meeting the Validation shipping requirements, CIF (Incoterms 2010) SAVARA's designated location. GEMA shall deliver the amounts ordered in each Purchase Order within twenty (20) days (plus or minus) of the delivery dates specified in each Purchase Order. SAVARA shall only be obligated to pay for quantities of API actually delivered in compliance with the applicable Purchase Order and the terms of this Agreement.

4.6 Shipping Documentation. Each shipment shall be accompanied by commercially appropriate shipping documentation (including bills of lading, commercial invoice), which shall, at a minimum: (a) identify the shipment and batch numbers comprised in the shipment; (b) state any order number for the shipment that has been provided by SAVARA; and (c) show the destination to which such shipment is being sent. In addition, each shipment shall be accompanied by the applicable Material Safety Data Sheet and such additional documentation that SAVARA may reasonably require from time to time under this Agreement.

4.7 Shortage of Supply. GEMA and SAVARA shall cooperate to establish reasonable plans and procedures to avoid any shortage of supply of any API. If, at any time, GEMA becomes unable, or concludes that it will be unable, to supply any API in accordance with the requirements of this Agreement in the quantities and within the time periods specified in applicable Purchase Orders and the then-current Rolling Forecast (a "**Shortage of Supply**"), GEMA shall immediately notify SAVARA in writing. In such event, the Parties shall promptly convene to identify the actions necessary to address the problem. GEMA shall use its best efforts to remedy any Shortage of Supply and resume supplying the API meeting the requirements of this Agreement to SAVARA as soon as possible and, upon SAVARA's request, GEMA shall fully cooperate with SAVARA to secure adequate supplies of API from alternative sources. Moreover, upon the occurrence of a Shortage of Supply and until such Shortage of Supply has been remedied as described in this Section 4.7, SAVARA shall be relieved from its obligations to purchase any quantities of API identified in any Purchase Order and may cancel any such quantities effective upon notice to GEMA. All costs and expenses required to remedy a Shortage of Supply and incurred by GEMA shall be borne solely by GEMA.

ARTICLE 5
STORAGE; API QUALITY

5.1 Storage of API. GEMA shall store all API Manufactured under this Agreement for SAVARA as set forth on Exhibit 5.1 attached hereto.

5.2 Release. Prior to each shipment of API to be delivered hereunder, GEMA will perform appropriate quality control procedures and inspections (including any such procedures and inspections specified in the API Specifications) to verify that API to be shipped conforms fully to the API Specifications, all applicable Regulatory Requirements and other requirements of any governmental authority for API. In addition, prior to each such shipment of API, GEMA will provide to SAVARA a copy of the executed batch records, a certificate of compliance, TSE/BSE statement and a certificate of analysis, in the form specified in the API Specifications, describing all current requirements of the API Specifications and results of tests performed certifying that the API to be shipped has been Manufactured according to the API Specifications, all applicable Regulatory Requirements and other requirements of any governmental authority for the API and applicable Product. SAVARA will, upon satisfactory review, release the applicable API for manufacturing Product, shipping and further use; provided that such review by SAVARA shall not be unreasonably delayed; provided further that any such release of API by SAVARA pursuant to the foregoing shall not limit SAVARA's rights under Sections 5.3 and 5.4 below or any other provision of this Agreement.

5.3 Rejection. SAVARA shall have sixty (60) days following its receipt of a shipment of API to reject such quantities of API on the grounds that all or part of the shipment fails to conform to the API Specifications or Regulatory Requirements or otherwise fails to conform to the warranties given by GEMA in Section 11.2 below, which rejection shall be accomplished by giving written notice to GEMA specifying the manner in which such shipment fails to meet the foregoing requirements. Payment for a shipment will not be deemed acceptance of such shipment, and if SAVARA rejects a shipment before the date on which payment is due, it may withhold fifty percent (50%) of such payment for such shipment or the rejected portion thereof and a credit for the other fifty percent (50%) will be issued by GEMA to SAVARA for use with future Purchase Orders. The warranties given by GEMA in Section 11.2 below shall survive any failure to reject by SAVARA under this Section 5.3.

5.4 Replacement. GEMA shall respond in writing to SAVARA accepting or refusing a rejection notice from SAVARA within twenty (20) days from the date of receipt of such rejection notice in accordance with Section 5.3 above. If GEMA does not agree with SAVARA's determination that such API fails to conform to the API Specifications or Regulatory Requirements for API or otherwise fails to conform to the warranties given by GEMA in Section 11.2 below, then the Parties shall use reasonable efforts to resolve such disagreement in good faith as promptly as possible. If the Parties are unable to resolve such disagreement within thirty (30) days of the date of the applicable rejection notice from SAVARA, either Party may submit a sample of such API to an independent Third Party laboratory selected by such Party and reasonably acceptable to the other Party (such agreement not to be unreasonably withheld or delayed) for a determination as to whether such API conforms to the API Specifications or Regulatory Requirements for API and the warranties given by GEMA in Section 11.2 below. The independent laboratory's determination shall be final and binding. Unless otherwise agreed by the Parties in writing, the non-prevailing Party shall bear the costs associated with the independent laboratory's testing and determination. GEMA shall use its best efforts to replace the quantities of API rejected by SAVARA within the shortest possible time, but no later than forty-five (45) days from the date of SAVARA's notice to GEMA specifying that such quantities have been rejected. If GEMA fails to replace such quantities of API within the aforesaid period, SAVARA shall have the right: (a) to cancel such replacement shipment by written notice; and (b) to reclaim immediately (either through refund or set off, at SAVARA's discretion) any amounts paid pursuant to Article 6 for the quantities of API that were rejected but not replaced, if such payment for such quantities had already been made to GEMA.

ARTICLE 6
PAYMENT

6.1 Price. The price for API supplied by GEMA to SAVARA in accordance with this Agreement ("**Purchase Price**") shall be as specified on the pricing and milestone schedule attached hereto as Exhibit 6.1 (the "**Pricing and Milestone Schedule**"). No more than once per year, GEMA shall be permitted to request a change in the Purchase Price due to increases in their costs to manufacture the API. Any such request shall include appropriate documentation showing the cost increases and their effect on the cost to manufacture the API. Upon receipt by SAVARA of such request, the parties shall negotiate in good faith regarding an adjustment to the Purchase Price. Changes to the pricing of API will be by mutual agreement of the Parties. Notwithstanding the foregoing, in no event will SAVARA be obligated to pay GEMA the Purchase Price for API supplied to SAVARA in the Validation batches, as compensation for the Validation activities shall be made pursuant to Section 6.2.

6.2 Milestones Payments. Within thirty (30) days after the achievement of each milestone event set forth in the Pricing and Milestone Schedule, SAVARA shall pay to GEMA the corresponding milestone payment. Each such milestone payment shall be payable only once. It is agreed by the Parties that partial milestones can be invoiced by GEMA and will be discounted from total milestone payment.

6.3 Royalties. SAVARA shall pay GEMA royalties in accordance with Exhibit 6.3.

6.4 Invoices; Payment. Subject to Section 6.1, GEMA may invoice SAVARA for the price of API (calculated in accordance with the Pricing and Milestone Schedule) upon the shipment of such API to SAVARA. Each such invoice shall specify the Purchase Order number to which it corresponds. Payment of all properly submitted invoices shall be made within sixty (60) days after the date of delivery in accordance with Section 4.5.2; provided that SAVARA has not rejected the applicable API in accordance with Section 5.3. Except as otherwise expressly set forth in this Agreement, SAVARA shall not be obligated to pay any amounts other than the price for API supplied by GEMA to SAVARA in accordance with this Agreement.

6.5 Payment Terms. All dollar amounts in this Agreement and in any invoice issued hereunder are or shall be stated in United States Dollars. All payments under this Agreement shall be made in United States Dollars.

6.6 Taxes. If applicable, the price for any API supplied by GEMA to SAVARA hereunder shall include any applicable sales, use, consumption, value-added or excise taxes, duties, tariffs and other similar assessments which, as a result of the sale of the API to SAVARA, may be imposed by any governmental authority in Argentina or in any other jurisdiction in which GEMA is eligible under applicable Laws to obtain a credit or rebate for such taxes, duties, tariffs or other assessments ("**Transfer Taxes**"); provided, however, that the Parties shall cooperate and take any reasonable steps necessary to reduce or eliminate any Transfer Taxes. SAVARA shall be entitled to deduct the amount of any withholding taxes payable or required to be withheld by SAVARA, to the extent SAVARA pays such taxes to the appropriate governmental authority on behalf of GEMA. SAVARA shall promptly deliver to GEMA proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto. Notwithstanding the foregoing, in no event shall SAVARA be responsible for any taxes, duties, levies, surcharges or similar assessments which may be imposed by any governmental authority as a result of any activity relating to the Manufacture or sale of any API occurring prior to the delivery of such API to SAVARA in accordance with Section 4.5 above.

ARTICLE 7
INSPECTIONS; RECORDS

7.1 Inspections.

7.1.1 By SAVARA. SAVARA (or its employees or consultants) shall have the right at its own cost and expense, upon reasonable advance notice of not less than thirty (30) days and during regular business hours, to inspect and audit: (a) the Manufacturing Facility or other facility at which any of the Manufacturing activities under this Agreement are performed; (b) any of GEMA's manufacturing and quality control records and all other documentation relating to the Manufacturing activities in connection with the API (including, any internal quality control audits or reviews conducted by GEMA); and (c) accounts and records for the purpose of determining the amounts payable or owed under this Agreement. Such inspections and audits shall be for the purpose of ascertaining Commercial Compliance and compliance with applicable Regulatory Requirements, the applicable Quality Technical Agreement, environmental, health and safety regulations and other aspects of this Agreement, reviewing correspondence, reports, filings and other documents from or to Regulatory Authorities to the extent related to the Manufacturing activities in connection with API, approving (where appropriate) all variances from applicable requirements hereunder or under the applicable Quality Technical Agreement, and evaluating the implementation of Commercial Compliance and all Manufacturing and process changes pursuant to this Agreement. Such inspection or audit right shall not be exercised by SAVARA more than once in any calendar year or cover a period ending more than thirty-six (36) months prior to the date of such request. Any information obtained by SAVARA through such inspections and audits shall be treated as Confidential Information of GEMA in accordance with Article 10 below. Subject to Section 3.1, if during any such inspection by SAVARA, SAVARA identifies that GEMA is not in compliance with applicable Regulatory Requirements, the applicable Quality Technical Agreement and environmental, health and safety regulations and other aspects of this Agreement, the following shall apply: (i) SAVARA may notify GEMA in writing of such non-compliance; (ii) GEMA shall promptly take action to remedy any non-compliance of a material or major nature as soon as possible and to remedy any other non-compliance as soon as practicable; and (iii) GEMA shall provide SAVARA with progress reports of the corrective actions being taken and reasonably documentary and other evidence that all compliance items have been corrected.

7.1.2 By GEMA. GEMA shall be responsible for conducting inspections and audits of all persons and other business entities who supply Materials to GEMA as described in Section 3.2.1 above (each a "**Supplier**") in accordance with GEMA's standard operating procedures applicable to the inspection and audit of Third Party suppliers; provided that SAVARA shall have the right to review and approve GEMA's implementation of such standard operating procedures with respect to GEMA's activities under this Section 7.1.2. If during any such inspection of any Materials Supplier, GEMA identifies that such Supplier is not in compliance with applicable Regulatory Requirements or the terms of the agreement between GEMA and such Supplier, GEMA shall: (a) promptly provide SAVARA with a detailed written notice of such non-compliance; (b) cause any non-compliance of a material or major nature to be remedied as soon as possible and any other non-compliance to be remedied as soon as practicable; and (c) provide SAVARA with progress reports of the corrective actions being taken and reasonably documentary and other evidence that all compliance items have been corrected.

7.2 Observation of Manufacturing Activities. Upon SAVARA's reasonable request from time to time, GEMA shall permit a reasonable number of SAVARA's employees or other representatives to visit the Manufacturing Facilities and/or any other facility at which any of the Manufacturing activities under this Agreement are performed in order to observe the conduct of such Manufacturing activities. For clarity, GEMA's rights under this Section 7.2 shall be in addition to and shall not limit SAVARA's right to conduct inspections and audits pursuant to Section 7.1.1 above.

7.3 Records. GEMA shall generate and maintain complete and accurate records (including, files, certificates and authorizations) and samples as necessary to evidence compliance with this Agreement and all applicable Laws, Regulatory Requirements and other requirements of applicable governmental authorities relating to the Manufacture of API, including, all Validation data, stability testing data, certificates of analysis, batch records, quality control and laboratory testing, and any other data required under cGMPs and other Regulatory Requirements. All such records and samples shall be securely maintained for the following periods after the date of expiration of the approved shelf life of each batch of the API to which such records or samples pertain: (a) in the case of records, ten (10) years after such expiration; and (b) in the case of samples and the Cell Line (including the Master Cell Bank and the Working Cell Bank), ten (10) years after such expiration (or, if longer, for a period of one (1) year after the final resolution of any dispute to which such records or samples are relevant); or, in the case of either clause (a) or (b), such longer period as may be required by applicable Regulatory Requirements. GEMA shall not dispose of records, Cell Line (including the Master Cell Bank and the Working Cell Bank) or samples generated in conjunction with this Agreement without first offering to transfer such records, Cell Line or samples to SAVARA or its designee at SAVARA's or its designee's expense. Upon the request of SAVARA, GEMA will provide SAVARA reasonable access to, and copies and portions of, such records and samples and any supporting data relating thereto (including laboratory notebooks and any applicable testing results).

ARTICLE 8
REGULATORY MATTERS

8.1 Regulatory Compliance.

8.1.1 GEMA will exercise all reasonable skill, care and diligence customary in the pharmaceutical industry in the performance of all Manufacturing activities under this Agreement and shall perform all such activities in accordance with the applicable API Specifications, Regulatory Requirements and Quality Technical Agreement.

8.1.2 GEMA shall obtain and maintain in good order, at its sole cost and expense, all Regulatory Filings (including all governmental registrations, permits, licenses and approvals) as are required by Regulatory Requirements for GEMA to Manufacture API for SAVARA and otherwise to perform its obligations under this Agreement (including, the importation of Materials used in the Manufacturing of API by GEMA and the export of API (including material from Validation batches). GEMA shall make copies of such Regulatory Filings and all related documents available to SAVARA and its employees or consultants for inspection, upon reasonable request from SAVARA. SAVARA will use commercially reasonable efforts to respond to GEMA's reasonable questions with respect to obtaining and maintaining such Regulatory Filings.

8.2 Regulatory Inspections and Communications.

8.2.1 GEMA will permit the FDA and other Regulatory Authorities to conduct inspections of the Manufacturing Facility as the FDA or other Regulatory Authorities may request or as SAVARA may request, and will cooperate with the FDA and other Regulatory Authorities with respect to the inspections and any related matters, in each case that is related to API Manufactured and supplied hereunder. GEMA will give SAVARA prior notice within two (2) business days of FDA's or such other Regulatory Authority's notice of inspection, to the extent practicable, of any such inspections and will permit SAVARA (and/or its employees or consultants) to assist in the preparation for, and be present at, such inspections.

8.2.2 GEMA shall notify SAVARA within five (5) business days if it receives any inspection reports and related correspondence of any Regulatory Authority concerning or impacting API or which might reasonably affect performance of any Manufacturing activities under this Agreement (including any applicable FDA Form 483 or other inspection reports, warning letters or citations or other similar Regulatory Authority notifications) and shall include with such notice a copy of such inspection report and/or related correspondence. GEMA shall discuss with SAVARA any Regulatory Authority comments concerning or impacting API or which might reasonably affect performance of any Manufacturing activities under this Agreement, and before GEMA submits a final response to such comments, GEMA shall give SAVARA no fewer than five (5) business days to comment on its proposed response to such comments, and any resultant SAVARA comments shall be incorporated into the response, if reasonably possible. GEMA shall promptly rectify or resolve any deficiencies noted by a Regulatory Authority in a report or correspondence issued to GEMA that concern or impact API or that otherwise relate to performance of any of the Manufacturing activities hereunder.

8.3 Regulatory Cooperation.

8.3.1 GEMA agrees to provide promptly to SAVARA, as requested, all information and data in GEMA's possession or control necessary or useful for SAVARA and/or its designees to apply for, obtain and maintain Regulatory Filings (and approvals therefor) for API and Products in any country, including information relating to the Manufacturing Facility and all information required to be submitted in the CMC section of a Regulatory Filing or required or requested to be provided to the FDA or other Regulatory Authorities. Except as provided in Section 8.3.2 below: (a) any such information and data shall be provided by GEMA at no additional cost to SAVARA.

8.3.2 Without limiting Section 8.3.1above, in support of an annual product review process (consistent with the provisions of 21 C.F.R. §211.180(e) or any comparable requirement under the Laws of a jurisdiction other than the United States) for Product, at no additional cost to SAVARA, GEMA shall conduct a review of the batches of API Manufactured during each applicable annual period (regardless of whether such batches were approved or rejected) and shall provide to SAVARA a report based on such review. Such report shall include the information required by SAVARA to satisfy the applicable Regulatory Requirements and any SAVARA standard operating procedures with respect to annual product reviews, as further specified in the Quality Technical Agreement. In addition, GEMA agrees to cooperate with SAVARA or its designees with respect to obligations to submit or report information relevant to each Product pursuant to FDA regulations and other applicable Laws.

8.4 Regulatory Filings. Except as provided in Section 8.1.2 above, as between the Parties, SAVARA shall be solely responsible for obtaining and maintaining such Regulatory Filings as are necessary for SAVARA to sell and/or distribute API Manufactured by GEMA or Products comprising or incorporating such API.

8.5 Validation Activities. GEMA shall be responsible for Validating all critical systems, processes, tests and equipment necessary in connection with the Manufacture of API for SAVARA under this Agreement in a timely manner as set forth in the API Specifications. Without limiting the foregoing, SAVARA shall have the right to review and approve (a) specified individual Validation protocols with respect to any processes relating to the Manufacture of API for SAVARA, prior to the implementation of the same and (b) a written process Validation report provided by GEMA to SAVARA upon completion of the Validation activities. In addition, upon completion of such Validation activities, GEMA shall provide to SAVARA all API Manufactured as a result of such Validation activities and SAVARA shall have the right to use or dispose of such quantities of API resulting for any purpose.

8.6 Stability Testing. GEMA shall be responsible for conducting stability studies in accordance with cGMP and ICH standards. Without limiting the foregoing, SAVARA shall have the right to review and approve(a) the protocols used for such stability studies and (b) a written report provided by GEMA to SAVARA upon completion of the stability studies. SAVARA shall have access to and the right to use all reference standards generated in the supply of API hereunder.

8.7 Responsibility for Handling Complaints. GEMA shall promptly forward to the designated representative for SAVARA all complaints associated with Products incorporating or comprising API. SAVARA or its designee shall be responsible for handling or responding to all Product complaints, including those associated with Manufacturing. GEMA shall cooperate in the investigation of Product complaints potentially involving the Manufacturing, as requested by SAVARA and in compliance with the Quality Technical Agreement.

8.8 Recalls. In the event that either Party should become aware of information that may require a recall of any Product, such Party shall notify the other Party in writing within twenty-four (24) hours of becoming aware of such information. SAVARA shall control the conduct of any recall (including any determination as to whether a recall is required) and shall implement and coordinate all activities reasonably necessary in connection with such recall, including making all contact with relevant Regulatory Authorities; provided however that, before initiating a recall, SAVARA shall first notify GEMA and, to the extent practicable, consult in good faith with GEMA. GEMA shall cooperate with SAVARA and provide assistance to SAVARA, as reasonably requested, in conducting such recall, including providing all pertinent records that SAVARA may reasonably request to assist in effecting such action. In the event of a recall due to any failure of a Product due to the API's failure to meet the applicable API Specifications or warranties set forth in Section 11.2, it is agreed and understood that any expenses (including reasonable fees of any experts or attorneys that may be utilized by either Party, government fines or penalties related to such recall) ("**Recall Costs**") shall be borne by GEMA. Otherwise the Recall Costs shall be borne by SAVARA.

ARTICLE 9
INTELLECTUAL PROPERTY

9.1 Inventions.

9.1.1 Ownership. All Inventions will be the sole and exclusive property of SAVARA, and GEMA hereby assigns, and will be deemed to have assigned, to SAVARA all Inventions. GEMA will promptly disclose to SAVARA any and all Inventions, and at SAVARA's request and expense, GEMA will undertake (or cause to be undertaken) all further actions required to perfect SAVARA's title to, and enjoyment of, such Inventions, including disclosure to SAVARA of all pertinent information and data with respect to all Inventions and the execution and delivery of any applications, assignments, oaths and other instruments and documentation requested by SAVARA. As used herein, "**Inventions**" mean any and all information, data, results, inventions and discoveries and other intellectual property, whether or not patentable or copyrightable, conceived, created or reduced to practice by GEMA, individually or in conjunction with others, in connection with the performance of its obligations hereunder or based on any Confidential Information of SAVARA (including, all information, data, results, inventions and discoveries relating to the Cell Line or Manufacturing of API contained in any Product or otherwise to the composition or use of any Product or which otherwise relate specifically to a Product or the Manufacture thereof) and all intellectual property rights therein and thereto.

9.1.2 Prosecution and Enforcement. SAVARA shall be solely responsible for the filing, prosecution and maintenance of any patents, trademarks and/or copyrights claiming or pertaining to Inventions and for enforcing its rights in any Inventions against an infringer thereof. GEMA agrees to cooperate and assist SAVARA with respect to such activities as reasonably requested and at the cost and expense of SAVARA.

9.1.3 Third Party Intellectual Property. GEMA shall not use any intellectual property owned or controlled by any Third Party in connection with the Manufacture of any API for SAVARA under this Agreement, unless GEMA first obtains SAVARA's prior written approval.

9.2 License Grants. SAVARA hereby grants to GEMA a limited, royalty-free, non-transferable (except in accordance with Section 14.4), non-exclusive license under SAVARA's patent rights in, and any know-how pertaining to API solely as necessary for GEMA to perform its obligations under this Agreement with respect to the Manufacture of API for SAVARA. GEMA hereby grants to SAVARA a limited, non-transferable (except in accordance with Section 14.4), non-exclusive license, with the right to grant and authorize sublicenses, under GEMA's patent rights in, and any know-how pertaining to, Manufacture of API solely as necessary for the Manufacture, use, sale, offer for sale, import, or other exploitation of API. Only the licenses granted pursuant to the express terms of this Agreement shall be of legal force and effect; and no other license rights shall be created by implication, estoppel or otherwise.

9.3 Trademarks. SAVARA, in its sole discretion, shall determine the trademarks and trade names to be used in connection with each Product (collectively, with respect to each Product, the "**Product Trademarks**") and which trademarks and trade names will appear on the labels, labeling and any promotional materials for such Product.

ARTICLE 10
CONFIDENTIALITY

10.1 Confidential Information. "**Confidential Information**" means all data, specifications, training and any other know-how related to the design, development, manufacture (including equipment and processes), marketing, distribution or performance of API and Cell Line (and Master Cell Bank and Working Cell Bank), as well as all other information and data provided by either Party to the other Party pursuant to this Agreement, to the extent the disclosing Party treats such other information and data as confidential. Confidential Information of SAVARA shall include all API Specifications, Inventions, batch records and other information pertaining to the API or Cell Line (or Master Cell Bank or Working Cell Bank), including all records maintained pursuant to Section 3.6.2 or 7.3 above, and exceptions (b) and (d) below shall not apply thereto. The term "Confidential Information" does not include any information that the receiving Party can prove: (a) is or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party; (b) is known to the receiving Party prior to receipt from the disclosing Party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing Party; (c) becomes known to the receiving Party (independently of disclosure by the disclosing Party) directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing Party; or (d) is independently developed by the receiving Party without use of or reference to the disclosing Party's Confidential Information.

10.2 Non-Disclosure and Non-Use. It is contemplated that a Party may from time to time disclose its Confidential Information to the other Party. Each Party shall not disclose to Third Parties any Confidential Information of the disclosing Party and shall not use any Confidential Information of the disclosing Party, except for the limited purposes of performing the receiving Party's obligations or exercising the receiving Party's rights as set forth in this Agreement. The receiving Party shall take all reasonable steps to prevent any unauthorized use or disclosure of the Confidential Information of the disclosing Party. The receiving Party may disclose Confidential Information to employees and Third Parties who have a need to have access to such Confidential Information in connection with such Party's performance of its obligations, and/or exercise of its rights, under this Agreement, provided that such employees and Third Parties are bound by confidentiality and non-disclosure obligations at least as protective of the disclosing Party and its Confidential Information as this Article 10. The provisions of this Section 10.2 shall survive termination or expiration of this Agreement and shall continue for ten (10) years after the date of such expiration or termination.

10.3 Disclosures Required By Law. The terms of this Article 10 shall not be construed to limit either Party's right to disclose the other Party's Confidential Information if: (a) required in response to a valid order of a court of competent jurisdiction or other governmental authority of competent jurisdiction; provided that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to seek the confidential treatment of such Confidential Information (through protective order, injunctive relief or otherwise) and shall reasonably cooperate with the disclosing Party in seeking such treatment; provided further that the Confidential Information disclosed in response to such court or governmental order shall be limited to that Confidential Information which is legally required to be disclosed; or (b) otherwise required by Law to be disclosed.

10.4 Confidential Terms. Each Party agrees not to disclose to any Third Party any of the terms of this Agreement without the prior written consent of the other Party, except that each Party may do so (a) to its legal and financial advisors, potential or actual investors, acquisition partners and others on a need-to-know basis, under reasonable obligations of confidentiality; and (b) as required by court order, judicial or administrative process or Law (including any regulation of the U.S. Securities and Exchange Commission or any exchange on which a Party's securities are traded).

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1 General. Each Party represents and warrants that: (a) it has the power and authority to enter into this Agreement and to perform its obligations hereunder and to grant to the other Party the rights granted to such other Party under this Agreement; (b) it has obtained all necessary corporate approvals to enter into and execute this Agreement; and (c) it is not presently a party to, nor will it enter into or assume during the Term, any contract or other obligation with a Third Party that would in any way limit the performance of its obligations under this Agreement.

11.2 Representations and Warranties of GEMA. GEMA represents and warrants that:

11.2.1 Specifications. All API Manufactured and supplied under this Agreement will: (a) be free from defects in materials and workmanship; (b) conform to the API Specifications; (c) have been Manufactured in accordance with the approved batch records and stored in accordance with the requirements specified in Section 5.1 above; (d) not be adulterated or misbranded within the meaning of the United States Federal Food, Drug and Cosmetic Act or other Regulatory Requirements at, or at any time prior to, delivery in accordance with Section 4.5 above; (e) shall have, at the time of delivery of such API to SAVARA, at least [***] of the shelf life approved for API by the applicable Regulatory Authority, unless otherwise agreed in writing by SAVARA on a case-by-case or lot-by-lot basis; and (f) have been Manufactured, labeled, packaged, stored, tested, documented, released and shipped in accordance with the applicable Regulatory Requirements, the terms of the applicable Quality Technical Agreement and all applicable Laws;

11.2.2 Facilities and Equipment. The Manufacturing Facility, all equipment used for the Manufacture of API within the Manufacturing Facility and the Manufacturing activities contemplated herein will meet all applicable Regulatory Requirements;

11.2.3 Permits and Approvals. It shall obtain and maintain all governmental registrations, permits, licenses and approvals necessary for GEMA to Manufacture API supplied under this Agreement;

11.2.4 No Encumbrance. Title to all API, Cell Lines, Master Cell Bank and Working Cell Bank supplied under this Agreement will pass as provided in this Agreement, free and clear of any security interest, lien, or other encumbrance;

11.2.5 Intellectual Property and Confidential Information. Each employee and subcontractor of GEMA's who will receive or have access to Confidential Information of SAVARA or perform obligations hereunder will agree in writing to assign any and all right, title and interest in and to all Inventions to GEMA and to protect the Confidential Information of SAVARA in accordance with this Agreement, prior to the earlier to occur of: (i) any disclosure of Confidential Information of SAVARA to such employee or subcontractor; or (ii) the commencement of any such performance by such employee or subcontractor; and

11.2.6 Debarment. Neither GEMA nor any of its employees or subcontractors performing or involved with its performance under this Agreement have been "debarred" by the FDA or a Regulatory Authority in any jurisdiction outside the United States, nor have debarment proceedings against GEMA or any of its employees or subcontractors been commenced. GEMA will promptly notify SAVARA in writing if any such proceedings have commenced or if GEMA or any of its employees or subcontractors is debarred by the FDA or a Regulatory Authority in any jurisdiction outside the United States.

11.3 Representations and Warranties of SAVARA.SAVARA represents and warrants to GEMA that SAVARA will comply in all material respects with all Laws, rules and regulations in effect from time to time applicable to the marketing and distribution of the API and Products.

11.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO ANY PRODUCTS, SERVICES OR INFORMATION PROVIDED HEREUNDER, INCLUDING, THE IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 12
INDEMNIFICATION; INSURANCE

12.1 SAVARA. SAVARA will indemnify, defend, and hold harmless GEMA and its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses or costs (including reasonable attorneys' fees and court costs) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a Third Party resulting from: (a) marketing, sale or use by or under authority of SAVARA or its Affiliates of API supplied by GEMA to SAVARA pursuant to and in accordance with this Agreement; (b) the gross negligence or willful misconduct of SAVARA; (c) any breach by SAVARA of its representations or warranties under Section 11.1 or 11.3; (d) any material breach by SAVARA of its obligations under this Agreement; or (e) a claim that the filing of a Regulatory Filing with a Regulatory Authority for approval to market and sell a Product, or the supply of API for such Product by GEMA to SAVARA at the locations designated by SAVARA pursuant to and in accordance with this Agreement infringes such Third Party's intellectual property rights under any patent, trademark or copyright registration issued to such Third Party; provided that the foregoing does not arise or result from, or is otherwise attributable to: (A) GEMA's breach of Section 9.1.2 above; (B) GEMA's misappropriation of any confidential information or intellectual property rights of such Third Party; or (C) GEMA's breach of any license or other arrangement with such Third Party with respect to the applicable patent, trademark or copyright; in each case, subject to the requirements set forth in Section 12.3. Notwithstanding, and without limiting, the foregoing, SAVARA will have no obligations under this Section 12.1for any liabilities, expenses or costs to the extent arising out of or relating to claims covered under Section 12.2.

12.2 GEMA. GEMA will indemnify, defend and hold harmless SAVARA and its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses and costs (including reasonable attorneys' fees and court costs) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a Third Party resulting from: (a) GEMA's or its subcontractor's Manufacturing activities performed pursuant to this Agreement; (b) failure of any API delivered hereunder to meet the applicable API Specifications; (c) the gross negligence or willful misconduct of GEMA; (d) any breach by GEMA of its representations or warranties under Section 11.1or 11.2; or (e) any material breach by GEMA of its obligations under this Agreement; in each case, subject to the requirements set forth in Section 12.3. Notwithstanding the foregoing, GEMA will have no obligations under this Section 12.2for any liabilities, expenses or costs to the extent arising out of or relating to claims covered under Section 12.1.

12.3 Indemnification Procedure. A Party that intends to claim indemnification under this Article 12 (the "**Indemnitee**") will promptly notify the indemnifying party (the "**Indemnitor**") in writing of any Third Party claim, suit or proceeding included within the indemnification described in this Article 12(each a "**Claim**") with respect to which the Indemnitee intends to claim such indemnification, and the Indemnitor will have sole control of the defense and settlement of such Claim. The failure to deliver written notice to the Indemnitor within a reasonable period of time after the commencement of a Claim shall relieve such Indemnitor of any liability to the Indemnitee under this Article 12 solely to the extent such failure is prejudicial to the Indemnitor's ability to defend such Claim. The Indemnitor will not enter into any settlement of such Claim that admits fault, wrongdoing or damages without the Indemnitee's prior written consent, which consent will not to be unreasonably withheld or delayed. The Indemnitee will have the right to participate, at its own expense, with counsel of its own choosing in the defense or settlement of such Claim. The indemnification under this Article 12will not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the Indemnitor. The Indemnitee under this Article 12, and its employees, at the Indemnitor's request and expense, will provide full information and reasonable assistance to the Indemnitor and its legal representatives with respect to Claims.

12.4 Insurance. During the Term, each Party shall maintain, with financially sound and reputable insurers, insurance reasonably sufficient to cover each Party's activities and obligations under this Agreement. Without limiting the foregoing, GEMA shall maintain: (a) general liability insurance with combined single limits of not less than Five Million Dollars ($5,000,000); and (b) product liability insurance with combined single limits of not less than Fifty Million Dollars ($50,000,000). At the reasonable request of a Party, the other Party shall provide to such Party copies of certificates of insurance evidencing coverage in accordance with this Section 12.4.

ARTICLE 13
TERM AND TERMINATION

13.1 Term. This Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to Sections 13.2, 13.3 or 14.1 below, shall continue in full force and effect, until the twentieth (20th) anniversary of the date of receipt of approval by a Regulatory Authority of the first Regulatory Filing for the marketing and sale of the first Product in any country (the "**Initial Term**"). Following the Initial Term, this Agreement may be extended for additional twelve (12) month periods (each, a "**Renewal Term**" and all such Renewal Terms together with the Initial Term, the "**Term**") by the written agreement of GEMA and SAVARA entered into at least two (2) years prior to the expiration of the then-current Term.

13.2 Termination for Breach. If either Party materially breaches this Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if such breach is not cured within sixty (60) days after written notice is given by the non-breaching Party to the breaching Party specifying the breach. Notwithstanding the foregoing, if the allegedly breaching Party in good faith disputes such material breach and provides written notice of that dispute to the other Party within such sixty (60) day period, the matter shall be addressed under the dispute resolution provisions in Section 14.3, and the termination shall not become effective unless and until the allegedly breaching Party has been determined under Section 14.3 to be in material breach of this Agreement and has failed to cure such breach within the time period provided in this Section13.2. It is understood and acknowledged that during the pendency of such a Dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

13.3 Termination by SAVARA.

13.3.1 Non-Commercialization of Product. SAVARA may terminate this Agreement immediately upon written notice to GEMA if: (a) SAVARA, in its sole discretion, determines that API or Products incorporating API shall not be marketed or shall be withdrawn from the market; or (b) the FDA or other Regulatory Authority withdraws marketing approval for, or fails to approve, the Manufacturing or marketing of API or Products incorporating API or SAVARA reasonably believes that the FDA or other Regulatory Authority will take (or, as context requires, fail to take) any such action.

13.3.2 Failure to Meet Regulatory Requirements. Without limiting any other provision of this Agreement, SAVARA shall have the right to terminate this Agreement immediately by written notice to GEMA if: (a) three (3) or more of lots or batches of API supplied in any six (6) month period fail to conform to the API Specifications; (b) GEMA receives an FDA Form 483 or Notice of Observation or other deficiency letter issued by a Regulatory Authority, in each case, relating to the API, its Manufacture or general manufacturing concerns (e.g., Manufacturing Facility compliance) and GEMA fails to respond adequately and to remedy to such deficiencies within a reasonable period of time thereafter (not to exceed ninety (90) days); (c) GEMA fails to respond adequately to any significant deficiencies in its Manufacturing and processing of API, as applicable, identified by SAVARA as a result of an inspection conducted pursuant to Sections 3.1, 7.1 or 7.2 above and to remedy such deficiencies within a reasonable period of time (not to exceed ninety (90) days) after GEMA's receipt of written notice thereof from SAVARA; or (c) fails to achieve Commercial Compliance by [***] prior to the Anticipated Launch Date.

13.4 Effects of Termination. Upon expiration or the termination of this Agreement for any reason whatsoever, the following shall apply:

13.4.1 SAVARA shall pay to GEMA (or, as may be applicable, GEMA shall return to SAVARA) all undisputed amounts due and payable up to the effective date of termination but not yet paid. Further upon the termination of this Agreement for any reason (except by GEMA for SAVARA's breach under Section 13.2 above), SAVARA shall have the obligation to purchase any API ordered in any then-outstanding Purchase Orders. Within thirty (30) days of the effective date of the expiration or termination of this Agreement or at such earlier time as SAVARA requests, GEMA shall notify SAVARA of any quantity of API or critical Materials remaining in GEMA's inventory and: (a) SAVARA shall have the option, upon notice to GEMA, to purchase any such quantities of API or critical Materials at: (i) in the case of API, the price that would have been payable for such API pursuant to the Pricing and Milestone Schedule immediately prior to the expiration or termination of this Agreement and subject to payment of royalties therefor in accordance with Section 6.3; and (b) in the case of any critical Materials, the price paid by GEMA to the applicable Supplier for such Materials.

13.4.2 GEMA shall promptly: (a) return to SAVARA or destroy, as directed by SAVARA, all SAVARA's Confidential Information (including all copies thereof); and (b) return to SAVARA all of the Cell Line (including the Working Cell Bank and Master Cell Bank) and all retention and reserve samples being held by GEMA. GEMA shall use diligent efforts to transition the Manufacture of API to another facility operated by SAVARA or its designee in a timely and orderly fashion; provided that SAVARA shall reimburse GEMA for the reasonable cost and expenses incurred by GEMA in fulfilling its obligations under this Section 13.4.2 as provided below. Such efforts shall include: (a) GEMA assigning or causing to be assigned to SAVARA or its designee (or, to the extent not so assignable, GEMA shall take all reasonable actions to make available to SAVARA or its designee the benefits of) any Regulatory Filings relating to the Manufacture of API for SAVARA that are not specific to the Manufacturing Facility; (b) to the extent not previously made available to SAVARA under this Agreement or any other agreement between the Parties relating to API, GEMA providing SAVARA with access to and the right to use in connection with the Manufacture of API (and to authorize the use of the same by its Affiliates and/or Third Parties for such purposes) any existing know-how or other Confidential Information of GEMA specifically directed to API or the Manufacture of API; and (c) GEMA reasonably cooperating with and assisting SAVARA and/or its designee as may be necessary or desirable in order to allow SAVARA to understand and utilize the know-how described in clause (b) above for the purposes described therein, including making reasonably available to SAVARA GEMA's personnel to answer questions regarding the same. If this Agreement is terminated by SAVARA pursuant to Section 13.3.1 or by GEMA pursuant to Section 13.2 as a result of SAVARA's breach, SAVARA shall reimburse GEMA for: (i) its direct, out-of-pocket costs incurred with respect to: (A) the assignment of Regulatory Filings pursuant to clause (a) above; (B) the provision of know-how or other Confidential Information of GEMA pursuant to clause (b) above (to the extent that GEMA did not otherwise have an obligation to SAVARA under this Agreement or any other agreement between the Parties relating to the API to provide such items without any cost to SAVARA) and/or (C) otherwise complying with the first sentence of this Section 13.4.2; and (ii) any direct, out-of-pocket costs incurred by GEMA in the provision of assistance to SAVARA in accordance with clause (c) above. If this Agreement is terminated by SAVARA pursuant to Sections 13.2 or 13.3.2, GEMA shall be solely responsible for any costs incurred in performing its obligations under this Section 13.4.2. If this Agreement is terminated by either Party pursuant to Section 14.1 below, the Parties shall share equally in any costs incurred by GEMA in performing its obligations under this Section 13.4.2.

13.5 Survival. Expiration or termination of this Agreement for any reason shall not affect the rights and obligations of either Party that may have accrued prior to the date of such expiration or termination, or any rights or obligations of a Party contained in Articles 1, 7-10 (inclusive), 12 and 14 and Sections 2.4, 3.6, 11.4, 13.4 and 13.5.

ARTICLE 14
MISCELLANEOUS

14.1 Force Majeure. No Party shall be responsible to the other under this Agreement for failure or delay in performing any obligations under this Agreement, other than payment obligations, due to factors beyond its reasonable control, including war, terrorism, sabotage, revolution, riot or civil commotion, strikes, lock-outs, failure of supplies of power or fuel, explosion, fire, flood, natural disaster or act of God, each to the extent the same are beyond the reasonable control of the affected Party (each such factor, an "**Event of Force Majeure**"). Upon the occurrence of an Event of Force Majeure, the Party failing or delaying performance shall promptly notify the other Party in writing, setting forth the nature of the occurrence, its expected duration, and how that Party's performance is affected. Any Party subject to an Event of Force Majeure shall resume performing its obligations under this Agreement as soon as practicable. Except as otherwise provided herein, if an Event of Force Majeure occurs, the affected Party shall be excused from performing and the time for performance shall be extended as long

as that Party is unable to perform as a result of the Event of Force Majeure. Notwithstanding the foregoing, if an Event of Force Majeure continues, or is reasonably expected to continue, for a period of ninety (90) days or more, and such Event of Force Majeure substantially impairs the affected Party's performance of its obligations under this Agreement (including, but not limited to, delivery of each Product), the Party whose performance is not affected by the Event of Force Majeure shall have the right and option to terminate this Agreement upon written notice thereof to the other Party.

14.2 Governing Law; Venue. This Agreement, and all questions regarding its validity or interpretation, or the breach or performance of this Agreement, will be governed by, and construed and enforced in accordance with, the laws of Ireland, without reference to conflict of law principles. The Parties hereby agree that the provisions of the U.N. Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded.

14.3 Dispute Resolution.

14.3.1 Referral to Senior Management. The Parties agree to attempt initially to seek to resolve any dispute, claim or controversy arising under, out of, or in connection with this Agreement (a "**Dispute**") by conducting good faith negotiations. Except with respect to any Dispute described in Section 5.4 above which shall be resolved in accordance with the procedures described therein, any Dispute which cannot be resolved by good faith negotiation within twenty (20) days (or as otherwise specified in this Agreement), shall be referred, by written notice from either Party to the other, to the Chief Executive Officer, or authorized representative designated by the Chief Executive Officer, of each Party. Such Chief Executive Officers (or their respective designees) shall negotiate in good faith to resolve such Dispute through discussions promptly following such written notice, and in any event within fifteen (15) days thereafter. If the Chief Executive Officers of the Parties (or their respective designees) are unable to resolve the Dispute within thirty (30) days after the date of the notice referring such Dispute to the Chief Executive Officers for resolution, either Party may, by written notice to the other Party, invoke the provisions of Section 14.3.2. Unless expressly set forth in this Agreement, all rights and remedies of the Parties will be cumulative and in addition to all other remedies provided for in this Agreement, in law and in equity.

14.3.2 Arbitration.

(a) Except as otherwise expressly provided in this Section 14.3.2, the Parties agree that if they are unable to resolve, in accordance with Section 14.3.1 above, any Dispute as to the breach, performance or interpretation of this Agreement, such Dispute shall, upon written notice of either Party to the other, be referred for resolution by final, binding arbitration in accordance with the provisions of this Section 14.3.2. The arbitration shall be conducted by JAMS under its rules of arbitration then in effect, except as modified in this Agreement. The arbitration shall be conducted in the English language, by a single arbitrator. The arbitrator shall engage an independent expert with experience in the subject matter of the Dispute to advise the arbitrator.

(b) With respect to any Dispute referred to arbitration pursuant to Section 14.3.2(a) above, the Parties and the arbitrator shall use all reasonable efforts to complete any such arbitration within six (6) months from the issuance of notice of a referral of any such Dispute to arbitration. The arbitrator shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the Parties must expend for discovery; provided that the arbitrator shall permit such discovery as he or she deems necessary to permit an equitable resolution of the Dispute.

(c) The Parties agree that the decision of the arbitrator shall be the sole, exclusive and binding remedy between them regarding the Dispute presented to the arbitrator. Any decision of the arbitrator may be entered in a court of competent jurisdiction for judicial recognition of the decision and an order of enforcement. The arbitration proceedings and the decision of the arbitrator shall not be made public without the joint consent of the Parties and each Party shall maintain the confidentiality of such proceedings and decision, unless each Party otherwise agrees in writing; provided that either Party may make such disclosures as are permitted for Confidential Information of the other Party under Article 10 above.

(d) Unless otherwise mutually agreed upon by the Parties, the arbitration proceedings shall be conducted in Ireland. The Parties agree that they shall share equally the cost of the arbitration filing and hearing fees, the cost of the independent expert retained by the arbitrator, and the cost of the arbitrator and administrative fees of JAMS. Each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses.

(e) Pending the selection of the arbitrator or pending the arbitrator's determination of the merits of any Dispute, either Party may seek appropriate interim or provisional relief from any court of competent jurisdiction as necessary to protect the rights or property of that Party.

14.4 Assignment. Neither Party may assign or otherwise transfer this Agreement, or its rights or obligations hereunder, without the prior written consent of the other Party; except that SAVARA may assign this Agreement without such consent from GEMA: (a) to an Affiliate; (b) to any successor to all or substantially all of SAVARA's assets or business to which this Agreement pertains (whether by stock purchase, asset purchase, merger, operation of law or otherwise); or (c) in the event of its merger, consolidation, change of control or similar transaction; provided that, in each case, SAVARA shall provide prompt written notice to GEMA following such assignment. In addition, SAVARA shall have the right, upon written notice to GEMA, to authorize any licensee of SAVARA's rights in and to a Product to order and purchase API from GEMA under this Agreement; provided that such licensee agrees in writing to comply with the applicable obligations of SAVARA hereunder with respect to the ordering and purchasing of such API. Any purported assignment in violation of this Section 14.4 will be null and void. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

14.5 Notices. All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file), and sent as an attachment to an e-mail message, where, when such message is received, a read receipt e-mail is received by the sender (and such read receipt e-mail is preserved by the Party sending the notice), provided further that a copy is promptly sent by an internationally recognized overnight delivery service (receipt requested) (although the sending of the e-mail message shall be when the notice is deemed to have been given), or (b) the earlier of when received by the addressee or five (5) days after it was sent, if sent by registered letter or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):

If to SAVARA:
Savara ApS
c/o Savara Inc.
6836 Bee Cave Road
Building 3, Suite 200
Austin, TX 78746
Email:rob.neville@savarapharma.com
Attention: Chief Executive Officer

If to GEMA:
GEMABIOTECH SAU
Fray Justo Sarmiento 2350
Edificio 2B, Piso 5°
Olivos, Province of Buenos Aires
Argentina
Email:frivera@amegabiotech.com
Attention: General Manager

14.6 Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. In the event of any conflict between the main body of this Agreement and any Exhibit hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (b) the word "day" or "year" means a calendar day or year unless otherwise specified; (c) the word "notice" shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (e) the words "shall" and "will" have interchangeable meanings for purposes of this Agreement; (f) the word "or" shall have the inclusive meaning commonly associated with "and/or"; (g) provisions that require that a Party, the Parties or a committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (h) words of any gender include the other gender; (i) words using the singular or plural number also include the plural or singular number, respectively; (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.

14.7 Waiver. Except as otherwise expressly provided in this Agreement, as applicable, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

14.8 Severability. If any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

14.9 Independent Contractors. It is expressly agreed that SAVARA and GEMA shall be independent contractors and that the relationship between the two Parties established by this Agreement shall not constitute a partnership, joint venture or agency or other fiduciary relationship. Neither SAVARA nor GEMA shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

14.10 Entire Agreement; Amendment. This Agreement (including the Schedules and Exhibits attached hereto) and each Quality Technical Agreement (when such agreement has been executed) constitute the entire understanding between the Parties with respect to the subject matter hereof and supersede all previous or contemporaneous communications, representations, agreements or understandings, either oral or written, between the Parties with respect to such subject matter, including the Original Supply Agreement and that certain Letter of Intent for a Commercial Supply Agreement between the Parties dated May 28, 2018. No agreement or understanding amending this Agreement will be binding upon either Party unless set forth in a writing which specifically refers to this Agreement and is signed by a duly authorized representative of each Party.

14.11 Export. Each Party acknowledges that the laws and regulations of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other Party in any form without appropriate United States and foreign government licenses.

14.12 Counterparts; Facsimile Signatures. This Agreement (and any amendments hereto) may be executed in counterparts, all of which will constitute one instrument. Signatures to this Agreement delivered by facsimile or similar electronic transmission will be deemed to be binding as originals.

[Remainder of this page is intentionally left blank; signature page follows.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

SAVARA APS	**GEMABIOTECH SAU**
By: /s/ Rob Neville_____	By: /s/ Federico Martin Rivera_____
	/s/ Diego de Souza Morales_____
Name:Rob Neville	Name:Federico Martin Rivera/ Diego de Souza Morales
Title:Chief Executive Officer	Title:General Manager/CFO

List of Exhibits[1]

Exhibit 1.3	**API** [Intentionally omitted.]
Exhibit 1.4	**API Specifications** [Intentionally omitted.]
Exhibit 1.11	**Master Cell Bank** [Intentionally omitted.]
Exhibit 3.1	**Manufacturing Facility Compliance** [Intentionally omitted.]
Exhibit 3.5	**Quality Technical Agreement** [Intentionally omitted.]
Exhibit 4.2	**Rolling Forecast** [Intentionally omitted.]
Exhibit 5.1	**Storage of API** [Intentionally omitted.]
Exhibit 6.1	**Pricing and Milestone Schedule**
Exhibit 6.3	**Royalties**

1 Omitted exhibits to be provided to the Securities and Exchange Commission upon request.

Exhibit 6.1
Pricing and Milestone Schedule

Purchase Price of API:

Prior to Market Authorization: $[***] per gram of Molgramostim API
Following Market Authorization: $[***] per gram of Molgramostim API

Milestone Payments

	Milestone Event	Activities	Milestone Payment (in USD)
1 [***]	Effective date of the Agreement	Batch N°18-GMCF-031-010 Release Batch N°18-GMCF-031-010 Samples Characterization	$[***]
2 [***]	Validations stage 1 completion	Protocol for Upstream Characterization Upstream Characterization Final Report Protocol for Downstream Characterization Downstream Characterization Final Report	$[***]
3 [***]	Validations of analytical method completion	New Analytical Methods Development Report New Analytical Methods Development SOPs Validation or Revalidation of IPC Protocol Validation or Revalidation of IPC Final Report Validation or Revalidation of Analytical Techniques for DS Protocols Validation or Revalidation of Analytical Techniques for DS Final Report	$[***]
4 [***]	Validations stage 2 completion	Reference standard, manufacturing and testing protocol Reference standard, manufacturing and report Stability study protocol Stability study start-up Protocols for Validation GMP batch Validation of GMP batch (including 3 batches –up to120 gr) CoA Validation of GMP batch Final Report	$[***]
5 [***]	Approval of FDA Audit	EQMS (Enterprise Quality Management Software) Validation EQMS (Enterprise Quality Management Software) Implementation HVAC: Modification and Replacement Redundant System Chilled Water Modification Supervision and Control System (Honeywell) GAP analysis completion report	$[***]
6 [***]	Marketing Authorization		$[***]
Total Potential Milestone Payments			$[***]

Exhibit 6.3
Royalties

On a Supplied Product-by-Supplied Product and country-by-country basis, beginning upon first receipt of marketing approval by SAVARA from a Regulatory Authority in such country for a Supplied Product for therapeutic use in humans and ending the earlier of (a) ten (10) years thereafter or (b) the date a Biosimilar of such Supplied Product is first sold in such country, SAVARA shall pay GEMA a royalty of [***] of the Net Sales in such country. For purposes of this Exhibit 6.3:

1. "Biosimilar" means, with respect to a Supplied Product, a biological product that is licensed and/or approved by a Regulatory Authority based on a showing that it is highly similar to such Supplied Product and has no clinically meaningful differences in safety and efficacy.

2. "Net Sales" means the gross invoiced price of Supplied Products sold by SAVARA, its Affiliates or its sublicensees (each, a "Selling Party") to independent third parties exclusively for money, less deductions of:

    a. any costs of insurance, carriage and freight, other transportation expenses, and other charges or fees related to the handling or distribution of Supplied Products;

    b. taxes (including, without limitation, any GST, value added, use, consumption, excise or sales taxes) duties (including, without limitation, any import duties or similar applicable government levies) and other governmental charges related to the production, sale, transportation, import, export, delivery or use of Supplied Products;

    c. cash, trade, quantity and usual and other customary discounts to the extent such are on account of sales of Supplied Products;

    d. rebates and chargebacks paid to individual or group purchasers of Supplied Products, including customers, wholesalers, distributors or resellers, to the extent such are on account of the purchase of such Supplied Products, including as required by law under any governmental special medical assistance or reimbursement programs;

    e. allowances and credits issued or amounts repaid for returns of Supplied Products recalled, returned or not accepted by customers, spoiled, damaged or outdated or for price adjustments, billing errors or retroactive price reductions; and

    f. amounts reserved and credited for uncollectable accounts with respect to invoiced amounts.

    Subject to the above, Net Sales shall be calculated in accordance with U.S. Generally Accepted Accounting Principles and the standard internal policies and procedures of the applicable Selling Party.

    Net Sales shall not include sales or other transfer between or among SAVARA or its Affiliates or sublicensees, provided that if a Selling Party further sells such Supplied Product to a non-Selling Party, Net Sales shall include the amounts invoiced by such Selling Party.

Notwithstanding the foregoing, the provision of Supplied Product transferred as samples or for the purpose of conducting research and development activities, including, without limitation, pre-clinical or clinical purposes, as samples or in compassionate use programs and as donations to non-profit institutions or government agencies, shall not be deemed to be a sale giving rise to Net Sales.

If any Supplied Product is sold as part of a combination product (being a product containing both a Supplied Product and one or more other active ingredients or a product in which both Supplied Product and one or more other active ingredients are packaged), the Net Sales from the combination product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the combination product (as defined in the standard Net Sales definition), during the applicable royalty period, by the fraction, A/(A+B), where A is the average per unit sale price of Supplied Product when sold separately as a stand-alone product in finished form in the country in which the combination product is sold and B is the average per unit sale of the other active ingredients contained in the combination product when sold separately as stand-alone products in finished form in the country in which the combination product is sold, in each case during the applicable royalty reporting period or, if sales of stand-alone Supplied Product or such other product did not occur in such period, then in the most recent royalty reporting period in which arm's length fair market sales of such Supplied Products or other product, as applicable, occurred. If such average sale price cannot be determined for the stand alone Supplied Products or the other products, Net Sales for the purposes of determining royalty payments shall be mutually agreed upon by the Parties based on the relative value contributed by each component, such agreement not to be unreasonably withheld.

3. "Supplied Product" means product incorporating API supplied to SAVARA by GEMA hereunder.

Exhibit 31.1

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

I, Robert Neville, 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 9, 2019

/s/ Robert Neville
Robert Neville
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

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

I, David Lowrance, certify that:

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

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

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

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

a. Designed such disclosure controls and procedures, or caused such disclosure controls and 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 9, 2019

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

Exhibit 32.1

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

In connection with the Quarterly Report of Savara Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Neville, 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.

March 9, 2019

/s/ Robert Neville
Robert Neville
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, 2019, 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 9, 2019

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