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, 2020

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) 614-1848
(Registrant's telephone number, including area code)

N/A

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

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

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

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

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

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

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

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

As of May 4, 2020, the registrant had 52,187,063 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

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

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 34,515	$ 49,804
Short-term investments	70,472	71,957
Prepaid expenses and other current assets	2,458	2,306
Total current assets	107,445	124,067
Property and equipment, net	294	352
In-process R&D	10,930	11,111
Other non-current assets	1,306	673
Total assets	$ 119,975	$ 136,203
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,227	$ 3,409
Accrued expenses and other current liabilities	6,502	5,471
Debt facility	—	2,000
Total current liabilities	7,729	10,880
Long-term liabilities:		
Debt facility	24,731	23,112
Other long-term liabilities	199	513
Total liabilities	32,659	34,505
Stockholders' equity:		
Common stock, $0.001 par value, 200,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 50,844,504 and 50,790,441 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	52	52
Additional paid-in capital	310,705	309,555
Accumulated other comprehensive loss	(128)	(17)
Accumulated deficit	(223,313)	(207,892)
Total stockholders' equity	87,316	101,698
Total liabilities and stockholders' equity	$ 119,975	$ 136,203

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,	
	2020	**2019**
Operating expenses:		
Research and development	$ 13,200	$ 10,019
General and administrative	2,982	2,763
Depreciation and amortization	58	138
Total operating expenses	16,240	12,920
Loss from operations	(16,240)	(12,920)
Other income, net:		
Interest expense, net	(160)	(20)
Foreign currency exchange gain (loss)	156	(59)
Tax credit income	821	964
Change in fair value of financial instruments	2	(77)
Total other income	819	808
Loss before income taxes	(15,421)	(12,112)
Income tax benefit	—	—
Net loss	$ (15,421)	$ (12,112)
Net loss per share:		
Basic and diluted	$ (0.27)	$ (0.34)
Weighted average common shares outstanding:		
Basic and diluted	57,364,265	36,016,406
Other comprehensive loss:		
Loss on foreign currency translation	(128)	(225)
Unrealized gain on short-term investments	17	26
Total comprehensive loss	$ (15,532)	$ (12,311)

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, 2020 and 2019
(In thousands, except share amounts)
(Unaudited)

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

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

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (15,421)	$ (12,112)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization including right-of-use assets	242	307
Acquired in-process research and development (Note 7)	5,367	—
Changes in fair value of financial instruments	(2)	77
Change in fair value of contingent consideration	—	133
Noncash interest (income) expense	133	(4)
Foreign currency (gain) loss	(156)	59
Amortization of debt issuance costs	134	147
Accretion on discount to short-term investments	(69)	(342)
Stock-based compensation	1,194	1,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(195)	69
Non-current assets	(821)	(953)
Accounts payable and accrued expenses and other current liabilities	(3,180)	953
Long-term liabilities	(305)	(193)
Net cash used in operating activities	$ (13,079)	$ (10,859)
Cash flows from investing activities:		
Purchase of property and equipment	(4)	(96)
Purchase in-process research and development (Note 7)	(3,247)	—
Purchase of available-for-sale securities, net	(35,614)	(46,035)
Maturities of available-for-sale securities	31,300	42,800
Sale of available-for-sale securities, net	5,780	10,651
Net cash (used in) provided by investing activities	$ (1,785)	$ 7,320
Cash flows from financing activities:		
Issuance of common stock upon at the market offerings, net	$ —	$ 4,890
Repayment of debt facility	(514)	—
Proceeds from exercise of stock options	48	6
Net cash (used in) provided by financing activities	$ (466)	$ 4,896
Effect of exchange rate changes on cash and cash equivalents	41	13
Increase (decrease) in cash and cash equivalents	$ (15,289)	$ 1,370
Cash and cash equivalents beginning of period	49,804	24,301
Cash and cash equivalents end of period	$ 34,515	$ 25,671
Non-cash transactions		
Acquisition of in-process research and development (Note 7)	$ (2,120)	$ —
Supplemental disclosure of cash flow information:		
Cash paid for interest and end of period charge due upon debt facility amendment	$ 990	$ 528

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

1. Description of Business and Basis of Presentation

Description of Business

Savara Inc. (together with its subsidiaries "Savara," the "Company," "we" or "us") is an orphan lung disease company with a pipeline that comprises three investigational compounds, all of which use an inhaled delivery route. The Company's lead program, Molgradex, is an inhaled granulocyte-macrophage colony-stimulating factor ("GM-CSF") in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP") and in Phase 2a development for nontuberculous mycobacterial ("NTM") lung infection in both non-cystic fibrosis ("CF") and CF-affected individuals. Apulmiq is an inhaled liposomal ciprofloxacin in Phase 3 development for non-CF bronchiectasis ("NCFB"). AeroVanc is an inhaled vancomycin in Phase 3 development for persistent methicillin-resistant Staphylococcus aureus ("MRSA") lung infection in people 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, 2019. 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, 2020, and its results of operations for the three months ended March 31, 2020 and 2019, and cash flows for the three months ended March 31, 2020 and 2019. 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, 2020 or for any other future annual or interim period. The December 31, 2019 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, 2019.

2. Summary of Significant Accounting Policies

Liquidity

As of March 31, 2020, the Company had an accumulated deficit of approximately $223.3 million. The Company also had negative cash flow from operations of approximately $13.1 million during the three months ended March 31, 2020. 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 is also continuously and critically reviewing our liquidity and anticipated capital requirements in light of the uncertainty resulting from the COVID-19 global pandemic. 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 with partner companies. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders.

While the Company had cash and cash equivalents of $34.5 million and short-term investments of $70.5 million as of March 31, 2020, the Company intends to continue to raise additional capital as needed through the issuance of additional equity securities and potentially through borrowings, and strategic alliances with partner companies. However, if such 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 (loss)." 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 and general and administrative costs, certain financial instruments recorded at fair value, contingent consideration, stock-based compensation, and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Accordingly, actual results could be materially different from those estimates.

Risks and Uncertainties

The product 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 and institutional bank money market accounts 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 (loss)" 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.

License and Collaboration Agreements

The Company enters into license and collaboration agreements with third parties whereby the Company purchases the rights to develop, market, sell and/or distribute the underlying pharmaceutical products or drug candidates. Pursuant to these agreements, the Company is generally required to make up-front payments, milestone payments contingent upon the achievement of certain pre-determined criteria, royalty payments based on specified sales levels of the underlying products and/or certain other payments. Up-front payments are either expensed immediately as research and development or capitalized. The determination to capitalize amounts related to licenses is based on management's judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products, and/or various other competitive factors. Milestone payments made prior to regulatory approval are generally expensed as incurred and milestone payments made subsequent to regulatory approval are generally capitalized as an intangible asset. Royalty payments are expensed as incurred. Other payments made pursuant to license and collaboration agreements, which are generally related to research and development activities, are expensed as incurred.

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

Although the Company does not have any goodwill as of March 31, 2020, it has adopted the following accounting policy. 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. Current 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 (quantitative calculation of 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. For instance, based upon the ultimate scope and scale of the COVID-19 global pandemic, there may be materially negative impacts to the assumptions made with respect to our IPR&D assets that could result in an impairment of such assets. For the three months ended March 31, 2020, the impact of COVID-19 did not trigger any impairment indicators.

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. For the three months ended March 31, 2020, the Company experienced a decrease of approximately $0.2 million in the carrying value of IPR&D, which was due to foreign currency translation.

Tax Credit Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS, as of March 31, 2020. 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, 2020, credits totaling $1.6 million had been generated but not yet received. Of this total Danish tax credit, $0.8 million is related to research and development activities incurred during the year ended December 31, 2019 and is recorded in “Prepaid expenses and other current assets” and expected to be received in the fourth quarter of 2020. The remaining portion of the Danish tax credit of $0.8 million, which was generated during the three months ended March 31, 2020, is recorded in “Other non-current assets” and is expected to be received in the fourth quarter of 2021.

The Company also recognized tax credit income for the three months ended March 31, 2020 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, 2020, credits totaling $0.5 million had been generated but not yet received. Of this total Australian tax credit, $0.4 million is related to research and development activities incurred during the year ended December 31, 2019 and is recorded in “Prepaid expenses and other current assets” and expected to be received during the year ending December 31, 2020. The remaining portion of the Australian tax credit of $0.1 million, which was generated during the three months ended March 31, 2020, is recorded in “Other non-current assets” and is expected to be received during the year ended December 31, 2021.

Leases

In February 2016, the FASB issued Accounting Standards Update (“ASU”) 2016-02, “Leases (Topic 842)” (“ASU 2016-02”) as codified in Accounting Standards Codification (“ASC”) 842 (“ASC 842”). ASU 2016-02, ASC 842, and additional issued guidance 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 11). 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 activities 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 (See Note 11).

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.

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, 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, which includes certain milestone payments to be remunerated by the licensee to Savara. In exchange, the Company granted the licensee an exclusive right to import, market, sell, distribute and promote Molgradex in Japan for the treatment of aPAP. 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.

In October 2018, the Company achieved a milestone payment pursuant to this license agreement resulting in the receipt of $0.3 million from the licensee. As of March 31, 2020, the Company has determined that it has not met all of the performance obligations under this 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. On February 21, 2020, the Company received notification from the licensee of its intent to terminate this license agreement. Accordingly, this license agreement shall terminate on August 21, 2020 upon which the Company shall recognize revenue related to this $0.3 million milestone payment.

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 12). Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise.

Manufacturing, Development, and Other Commitments and Contingencies

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

Under a license and collaboration agreement for the rights to develop and commercialize Apulmiq, the Company is subject to certain contingent development payments and contingent sales payments due to the licensor upon the achievement of certain milestones up to amounts as set forth in the following table (see Note 7). The Company will also owe the licensor low double-digit tiered royalties based on annual global net sales of licensed products (on a product-by-product basis), which are subject to reduction if another inhaled ciprofloxacin product is introduced into the market.

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. The change in the amount of the milestone payments from December 31, 2019 to March 31, 2020 was related to changes in foreign currency exchange rates and the accrual of a milestone equal to approximately $0.2 million due to the completion of our Phase 2a study of the use of Molgradex for the treatment of NTM in patients not affected by CF. Furthermore, milestone payments totaling 4.3 million euros relate to types of nebulizer delivery systems that are not currently being utilized in any of the studies in our development pipeline. 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, Development, and Other Contingent Milestone Payments (in thousands):

	March 31, 2020
Molgradex API manufacturer:	
Achievement of certain milestones related to validation of API and regulatory approval of Molgradex	$ 2,300
Molgradex nebulizer manufacturer:	
Achievement of various development activities and regulatory approval of nebulizer utilized to administer Molgradex	7,331
Medical education and research foundation (Molgradex):	
First commercial sale in the U.S. of Molgradex in treatment of NTM	500
Apulmiq Licensor:	
Achievement of various development activities and regulatory approval of Apulmiq for the treatment of NCFB	50,000
Achievement of various sales activities of Apulmiq for treatment of NCFB	100,000
Total manufacturing and other commitments	**$ 160,131**

The milestone commitments disclosed above reflect the activities that have (i) not been met or incurred; (ii) not been remunerated; and (iii) not accrued, as the activities are not deemed probable or reasonably estimable, as of March 31, 2020.

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 February 2020, the FASB issued ASU 2020-02, “Financial Instruments—Credit Losses (Topic 326) and Leases (Topic 842)—Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update 2016-02, Leases (Topic 842) (SEC Update).” The company has reviewed ASU 2020-02 and concluded that it does not have a material impact on our condensed consolidated financial statements.

In March 2020, the FASB issued ASU 2020-03, “Codification Improvements to Financial Instruments,” which addressed various issues including the following: (i) clarification that all entities are required to provide the (“ASU 2020-03”) fair value option disclosures in paragraphs 825-10-50-24 through 50-32 of the FASB’s ASC, (ii) clarification that the contractual term of a net investment in a lease determined in accordance with ASC 842, “Leases,” should be the contractual term used to measure expected credit losses under ASC 326, “Financial Instruments – Credit Losses,” and (iii) amendment of ASC 860-20, “Transfers and Servicing – Sales of Financial Assets,” clarifying that when an entity regains control of financial assets sold, an allowance for credit losses should be recorded in accordance with ASC 326. The Company has reviewed ASU 2020-3 and concluded that it does not have a material impact on our condensed consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, “Reference Rate Reform (Topic 848)” which provides optional guidance for a limited period of time to ease the potential burden in accounting for the effects of the transition away from LIBOR and other reference rates.” The company has reviewed ASU 2020-04 and concluded that it has no impact on our condensed consolidated financial statements.

3. Prepaid expenses and other current assets

Prepaid expenses consisted of (in thousands):

	March 31, 2020	December 31, 2019
R&D tax credit receivable	$ 1,233	$ 1,253
Prepaid contracted research and development costs	422	184
VAT receivable	356	364
Prepaid insurance	86	247
Foreign currency exchange derivative	—	7
Deposits and other	361	251
Total prepaid expenses and other current assets	**$ 2,458**	**$ 2,306**

4. Accrued expenses and other current liabilities

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

	March 31, 2020	December 31, 2019
Accrued contracted research and development costs	$ 2,100	$ 2,018
Accrued general and administrative costs	820	1,710
Accrued closing costs for previous issuance of securities in private placement	120	—
Accrued compensation	705	1,303
Foreign currency exchange derivative	88	—
Deferred revenue	238	—
Common stock due for in-licensing of development and commercialization rights	2,120	—
Lease liability	311	440
Total accrued expenses and other current liabilities	**$ 6,502**	**$ 5,471**

5. Short-term Investments

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

As of March 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 15,624	$ 121	$ —	$ 15,745
Asset backed securities	3,027	—	—	3,027
Corporate securities	25,395	6	(62)	25,339
Commercial paper	26,361	—	—	26,361
Total short-term investments	**$ 70,407**	**$ 127**	**$ (62)**	**$ 70,472**

As of December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 15,629	$ 11	$ (2)	$ 15,638
Asset backed securities	8,789	10	—	8,799
Corporate securities	30,556	30	(1)	30,585
Commercial paper	16,935	—	—	16,935
Total short-term investments	**$ 71,909**	**$ 51**	**$ (3)**	**$ 71,957**

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 (loss)" 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, 2020 and March 31, 2019.

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 and December 4, 2018 (the "Loan Agreement"). The Company executed a third amendment (the "Third Amendment") to the Loan Agreement on January 31, 2020, which provides for a $25 million term debt facility. The Third Amendment extends the interest-only period of the loan repayment through June 30, 2022, with payments thereafter in equal monthly installments of principal plus interest over 18 months. However, if by March 31, 2021, the Company does not have an ongoing Phase 3 or Phase 4 clinical trial evaluating its Molgradex product for the treatment of aPAP in which the first patient has been dosed, the interest-only period will end and principal plus interest will be due in equal monthly installments over 24 months beginning on April 1, 2021.

Following the effective date of the Third Amendment, the Company was required to pay a portion of the end of period charge equal to $0.5 million under the Loan Agreement to Silicon Valley Bank. The loans bear interest at the greater of (i) the prime rate reported in The Wall Street Journal, plus a spread of 3.0% or (ii) 7.75%. The Loan Agreement, as amended by the Third Amendment (the "Amended Loan Agreement") will also require a prepayment fee (2.0% of funded amounts in months 13-24, and 1.0% thereafter), and an end of term charge equal to 6.0% of the amount of principal borrowed.

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 Amended 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. In addition, the Amended Loan Agreement contains an affirmative covenant requiring Savara to deliver evidence by June 30, 2021, of the receipt of gross cash proceeds of at least $25 million from the exercise of currently outstanding warrants or the issuance of other equity securities.

Pursuant to the execution and funding of the Loan Agreement and subsequent amendments, the Company issued Silicon Valley Bank and its affiliate warrants to purchase (i) 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"); (ii) 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"); and (iii) 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 warrants were valued using the Black-Scholes-Merton option pricing model at the respective issue date, and the collective fair value of the warrants has been recorded as a debt discount which is being amortized through interest expense using the effective interest method through the scheduled maturity date.

In connection with the execution of the Third Amendment, the Company entered into amendments to each of the outstanding warrants previously issued to Silicon Valley Bank and its affiliate, totaling 77,793 shares, to amend the exercise price to be $2.87 per share. That amendment results in a minimal incremental increase to the fair value of these warrants, determined in accordance with the Black-Scholes-Merton option pricing model and ASC 718-20-55, which has been recognized as interest expense.

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

The Company has analyzed the Third Loan Amendment and concluded that the debt restructuring results in modification accounting under ASC 470 "Simplifying the Classification of Debt in a Classified Balance Sheet (Current versus Noncurrent)."

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, 2020	
	Short-term	**Long-term**
Principal payments to lender and end of term charge	$ —	$ 25,064
Debt Issuance costs		$ (189)
Debt discount related to warrants	—	(144)
Carrying Value	$ —	$ 24,731

The carrying value of the debt facility approximates fair value.

7. Apulmiq License Agreement

On January 7, 2020, the Company entered into a license and collaboration agreement with Grifols, S.A., a company organized under the laws of Spain ("Grifols"), which was subsequently amended on February 18, 2020 and March 31, 2020 (the "License"). On March 31, 2020, the final condition precedent to the effectiveness of the License was satisfied, and the License became effective.

The License provides Savara with an exclusive, worldwide, royalty-bearing license, with rights to sublicense, patent rights owned or controlled by Grifols (the "Grifols Patents") and know-how owned or controlled by Grifols to make, have made, use, develop, import and export, supply, offer for sale, and sell or otherwise commercialize pharmaceutical preparations containing ciprofloxacin in a liposomal formulation and/or ciprofloxacin that is not encapsulated in liposomes (each such pharmaceutical preparation a "Licensed Product") for all uses.

Under the License, the Company has sole responsibility for the activities and costs related to the development of (1) a Licensed Product for the treatment of either NCFB or pulmonary infections associated with NCFB (the "Initial Indication") and (2) any Licensed Product for another indication, of which none are currently approved, (an "Additional Indication"), including the conduct of a confirmatory Phase 3 clinical trial in the Initial Indication. The Company is responsible for all regulatory and commercialization activities and the associated costs for each Licensed Product and is obligated to use Diligent Efforts (as defined in the License) to obtain regulatory approval in the U.S. and E.U. of a Licensed Product in the Initial Indication and any Additional Indications.

The Company agreed to pay Grifols (i) an upfront cash payment of approximately $3.3 million and (ii) an upfront payment of one million shares of the Company's common stock valued at approximately $2.1 million on the date of issuance (the "Consideration Shares") upon effectiveness of the License, (collectively the "Upfront Payments"). The Company also agreed to pay Grifols (i) certain developmental milestone payments totaling up to $50 million for the development of the Licensed Products for the treatment of NCFB upon approval of a Licensed Product for commercial sale by the FDA and EMA and (ii) certain sales milestone payments totaling up to $100 million upon the first achievement of annual global net sales of (a) $100 million, (b) $300 million, and (c) $500 million (collectively, the "Contingent Consideration"). Additionally, the Company agreed to pay Grifols low double-digit tiered royalties based on annual global net sales of all Licensed Products, which are subject to reduction if another inhaled ciprofloxacin product is introduced into the market. The Company is obligated to make such royalty payments on a country-by-country and Licensed Product-by-Licensed Product basis until the later of (i) ten (10) years after the first commercial sale of a Licensed Product in a country, (ii) expiration of the last Grifols Patent covering that Licensed Product in that country, or (iii) the date a generic inhaled liposomal ciprofloxacin is introduced in that country (the "Royalty Term"). At the end of the Royalty Term, the Company will have a fully paid-up license for the applicable Licensed Product.

The Company has accounted for the License as an asset acquisition in accordance with ASU 2017-01 "Business Combinations (Topic 805) - Clarifying the Definition of a Business" and ASC 805 "Business Combinations." Since the Licensed Product has not yet achieved regulatory approval and there is deemed to be no alternative future use, the Company has recorded research and development expense of approximately $5.4 million for the Upfront Payments.

The Company has determined that the Contingent Consideration is currently neither probable nor can the amount be reasonably estimated, and therefore, no related liability has been recorded as of March 31, 2020.

The term of the License continues until the Royalty Term expires in all countries for all Licensed Products. Grifols may terminate the License immediately if (i) the Company or one of its affiliates files a challenge to a Grifols Patent or (ii) the Company fails to develop Licensed Products or execute its Development Plan (as defined in the License) by failing to allocate material funds, full-time equivalents and resources for twelve (12) consecutive months (net of any delay due to force majeure). Either party can terminate for the other party's material breach following a cure period or upon certain insolvency events. The License also contains customary representations, warranties, mutual indemnities, limitations of liability, and confidentiality provisions.

The Company also incurred approximately $0.5 million in legal fees in conjunction with the License of which $0.3 million and $0.2 million were incurred and expensed in the year ended December 31, 2019 and during the three months ended March 31, 2020, respectively.

8. 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 fair value of these instruments as of March 31, 2020 and December 31, 2019 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, 2020			
Cash equivalents:			
U.S. Treasury money market funds	$ 30,268	$ —	$ —
Short-term investments:			
U.S. government securities	$ 15,745	$ —	$ —
Asset backed securities	—	3,027	—
Corporate securities	—	25,339	—
Commercial paper	—	26,361	—
Other liabilities:			
Foreign exchange derivatives not designated as hedging instruments	$ —	$ 88	$ —
As of December 31, 2019			
Cash equivalents:			
U.S. Treasury money market funds	$ 13,530	$ —	$ —
Repurchase agreements	—	6,000	—
Short-term investments:			
U.S. government securities	$ 15,638	$ —	$ —
Asset backed securities	—	8,799	—
Corporate securities	—	30,585	—
Commercial paper	—	16,935	—
Other assets:			
Foreign exchange derivatives not designated as hedging instruments	$ —	$ 7	$ —

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 year ended December 31, 2019 as there were no Level 3 financial instruments for the three months ended March 31, 2020:

	Contingent Consideration
Balance at December 31, 2018	**$ 12,214**
Change in fair value	219
Settlement of contingent liability	(12,433)
Balance at December 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, 2020 and year ended December 31, 2019.

9. Derivative Financial Instruments

In the normal course of business, the Company is exposed to the impact of foreign currency fluctuations. The Company seeks to limit these risks by following risk management policies and procedures, including the use of derivatives. The Company's derivative contracts, which are not designated as hedging instruments, principally address short-term foreign currency exchange. The estimated fair value of the derivative contracts was based upon the relative exchange rate as of the balance sheet date. Accordingly, any gains or losses resulting from variances between this exchange rate and the exchange rate at the contract inception date were recognized in "Other income, net" in the condensed consolidated statements of operations and comprehensive loss. As of March 31, 2020, there was an asset of approximately $6 million consisting of unsettled forward exchange contracts to purchase foreign currency and a corresponding liability of approximately $6 million consisting of forward exchange contract obligations, resulting in a net derivative financial instrument of approximatley $0.1 million, recorded at their estimated fair value in "Accrued expenses and other current liabilities."

10. 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 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 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% 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, 2020, the Company did not sell any shares of common stock under the Sales Agreement.

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, 2020 and December 31, 2019.

	March 31, 2020	December 31, 2019
Common stock authorized	200,000,000	200,000,000
Common stock outstanding	50,844,504	50,790,441

The Company's shares of common stock reserved for issuance as of March 31, 2020 and December 31, 2019 were as follows:

	March 31, 2020	December 31, 2019
Warrants acquired in merger	403,927	403,927
Warrants converted in connection with merger	72,869	72,869
April 2017 Warrants	24,725	24,725
June 2017 Warrants	41,736	41,736
December 2018 Warrants	11,332	11,332
2017 Pre-funded Warrants	775,000	775,000
Pre-funded PIPE Warrants	5,780,537	5,780,537
Milestone Warrants	32,577,209	32,577,209
Stock options outstanding	4,473,477	4,541,432
Issued and nonvested RSUs	302,875	315,625
Total shares reserved	**44,463,687**	**44,544,392**

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of March 31, 2020:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
403,927	$	29.40	February 2021
72,869	$	8.98	June 2021
775,000	$	0.01	October 2024
24,725	$	2.87	April 2027
41,736	$	2.87	June 2027
11,332	$	2.87	December 2028
5,780,537	$	0.001	None
32,577,209	$	1.48	December 2021 or 30 days after clinical milestone
39,687,335			

11. 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 office space for our corporate headquarters in Austin, Texas. The term of the sublease 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 lease office space in Copenhagen, Denmark under a lease with an effective date of November 1, 2018 and that expires 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 quarter ended March 31, 2020, 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 December 31, 2019, annual rent under the sub-sublease is approximately $0.5 million, payable in monthly installments.

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, 2020 (in thousands):

Year ending December 31,		
2020		276
2021		183
2022		67
Total future minimum lease payments	**$**	**526**
Less imputed interest		(23)
Total	**$**	**503**

	For the three months ended March 31, 2020
Lease cost:	
Operating lease cost	$ 385
Sublease income	(136)
Total lease cost	**$ 249**
Other information:	
Operating cash flows from operating leases	$ 200
Weighted-average remaining lease term (in months) - operating leases	18.9
Weighted-average discount rate - operating leases	8.5%

As of March 31, 2020, the carrying value of the right-of-use assets for the operating leases was $0.5 million, which is reflected in “Other non-current assets,” and the carrying value of the lease liabilities for operating leases was $0.5 million, of which $0.3 million related to the current portion of the lease liabilities is recorded in “Accrued expenses and other current liabilities,” and $0.2 million related to the non-current portion of the lease liabilities is recorded in “Other long-term liabilities.”

Risk Management

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

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.

12. Stock-Based Compensation

A. Equity Incentive Plans

2008 Stock Option Plan

The Company adopted the Savara Inc. Stock Option Plan (the “2008 Plan”), pursuant to which the Company 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"), the amendment and restatement of which was 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, 2020, the number of shares of our common stock available for grant under the 2015 Plan was 298,853 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, 2020 and 2019:

	Three months ended March 31, 2020			Three months ended March 31, 2019		
	Stock Options	**RSUs**	**Total**	**Stock Options**	**RSUs**	**Total**
Outstanding as of December 31	**4,541,432**	**315,625**	**4,857,057**	**3,077,264**	**156,250**	**3,233,514**
Granted	12,000	—	12,000	90,000	—	90,000
Exercised	(41,313)	(12,750)	(54,063)	(23,593)	(13,125)	(36,718)
Forfeited	(38,642)	—	(38,642)	(9,844)	—	(9,844)
Outstanding as of March 31	**4,473,477**	**302,875**	**4,776,352**	**3,133,827**	**143,125**	**3,276,952**

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, 2020 and 2019 (in thousands):

	Three Months Ended	
	March 31, 2020	**March 31, 2019**
Research and development	$ 593	$ 452
General and administrative	601	548
Total stock-based compensation	**$ 1,194**	**$ 1,000**

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, 2020	March 31, 2019
Awards under equity incentive plan	4,473,477	3,133,827
Nonvested restricted shares and restricted stock units	302,875	143,125
Warrants to purchase common stock	33,131,798	901,502
Total	**37,908,150**	**4,178,454**

The following table calculates basic earnings per share of common stock and diluted earnings per share of common stock for the three months ended March 31, 2020 and 2019 (in thousands, except share and per share amounts):

	Three Months Ended	
	March 31, 2020	March 31, 2019
Net loss	$ (15,421)	$ (12,112)
Net loss attributable to common stockholders	(15,421)	(12,112)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	(15,421)	(12,112)
Weighted average common shares outstanding, basic and diluted	57,364,265	36,016,406
Basic and diluted EPS	**$ (0.27)**	**$ (0.34)**

The weighted average common shares outstanding, basic and diluted, for the three months ended March 31, 2020, includes one million shares due under the License (see Note 7), which were not issued to licensor until after March 31, 2020, and pre-funded warrants outstanding during the period.

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, natural disasters and pandemics (such as the scope, scale and duration of the impact of the novel coronavirus, COVID-19), and those discussed in the section entitled "Risk Factors" in this Quarterly Report on pages 31 through 54.

Overview

We are an orphan lung disease company with a pipeline that comprises three investigational compounds, all of which use an inhaled delivery route. Our lead program, Molgradex, is an inhaled granulocyte-macrophage colony-stimulating factor ("GM-CSF") in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP") and in Phase 2a development for nontuberculous mycobacterial ("NTM") lung infection in both non-cystic fibrosis ("CF") and CF-affected individuals. Apulmiq is an inhaled liposomal ciprofloxacin in Phase 3 development for non-CF bronchiectasis ("NCFB"). AeroVanc is an inhaled vancomycin in Phase 3 development for persistent methicillin-resistant Staphylococcus aureus ("MRSA") lung infection in people 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 product revenue from inception to date as we have not yet commenced commercial operations. From our inception to March 31, 2020, we have raised net cash proceeds of approximately $264 million from public offerings of common stock, private placements of convertible preferred stock and common stock, and debt financings.

We have never been profitable and have incurred operating losses in each year since inception. Our net losses were $15.4 million for the three months ended March 31, 2020 and $78.2 million for the year ended December 31, 2019. As of March 31, 2020, we had an accumulated deficit of $223.3 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We have chosen to operate by outsourcing our manufacturing and most of our clinical operations. We expect to incur significant additional expenses and increase our cumulative 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, 2020, we had cash and cash equivalents of $34.5 million and short-term investments of $70.5 million. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Although we have sufficient capital to fund our planned operations into 2022, we may need to continue to raise substantial additional capital to support operations, activities, and studies including an additional Phase 3 for Molgradex in aPAP and a Phase 3 for Apulmiq in NCFB. 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

COVID-19

The new coronavirus, COVID-19, global pandemic may pose significant risks to our business. It is too early to quantify the impact this situation will have on our financial performance for the remainder of our fiscal year ended December 31, 2020 or beyond, but the public health actions being undertaken to reduce spread of the virus are and may continue to create significant disruptions to our operations. Accordingly, management, on an on-going basis, is evaluating our liquidity position, communicating with and monitoring the actions of our service providers, manufacturers, and suppliers and reviewing our near-term financial performance as we manage Savara through the uncertainty related to COVID-19.

As of the date of this report:

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

We are adhering to government restrictions and operating out of an abundance of caution for the safety of our personnel and patients, including social distancing protocols and enabling remote working for our personnel. We are closely monitoring our liquidity and capital resources through the disruption caused by the COVID-19 pandemic including the operating performance of our business with focus on our operating expenses, loss per share, and cash flow from operations. The COVID-19 pandemic remains extremely fluid and we are continuing to re-assess the effect on our operations, making necessary operational and strategic decisions where possible, to mitigate the negative impact of the virus on our operations, by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world**.**

Apulmiq License Agreement

Effective March 31, 2020, we obtained an exclusive, worldwide, royalty-bearing license (the "License"), with rights to sublicense, certain patent rights and know-how owned or controlled by Grifols, S.A. ("Grifols") to make, have made, use, develop, import and export, supply, offer for sale, and sell or otherwise commercialize pharmaceutical preparations containing ciprofloxacin in a liposomal formulation and/or ciprofloxacin that is not encapsulated in liposomes (each such pharmaceutical preparation a "Licensed Product") for all uses. Under the License, we have sole responsibility for the activities and costs related to the development of (1) a Licensed Product for the treatment of either NCFB or pulmonary infections associated with NCFB (the "Initial Indication") and (2) any Licensed Product for another indication (each, an "Additional Indication"), including the conduct of a Phase 3 clinical trial in the Initial Indication. We are responsible for all regulatory and commercialization activities and the associated costs for each Licensed Product and are obligated to use Diligent Efforts (as defined in the License) to obtain regulatory approval in the U.S. and E.U. of a Licensed Product in the Initial Indication and any Additional Indications. In exchange for such License we agreed to pay Grifols (1) an upfront cash payment of approximately $3,2 million, (2) an upfront payment of one million shares of our common stock, (3) developmental milestone payments upon (i) approval of a Licensed Product for commercial sale by the U.S. Food and Drug Administration ("FDA") and (ii) approval of a Licensed Product for commercial sale by the European Medicines Agency, (4) sales milestone payments upon the first achievement of annual global net sales in excess of certain thresholds, and (5) certain royalties based on annual global net sales of all Licensed Products.

Debt Facility Amendment

On January 31, 2020, we executed a third amendment (the "Third Amendment") to the loan and security agreement dated April 28, 2017, as amended October 31, 2017 and December 4, 2018 with Silicon Valley Bank (the "Loan Agreement"), which provides for a $25 million term loan facility. The Third Amendment extends the interest-only period of the loan repayment through June 30, 2022, with payments thereafter in equal monthly installments of principal plus interest over 18 months. However, if by March 31, 2021, we do not have an ongoing Phase 3 or Phase 4 clinical trial evaluating our Molgradex product for the treatment of aPAP in which the first patient has been dosed, the interest-only period will end and principal plus interest will be due in equal monthly installments over 24 months beginning on April 1, 2021.

Following the effective date of the Third Amendment, we were required to pay a portion of the end of period charge equal to $0.5 million under the Loan Agreement to Silicon Valley Bank. The loans bear interest at the greater of (i) the prime rate reported in The Wall Street Journal, plus a spread of 3.0% or (ii) 7.75%. The Loan Agreement, as amended by the Third Amendment (the "Amended Loan Agreement") will also require a prepayment fee (2.0% of funded amounts in months 13-24, and 1.0% thereafter), and an end of term charge equal to 6.0% of the amount of principal borrowed.

In addition to customary affirmative and negative covenants, the Amended Loan Agreement contains an affirmative covenant requiring us to deliver evidence by June 30, 2021, of the receipt of gross cash proceeds of at least $25 million from the exercise of currently outstanding warrants or the issuance of other equity securities.

Income Taxes and the CARES Act

In response to the COVID-19 pandemic, many governments are contemplating measures to provide aid and economic stimulus. These measures may include deferring the due dates of tax payments or other changes to their income and non-income-based tax laws. The CARES Act, which was enacted on March 27, 2020 in the U.S., includes many measures to assist companies, including temporary changes to income and non-income-based tax laws. Some of the key tax-related provisions of the bill include:

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

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

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

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, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Product candidates:		
AeroVanc	$ 2,844	$ 3,304
Molgradex	4,989	6,685
Apulmiq	5,367	—
Other	—	30
Total research and development expenses	**$ 13,200**	**$ 10,019**

We expect to continue to incur significant research and development expenses in the future as we advance our product candidates into and through clinical trials and pursue regulatory approvals, which will require a significant 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

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

Critical Accounting Policies and Estimates

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

Although the Company does not have any goodwill as of March 31, 2020, it has adopted the following accounting policy. 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. For instance, based upon the ultimate scope and scale of the COVID-19 global pandemic, there may be materially negative impacts to the assumptions made with respect to our IPR&D assets that could result in an impairment of such assets.

Accounting Standards Update ("ASU") 2017-04, "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment," outlines an impairment model providing us the option to implement a one-step method for determining impairment of goodwill, thereby simplifying the subsequent measurement of goodwill by eliminating Step 2 (quantitative calculation of 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," provide 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 30 utilizing a qualitative approach and determining if it was more-likely-than not that the fair value was impaired. We evaluate potential impairment of our acquired goodwill annually on June 30, 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-Merton 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 the license agreement related to our Molgradex product (see Note 2 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, 2020 and 2019

	Three Months Ended March 31,		Dollar
	2020	2019	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 13,200	$ 10,019	$ 3,181
General and administrative	2,982	2,763	219
Depreciation	58	138	(80)
Total operating expenses	16,240	12,920	3,320
Loss from operations	(16,240)	(12,920)	(3,320)
Other income (loss), net	819	808	11
Net loss before income taxes	(15,421)	(12,112)	(3,309)
Income tax benefit	—	—	—
Net loss	**$ (15,421)**	**$ (12,112)**	**$ (3,309)**

Research and Development

Research and development expenses increased by $3.2 million, or 31.7%, to $13.2 million for the three months ended March 31, 2020 from $10.0 million for the three months ended March 31, 2019. The increase was primarily due to approximately $5.4 million equal to the aggregate of the fair value of Savara common stock to be issued and cash remunerated to the licensor under the License for the development and commercialization rights to Apulmiq, which was recorded as research and development expense. The upfront license payment expenses were offset by decreased development costs associated with the development of Molgradex and AeroVanc in the amount of $1.7 million and $0.5 million, respectively.

General and Administrative

General and administrative expenses increased by $0.2 million, or 7.9%, to $3.0 million for the three months ended March 31, 2020 from $2.8 million for the three months ended March 31, 2019. The increase was primarily due to increased noncash stock-based compensation charges, personnel costs, and corporate insurance costs for the three months ended March 31, 2020.

Liquidity and Capital Resources

As of March 31, 2020, we had $34.5 million in cash and cash equivalents, $70.5 million in short-term investments and an accumulated deficit of $223.3 million. We entered into a loan and security agreement with Silicon Valley Bank during the year ended December 31, 2017, which was amended a third time in January 2020, under which we have drawn a total of $25 million. We continue to sell our common stock through "at the market offerings" under the Sales Agreement and have raised net proceeds of $31.9 million under the Sales Agreement since April 2017. Since June 2017, we have completed three public offerings with combined net proceeds, after deducting the underwriting discounts and commissions and offering expenses, of approximately $135.4 million.

On December 24, 2019, we completed a private placement in a public entity for net proceeds of $25.1 million and issued accompanying warrants, which have a two year expiry date, to purchase additional shares of our common stock which may result in approximately $48.2 million in additional proceeds to us before customary closing fees.

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 pre-commercialization activities, and general and administrative expenses. We are also continuously and critically reviewing our liquidity and anticipated capital requirements in light of the uncertainty created by the COVID-19 global pandemic.

Cash Flows

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

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Cash used in operating activities	$ (13,079)	$ (10,859)
Cash (used in) provided by investing activities	(1,785)	7,320
Cash (used in) provided by financing activities	(466)	4,896
Effect of exchange rate changes	41	13
Net increase (decrease) in cash	**$ (15,289)**	**$ 1,370**

Cash flows from operating activities

Cash used in operating activities for the three months ended March 31, 2020 was $13.1 million, consisting of a net loss of $15.4 million, which was partially offset by approximately $1.4 million of noncash charges, comprised of depreciation and amortization including right-of-use assets, fair value changes, accretion on discount to short-term investments, amortization of debt issuance costs, and stock-based compensation, and $5.4 million of charges related to the upfront payment of the License, of which $2.1 million was noncash. The cash used in operating activities was further increased by a positive change in assets and liabilities of $4.5 million.

Cash flows from investing activities

Cash used in investing activities for the three months ended March 31, 2020 was primarily the result of a $3.2 million upfront cash payment for the License as offset by proceeds from the net sales and maturities of short-term investments in excess of cash used for purchases of short-term investments in the amount of $1.5 million.

Cash flows from financing activities

Cash used in financing activities for the three months ended March 31, 2020 was primarily related to the payment of a portion of the end of period charge equal to $0.5 million under the Loan Agreement to Silicon Valley Bank following the Third Amendment.

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, 2020, we had cash, cash equivalents, and short-term investments of approximately $105 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 securities 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

Other than the developmental milestone payments, sales milestone payments, and royalties under the License with Grifols for rights to develop and commercialize Apulmiq, effective March 31, 2020, there were no material changes outside of the ordinary course of business in our contractual obligations during the three months ended March 31, 2020 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, 2019 filed with the SEC on March 12, 2020.

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, 2020, the outstanding gross principal amount of the secured term loan was $25 million. The loan agreement bears interest at the greater of (i) prime rate reported in The Wall Street Journal, plus a spread of 3.0% or (ii) 7.75%. Changes in the prime rate may therefore affect our interest expense associated with our secured term loan. If a 10% change in interest rates from the interest rates on March 31, 2020 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, 2020 and 2019. 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, 2020 would not have had a material effect on our results of operations or financial condition.

Although we do not believe that we are currently exposed to material changes in our cash, cash equivalents, and short-term investment securities, interest rates of our loan and security agreement with Silicon Valley Bank, or foreign currency exchange rates, we are cautiously and actively monitoring the effects of the COVID-19 pandemic on these instruments.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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, 2020. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of March 31, 2020 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 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 and 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, 2020, we incurred a net loss of $15.4 million, and net cash used in operating activities was $13.1 million. At March 31, 2020, our cash, cash equivalents and short-term investment securities were approximately $105 million, and working capital was approximately $100 million. At March 31, 2020, we had an accumulated deficit of $223.3 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 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 are also continuously and critically reviewing our liquidity and anticipated capital requirements in light of the significant uncertainty created by the COVID-19 global pandemic.

We will require additional financing to obtain regulatory approval for Molgradex, Apulmiq, 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, Apulmiq, and AeroVanc. Under our current operating plan, we believe that our existing capital resources will be sufficient to fund our planned operations into 2022. However, we may raise additional capital, including through our “at the market offering” program to fund new studies, including an additional Phase 3 for Molgradex in aPAP and a Phase 3 for Apulmiq, 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;
- the costs involved in establishing, enforcing, or defending patent claims and other proprietary rights; and
- negative impacts from the scope and spread of COVID-19.

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, 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. In particular, due to the price per share of our common stock, any sale of our equity securities to raise significant capital would result in substantial ownership dilution to our stockholders. 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.

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.

If we engage in acquisitions of companies, products or technologies in order to execute our business strategy, we may need to raise additional capital. We may raise additional capital in the future through one or more financing vehicles that may be available to us including (i) new collaborative agreements; (ii) expansions or revisions to existing collaborative relationships; (iii) private financings; (iv) other equity or debt financings; (v) monetizing assets; and/or (vi) the public offering of securities.

For example, our recent acquisition of the rights to develop Apulmiq will require us to increase our workforce to manage the required development activities. If we are required to raise additional capital in the future, it may not be available on favorable financing terms within the time required, or at all. If additional capital is not available on favorable terms when needed, we will be required to raise capital on adverse terms or significantly reduce operating expenses through the restructuring of our operations or deferral of strategic business initiatives. If we raise additional capital through a public offering of securities or equity, a substantial number of additional shares may be issued, which may negatively affect our stock price and these additional shares will dilute the ownership interest of our current investors.

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 or accelerate principal payments.

On April 28, 2017, we entered into a Loan and Security Agreement, as subsequently amended on October 31, 2017, December 4, 2018, and January 31, 2020 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, maintain insurance, and satisfy an equity-based milestone. If we are not able to comply with these covenants, the outstanding loans under the Amended 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. Additionally, if by March 31, 2021, we do not have an ongoing Phase 3 or Phase 4 clinical trial evaluating its Molgradex product for the treatment of aPAP in which the first patient has been dosed, the interest-only period will end and principal plus interest will be due in equal monthly installments over 24 months beginning on April 1, 2021.

We have significant IPR&D and future impairment of IPR&D may have a significant adverse impact on our future financial condition and results of operations. Our goodwill was fully impaired during the year ended December 31, 2019.

As of March 31, 2020, we had IPR&D of approximately $10.9 million. These intangible assets have been previously impaired and remain subject to additional impairment analyses whenever an event or change in circumstances indicates the carrying amount of such an asset may not be recoverable. We test our goodwill, if any, 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 consolidated 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, such as the ultimate scope and scale of the COVID-19 global pandemic. Events or changes in circumstances may lead to significant impairment charges on our 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, Apulmiq, 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 in both non-CF and CF-affected individuals, Apulmiq for the treatment of NCFB, and AeroVanc for the treatment of MRSA infection in the lungs of CF patients.

The topline results of the Molgradex Phase 3 clinical study for the treatment of aPAP, designated as IMPALA, were announced on June 12, 2019. The study did not meet its primary endpoint of alveolar-arterial oxygen gradient ("A-aDO2") compared to placebo. The continuous treatment arm (Molgradex 300 µg administered once daily continuously over 24 weeks) did show a 12.1 mmHG improvement which is similar to what has been observed in previously published studies, but a larger-than-expected placebo effect was also seen (8.8 mmHg improvement). However, results from IMPALA did show statistically significant improvement in two secondary endpoints: the St. George's Respiratory Questionnaire ("SGRQ") and diffusing capacity of the lungs for carbon monoxide ("DLCO"). Two other secondary endpoints were numerically in favor of the continuous dosing arm of Molgradex but were not statistically significant (six-minute walk distance and time to whole lung lavage), while adverse event frequencies were similar between the treatment arms and placebo.

On October 1, 2019, we received a written response from the FDA in connection with a Type C meeting regarding the Molgradex development program for aPAP and results from the IMPALA study in which the FDA indicated that the data provided in the briefing package for the Type C meeting did not provide sufficient evidence of efficacy and safety.

On December 23, 2019, the FDA granted us Breakthrough Therapy designation for Molgradex for the treatment of aPAP, a process designed to expedite the development and review of drugs that are intended to treat a serious condition and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). As such, we are working to determine the next steps for our Molgradex development program focusing on the scope and design of an additional Phase 3 study. The timing and cost of commencement and the likelihood of success of such additional Phase 3 study is currently not known.

On March 12, 2020, we announced top line microbiology results from our Phase 2a, exploratory, open-label, non-controlled clinical study evaluating Molgradex for the treatment of NTM lung infection in patients not affected by CF, designated as OPTIMA.

Due to the COVID-19 pandemic, and out of an abundance of caution for people living with CF and clinical study staff, we announced the termination of enrollment in our Phase 3 study of AeroVanc to treat persistent MRSA lung infection in individuals living with CF, designated as AVAIL, and the termination of enrollment in our Phase 2a study of the use of Molgradex for the treatment of NTM in patients living with CF, designated as ENCORE, on March 30, 2020. With patient safety at the forefront of the decision, and in accordance with guidelines established by the FDA, efforts will be made to allow enrolled patients to continue with study treatments and site visit protocols, where possible. Top line results from the AVAIL study are expected in early 2021.

Clinical testing is expensive, 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 as demonstrated by our recent IMPALA study results. 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 or negative 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.

The COVID-19 global pandemic has required us to adapt our operations, such as enabling employees to work remotely, which may affect their employment satisfaction or productivity.

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. For example, the impacts of the current COVID-19 global pandemic are rapidly evolving. The extent to which the pandemic impacts our ability to procure sufficient supplies for the development and commercialization of our products and product candidates will depend on the severity and duration of the spread of COVID-19, and the actions undertaken to contain the pandemic or treat its effects.

All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with 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. Although 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 trials or commercial sale, 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. In addition, our CROs may be affected by business or workforce interruptions for many reasons, including as a result of an outbreak of COVID-19 or another infectious disease, over which they and we have limited control. 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. Additionally, the COVID-19 global pandemic may pose significant risks to our development and commercialization of our product candidates as our third-party service providers, manufacturers, and suppliers are experiencing restrictions and challenges which could negatively impact our supply-chain and progress of our development pipeline.

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 7, 2020, we had 42 full-time employees, including 30 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 maintain or 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.

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. As an example, due to the COVID-19 pandemic, we have stopped enrollment in our AVAIL and ENCORE studies. 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 were 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 ("IT") systems, including third-party "cloud based" service providers, to keep financial records, maintain laboratory data, 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 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 IT 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 IT 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, or if we or our vendors fail to comply with applicable data privacy laws, including the GDPR or the CCPA, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted.

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 Euros 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. Similarly, in June 2018, California enacted the California Consumer Privacy Act of 2018 (the "CCPA"), which became effective in January 2020. The CCPA, among other things, requires covered companies to provide new disclosures to California consumers and afford such consumers new rights to opt-out of certain sales of personal information. The CCPA creates a private right of action for statutory damages for certain breaches of information. The California Attorney General has proposed regulations under the CCPA, but these regulations have yet to be finalized. Aspects of the CCPA and its interpretation and enforcement remain unclear at this time. In addition, other states have enacted or proposed legislation that regulates the collection, use, and sale of personal information, and such regimes might not be compatible with either the GDPR or the CCPA. We may be required to implement additional mechanisms to comply with the CCPA or such other state laws, which may be difficult to implement and may require 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 and financial results could be adversely impacted by the occurrence of a natural disaster, war, system malfunction, terrorism, telecommunication and electrical failures or other catastrophic event, or public health crises, such as the 2019 COVID-19 pandemic.

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, public health crises, or severe weather conditions could significantly disrupt our operations and result in additional, unplanned expense. As a small company with limited resources, we are currently preparing or implementing 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.

During the first quarter of 2020, COVID-19 was declared a pandemic by the WHO, resulting in significant disruptions to U.S. and international manufacturing and supply chain as well as travel restrictions in the U.S., Denmark, and many other countries. While the extent of the impact of the current COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a negative impact on our business, financial condition and operating results. As a result of the COVID-19 pandemic, there could be delays in the manufacturing supply chain for our product candidates, including delays in procurement of materials for certain of our clinical studies due to the outbreak, delays in clinical trials or recruitment, or in a more severe scenario, our business, financial condition and operating results could be more severely affected. Given the dynamic nature of these circumstances, the duration of any business disruption or potential impact to our business of the COVID-19 pandemic is difficult to predict.

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 us, 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. For example, as a result of our IMPALA study results and related correspondence from the FDA, we are planning an additional Phase 3 study of Molgradex for the treatment of aPAP. 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, Apulmiq, and AeroVanc have received Orphan Drug Designation by the FDA and Molgradex has also received Orphan Drug Designation 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 EMA for the treatment of aPAP, Apulmiq has been granted Orphan Drug Designation in the U.S. by the FDA for the treatment of lung infection in NCFB patients, 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 Molgradex, Apulmiq, or AeroVanc for the respective indications, the FDA will not approve a similar product, with the same active ingredient, to Molgradex, Apulmiq, 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;
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data; and
- delays, inconsistencies, or negative results in statistical analyses of clinical study 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 and 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, for personal reasons, without reason, or by patients who fail to return for or complete post-treatment follow-up. On March 30, 2020, due to the COVID-19 pandemic, and out of an abundance of caution for people living with CF and clinical study staff, we announced the close-out of enrollment in our Phase 3 AVAIL and Phase 2a ENCORE studies. With patient safety at the forefront of the decision, and in accordance with guidelines established by the FDA, efforts will be made to allow enrolled patients to continue with study treatments and site visit protocols, where possible. However, the COVID-19 pandemic may cause further delays in our clinical trials and have a negative impact on our business, financial condition and operating results.

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 have in the past and may in the future 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 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 in Phase 3 clinical testing. The clinical study topline results were released by us on June 12, 2019 and did not meet all of the statistical goals and protocol end points. On October 1, 2019, we received a written response from the FDA in connection with a Type C meeting regarding the Molgradex development program for aPAP and results from the IMPALA Phase 3 study in which the FDA indicated that the data provided in the briefing package for the Type C meeting did not provide sufficient evidence of efficacy and safety for the treatment of aPAP.

On December 23, 2019, the FDA provided communication to us regarding the granting of Breakthrough Therapy designation, a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on clinically significant endpoint(s), for Molgradex for the treatment of aPAP. As such, we are working with the FDA and EMA to determine the scope and design of an additional Phase 3 study for the Molgradex development program for the treatment of aPAP. The scope, powering, cost, and timing of the additional study is not currently definitive, but the additional Phase 3 study will require us to expend substantial additional resources, significantly extend the timeline for clinical development prior to market approval, and may result in failure to complete the clinical development or gain regulatory approval of Molgradex for the treatment of aPAP.

We are currently planning a new Phase 3 clinical study of Apulmiq in NCFB patients. Apulmiq's original developer, Aradigm, submitted an NDA for Apulmiq to the FDA in July 2017, based on the results from their ORBIT4 study, and supportive evidence from their ORBIT2 and ORBIT3 studies. In January 2018, Aradigm received a complete response letter ("CRL") from the FDA regarding the NDA for Apulmiq, which stated that the FDA determined it cannot approve the NDA as submitted, and provided recommendations needed for resubmission. The areas of concern included clinical data, human factors validation study and product quality. Most importantly, the recommendations in the CRL included an additional Phase 3 clinical study that demonstrates a significant treatment effect on clinically meaningful endpoints. The CRL also included a request to conduct another human factors study to demonstrate that the product packaging and instructions for use are effective, and the CRL requested, among other things, additional product quality information with respect to microbiology and a new in vitro drug release method development report. We now plan to engage in discussions with the FDA to discuss the topics covered in the CRL, with a focus on the design and endpoints of another Phase 3 clinical study that would support a resubmission of the NDA for Apulmiq. While we believe we have a reasonable plan for a new Phase 3 study, we cannot provide assurance that we will be able to reach agreement with the FDA on a feasible study design. For example, the FDA may require us to use endpoints that necessitate the study to be excessively large, or to apply a treatment duration that would be excessively long, both of which may make a new study unfeasible. In the case that we are successful in reaching agreement with the FDA on the study design, we cannot provide assurance that we will be able to conduct such study with positive results, and to be able to resubmit the NDA. Even if we resubmit the NDA, we may not be successful in obtaining FDA approval of Apulmiq. For example, the FDA could require us to complete further clinical, or other studies, which could further delay or preclude any approval of the NDA and require us to obtain significant additional funding.

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. However, due to the COVID-19 pandemic, and out of an abundance of caution for people living with CF and clinical study staff, we announced the termination of enrollment in our Phase 3 AVAIL study on March 30, 2020. With patient safety at the forefront of the decision, and in accordance with guidelines established by the FDA, efforts will be made to allow enrolled patients to continue with study treatments and site visit protocols, where possible. 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. Additionally, 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, Apulmiq, 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, whether to 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 our 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 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 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 ones 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. Further, regulatory oversight and actions may be disrupted or delayed in regions particularly impacted by COVID-19 if regulators and industry professionals are expending significant and unexpected resources addressing the outbreak.

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, Molgradex with restrictions for use only by patients unresponsive to the current standard of care, or Apulmiq with restrictions for use only by NCFB patients colonized by specific bacteria or having had a specified number of recent exacerbations. They may limit the label of Molgradex, Alpumiq, 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 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;
- difficulties identifying patients;
- 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, 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.

We have exclusive development and commercialization rights to Alpumiq under a development and commercialization license agreement of which related patents are owned by licensor. For example, Apulmiq is the subject of patents and patent applications focused on formulations of ciprofloxacin for inhalation. We also believe Apulmiq is protected by its difficult to manufacture liposomal formulation that relies on substantial know-how and trade secrets and that is also protected by our exclusive agreement with Apulmiq's contract manufacturer. In the U.S, Apulmiq has been granted orphan drug designation for the management of bronchiectasis and has also been designated a Orphan Drug and Qualified Infectious Disease Product ("QIDP") for treatment of NCFB patients with chronic lung infections with Pseudomonas aeruginosa; as such, Apulmiq may be protected by 12 years of regulatory exclusivity in the U.S. However, we may not be able to receive such designations or protections in other regions.

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 15, 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. Additionally, while regulatory exclusivity (given Apulmiq's Orphan Drug and QIDP designations) may be a key component of Apulmiq's protection in the U.S., there are no assurances that Apulmiq, if approved, will benefit from this type of market protection in the U.S., and additionally, no similar designations have been received in other regions.

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 Molgradex, Alpumiq, and AeroVanc 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 the 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 pending patent applications and issued patents in the U.S. and other countries covering the formulation of AeroVanc. However, these patents 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. 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 exclusive development and commercialization rights to Alpumiq under a development and commercialization license agreement of which related patents are owned by licensor but may still be contested.

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 infections and AeroVanc for the treatment of MRSA infection in the lungs of CF patients. The potential use and potential therapeutic benefits of systemically administered GM-CSF for systemic NTM disease have been described in case reports in published 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.

While Apulmiq has been granted orphan drug designation as well as designated a QIDP in the U.S., Apulmiq has not received such designations elsewhere and we may not be able to receive such designations due to region-specific patient population sizes or other factors. As such, patent protection, manufaccturing trade secrets, know-how and our exclusive contract manufacturer relationship may be especially important for protecting Apulmiq outside the U.S. We may not be able to obtain or protect such patents, and other liposomal product manufacturers may develop their own processes for manufacturing liposomal ciprofloxacin for products that could compete with Apulmiq.

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 to 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 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 been 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.

Specifically, we use a liposomal formulation of ciprofloxacin in our Apulmiq product. A third party has been granted patent rights covering various liposomal formulations of inhaled antibiotics, including formulations containing ciprofloxacin. Whereas we do not believe these patent rights constitute a material obstacle for the commercialization of Apulmiq, there is a possibility that the third party may claim we are infringing their patent rights with our formulation. If that were to occur, we may need to enter into a license agreement with that party, and it may take us a long time to reach such agreement, or we may not succeed in reaching such agreement.

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, Apulmiq, 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 seven years and ten years in Europe, but only if (i) Molgradex, Apulmiq, and AeroVanc receive market approval before a competitor using the same active compound for the same indication, (ii) we are able to produce sufficient supply to meet demand in the marketplace, and (iii) another product with the same active ingredient is not deemed clinically superior. AeroVanc and Apulmiq have 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 experienced substantial declines since we announced the top-line results of our IMPALA Phase 3 study of Molgradex for aPAP on June 12, 2019, and our stock price has been and is expected to continue to be subject to significant volatility and 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:

- impact of the COVID-19 pandemic on the global economy, financial markets, and liquidity and availability of capital;
- failed or inconclusive data results from our clinical studies;
- 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, NTCB, 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 our products;
- 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, such as the decline in our stock price, 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.

If we fail to satisfy all applicable Nasdaq continued listing requirements, including the $1.00 minimum closing bid price requirement, our common stock may be delisted from Nasdaq, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on the Nasdaq Global Select Market, which has qualitative and quantitative continued listing requirements, including corporate governance requirements, public float requirements, and a $1.00 minimum closing bid price requirement. If our common stock trades at closing bid prices below $1.00 for 30 consecutive business days, or if we are unable to satisfy any of the other continued listing requirements, Nasdaq may take steps to delist our common stock. Such a delisting would likely have an adverse effect on the market liquidity of our common stock, decrease the market price of our common stock, result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities, and adversely affect our ability to obtain financing for the continuation of our operations.

For example, on November 15, 2019, we received written notice from The Nasdaq Stock Market LLC indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5550(a)(2). However, on December 10, 2019, we received written notice from The Nasdaq Stock Market LLC stating that because our shares had a closing bid price at or above $1.00 per share for a minimum of ten consecutive business days, our stock had regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the Nasdaq Global Select Market, as set forth in NASDAQ Listing Rule 5450(a)(1).

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

As a public company, 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 U.S. Securities and Exchange Commission ("SEC") and Nasdaq. 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.

In March 2020, the SEC amended the definitions of accelerated filer and large accelerated filer to exclude smaller reporting companies that have not yet begun to generate significant revenue. Accordingly, we will be changing our status from a smaller reporting company, accelerated filer, to a smaller reporting company, non-accelerated filer, effective for our December 31, 2020 annual report. We are currently assessing the impact of these changes to our compliance with Sarbanes-Oxley 404(b).

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 and do not expect to pay any cash dividends. 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 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 that have not been previously disclosed.

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+	License and Collaboration Agreement between Savara Inc. and Grifols, S.A, dated January 7, 2020, as amended by Amendment No. 1, dated February 18, 2020, and Amendment No. 2, dated March 31, 2020.
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 7, 2020

By: /s/ David Lowrance

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

Date: May 7, 2020

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.

LICENSE AND COLLABORATION AGREEMENT

This **License and Collaboration Agreement** (the "**Agreement**") is entered into as of January 7, 2020 (the "**Effective Date**") by and between **Grifols, S.A.**, a company (*sociedad anónima*) organized under the laws of Spain having a principal place of business at Avinguda de la Generalitat, 152, Parc empresarial Can Sant Joan, 08174 Sant Cugat del Vallès, Barcelona, Spain ("**Grifols**"), and **Savara Inc.**, a Delaware corporation, and its affiliates (collectively, "**Savara**"). Grifols and Savara may each be referred to as a "**Party**" or collectively as the "**Parties**".

RECITALS

Whereas, Grifols intends to acquire certain technology and intellectual property, including technology and intellectual property related to inhaled ciprofloxacin and is willing to license such technology to Savara, and Savara desires to accept such license (the "**License**");

Whereas, Grifols and Savara desire to enter into this License for purposes of the development and commercialization of products using inhaled ciprofloxacin for the treatment and prevention of respiratory diseases in accordance with the terms and conditions set forth herein;

Whereas, on May 16, 2019, Grifols and Savara entered into a Letter of Intent and on September 27, 2019 amended and extended it (collectively, the "**Letter of Intent**"), pursuant to which, in connection with the License and upon the Effective Date of this Agreement, Savara agreed to issue to Grifols one million (1,000,0000) shares of Savara common stock (the "**Common Stock**") and pay three million dollars ($3,000,000) to Grifols;

Whereas, as a condition precedent to the effectiveness of this Agreement, Grifols and Aradigm Corporation, a California corporation ("**Aradigm**"), shall execute and close an Asset Purchase Agreement (the "**Asset Purchase Agreement**"), subject to the approval of the United States Bankruptcy Court for the Northern District of California (the "**Bankruptcy Court Approval**"), by which Grifols shall purchase all of the assets, personal and mixed, tangible and intangible owned by Aradigm (other than the Excluded Assets (as defined therein)), on the terms and conditions set forth in the Asset Purchase Agreement and in accordance with Sections 105, 363(b), 363(f), and 365 and other applicable provisions of Chapter 11 of Title 11 of the United States Code, 11 U.S.C. §§ 101 et seq; and

Now, Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated elsewhere in this Agreement (and derivative forms of them shall be interpreted accordingly). The terms "include," "includes," "including" and derivative forms of them shall be deemed followed by the phrase "without limitation" regardless of whether such phrase appears there (and with no implication being drawn from its inconsistent inclusion or non-inclusion).

1.1 "**AAA**" has the meaning set forth in Section 12.3.

1.2 "**Additional Licensed Product**" means each Licensed Product elected by Savara to be Developed for an Additional Indication pursuant to Section 4.1.

1.3 "**Additional Development Plan**" has the meaning set forth in Section 4.1.

1.4 "**Additional Indications**" means cystic fibrosis, non-tuberculosis mycobacteria, chronic obstructive pulmonary disease, and/or a bio-defense application, or any additional indication proposed by Savara in accordance with Section 4.1.

1.5 "**Affiliate**" means, with respect to a Person, any Person that controls, is controlled by or is under common control with such first Person. For purposes of this definition only, "**control**" means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, fifty percent (50%) or more of the outstanding securities or other ownership interest of such Person. For the purposes of this Agreement, neither Party shall be considered an Affiliate of the other, and the Affiliates of each Party shall not be considered Affiliates of the other Party or of any of such other Party's Affiliates.

1.6 "**Agreement**" has the meaning set forth in the Preamble.

1.7 "**Aradigm**" has the meaning set forth in the Recitals.

1.8 "**Asset Purchase Agreement**" has the meaning set forth in the Recitals

1.9 "**Auction**" has the meaning set forth in Section 8.4(a).

1.10 "**Audited Party**" has the meaning set forth in Section 6.8a

1.11 "**Auditing Party**" has the meaning set forth in Section 6.8.

1.12 "**Bankrupt Party**" has the meaning set forth in Section 11.5.

1.13 "**Bankruptcy Code**" has the meaning set forth in Section 11.5.

1.14 "**Bankruptcy Court**" has the meaning set forth in Section 8.4(a).

1.15 "**Bankruptcy Court Approval**" has the meaning set forth in the Recitals.

1.16 "**Bid Deadline**" has the meaning set forth in Section 8.4(a).

1.17 "**[***]**" has the meaning set forth in [***].

1.18 "**Budget**" has the meaning set forth in Section 3.1.

1.19 "**Business Day**" means any day (other than a Saturday, Sunday or a legal holiday) on which banks are open for general business in Barcelona, Spain and New York, New York, United States of America.

1.20 "**Claims**" has the meaning set forth in Section 9.1.

1.21 "**Commercialization Plan**" has the meaning set forth in Section 5.2.

1.22 "**Commercialization Records**" has the meaning set forth in Section 5.4.

1.23 "**Commercialize**" or "**Commercialization**" means to manufacture commercial supplies, market, promote, sell, offer for sale and/or distribute.

1.24 "**Common Stock**" has the meaning set forth in the recitals.

1.25 "**Compound**" means ciprofloxacin in a liposomal formulation and/or Free Ciprofloxacin, and any improvements and enhancements to such formulations, and any other modifications and derivatives thereto.

1.26 "**Confidential Information**" of a Party means any and all information of a confidential or proprietary nature disclosed by such Party to the other Party under this Agreement, whether in oral, written, graphic or electronic form.

1.27 "**Control**" means, with respect to any particular Know-How or Patent, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such Know-How or Patent and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to such Know-How or Patent on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

1.28 "**Cover**" means, with respect to a particular item and a particular Patent, that such Patent claims or covers, in any of the countries of manufacture, use, and/or sale, (a) the composition of such item, any of its ingredients or formulations or any product containing or that is made using such item (by virtue of such product containing or being made using such item); (b) a method of making or using any of the foregoing things referred to in (a); (c) an item used or present in the manufacture of any of the foregoing things referred to in (a); and/or (d) the method by which such item was discovered or identified, or another item present during or used in such method.

1.29 "**Develop**" or "**Development**" means activities that relate to obtaining Regulatory Approval of a Licensed Product, including manufacturing of the Licensed Product for clinical supplies, quality control, preclinical testing, toxicology testing, clinical trials, and preparation and submission of applications for obtaining Regulatory Approval of a Licensed Product. Development shall exclude Commercialization and the building of commercial inventory of a Licensed Product.

1.30 "**Development Costs**" means the out-of-pocket and internal costs and expenses associated with particular Development activities through the submission and approval of an application for obtaining Regulatory Approval of such Licensed Product, as set forth from time to time in the Development Plan. Such costs and expenses shall include, without limitation, reimbursement of fully-burdened FTEs (including overhead), all expenditures arising from or relating to the supply of clinical product, all expenditures arising from or relating to any clinical trials, the preparation and submission of applications for obtaining Regulatory Approval, and any other expenses or direct payments to consultants, contractors, service providers and other Third Parties arising directly from or relating directly to the Development Plan.

1.31 "**Development Plan**" means the plan set forth on Exhibit B (as may be amended in accordance with the terms hereof) setting forth the activities to be conducted to Develop the Compound for the Initial Indication in accordance with the terms of ARTICLE 3.

1.32 "**Development Records**" has the meaning set forth in Section 3.4.

1.33 "**Diligent Efforts**" means, with respect to a Party's obligations under this Agreement, the carrying out of such obligations with a level of effort and resources consistent with those commercially reasonable efforts and practices of a company comparable with such Party under the circumstances.

1.34 "**Dollar**" or "**$**" means a USA dollar.

1.35 "**Effective Date**" has the meaning set forth in the Preamble.

1.36 "**EMA**" means the European Medicines Agency or any successor entity.

1.37 "**EU**" or "**European Union**" means the European Union member states as then constituted, plus the United Kingdom, regardless of whether the United Kingdom is a European Union member state at such time. As of the Effective Date, the European Union member states are Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

1.38 "**Event of Bankruptcy**" has the meaning set forth in Section 11.5(a).

1.39 "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.40 "**Executive Officer**" means, with respect to Grifols, its Chief Executive Officer, and with respect to Savara, its Chief Executive Officer or his designee.

1.41 "**FD&C Act**" means the USA Federal Food, Drug and Cosmetic Act, as amended.

1.42 "**FDA**" means the USA Food and Drug Administration or any successor entity.

1.43 "**Field**" means all uses.

1.44 "**First Commercial Sale**" means, with respect to a Licensed Product, the first sale, transfer or disposition for value to a Third Party of such Licensed Product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction.

1.45 "**Free Ciprofloxacin**" means ciprofloxacin that is not encapsulated in liposomes.

1.46 "**Grifols**" has the meaning set forth in the Preamble.

1.47 "**Grifols Breach**" has the meaning set forth in Section 11.4(a).

1.48 "**Grifols Indemnitees**" has the meaning set forth in Section 9.2.

1.49 "**Grifols Know-How**" means all Know-How Controlled by Grifols as of the Effective Date or during the Term, to the extent it is necessary for, and actually used by Grifols in, the Development of the Licensed Products.

1.50 "**Grifols Patents**" means all Patents Controlled by Grifols as of the Effective Date or during the Term which Cover the Licensed Products, including the Patents listed in Exhibit A. For the avoidance of doubt, "Grifols Patents" shall include all Patents Controlled by Grifols which Cover Lipoquin®, Free Ciprofloxacin, and Pulmaquin® (and any derivatives, analogs, homologs, and isomers, including constitutional and structural isomers, stereroisomers, including diastereomers, regioisomers, geometric isomers, enantiomers, cis/trans isomers, conformers, and rotamers; of ciprofloxacin, contained therein; and formulations or other dosage forms and delivery systems thereof).

1.51 "**Grifols Technology**" means the Grifols Know-How and the Grifols Patents.

1.52 "**Governmental Authority**" means any multi-national, federal, regional, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.53 "**Group**" shall mean any group of Persons formed for the purpose of acquiring, holding, voting, disposing of or beneficially owning equity securities, which group of Persons would be required under Section 13(d) of the Exchange Act to file a statement on Schedule 13D pursuant to Rule 13d-1(a) or a Schedule 13G pursuant to Rule 13d-1(c) with the Securities and Exchange Commission as a "person" within the meaning of Section 13(d)(3) of the Exchange Act if such group beneficially owned equity securities representing more than 5% of any class of equity securities then outstanding.

1.54 "**Indemnified Party**" has the meaning set forth in Section 9.3.

1.55 "**Indemnifying Party**" has the meaning set forth in Section 9.3.

1.56 "**Infringement**" has the meaning set forth in Section 7.2(a).

1.57 "**Initial Indication**" means the treatment of one of the following with the Licensed Product: (i) non-cystic fibrosis bronchiectasis, or (ii) pulmonary infections associated with non-cystic fibrosis bronchiectasis.

1.58 "**Know-How**" means all technical information and know-how, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, expertise, materials, methods, protocols and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formula, and expertise owned or controlled by Grifols, or any of its contracted sublicensees, subcontractors, distributors, development partners, manufacturing suppliers and other Third Parties, as of the effective date of this Agreement that are necessary or useful for the development or commercialization of the Products, including the Know-How at one time held by Aradigm Corporation (excluding Excluded Assets, as defined in the Asset Purchase Agreement).

1.59 "**Laws**" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, regional, state, provincial, county, city or other political subdivision, domestic or foreign, including common law.

1.60 "**Letter of Intent**" has the meaning set forth in the Recitals.

1.61 "**Liabilities**" has the meaning set forth in Section 9.1.

1.62 "**License**" has the meaning set forth in the Recitals.

1.63 "**Licensed Product**" means any pharmaceutical preparation containing the Compound and includes any Additional Licensed Product.

1.64 "**Licensed Rights**" means the rights granted to Savara by Grifols to the Grifols Technology under Section 2.1(a).

1.65 "**Lipoquin®**" means the Licensed Product that is a liposomal formulation without Free Ciprofloxacin trademarked "Lipoquin®".

1.66 "**Milestone Event**" has the meaning set forth in Section 6.2.

1.67 "**Milestone Payment**" has the meaning set forth in Section 6.2.

1.68 "**NCFB**" has the meaning set forth in Section 6.2.

1.69 "**NDA**" means a New Drug Application, as defined in the FD&C Act, as amended, and applicable regulations promulgated thereunder by the FDA, and the equivalent application to the equivalent agency in any other regulatory jurisdiction.

1.70 "**Net Sales**" means, with respect to any Licensed Product, the gross amounts received by a Party and its Affiliates and their respective licensees and sublicensees for the sale, transfer, or other disposition of such Licensed Product, to Third Parties less the following deductions to the extent reasonable and customary and actually allowed and taken with respect to such sale, transfer or other disposition:

(a) reasonable cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government;

(b) credits, rebates or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Licensed Product, including in connection with recalls;

(c) freight, postage, shipping, transportation and insurance charges, in each case actually allowed or paid for delivery of such Licensed Product; and

(d) taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of such Licensed Product, including VAT, excise taxes and sales taxes.

Notwithstanding the foregoing, amounts received or invoiced by a Party, its Affiliates or their licensees or sublicensees for the sale of such Licensed Product, to Affiliates, licensees or sublicensees shall not be included in the computation of Net Sales hereunder. For the purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when payment has been received by Savara or its Affiliates or Grifols, as applicable, for such Licensed Product. Net Sales shall be accounted for in accordance with the International Financial Reporting Standards, consistently applied in such country in the Territory. For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales.

With respect to any sale of any Licensed Product, in a given country for consideration other than monetary consideration, for the purposes of calculating the Net Sales under this Agreement, such Licensed Product, shall be deemed to be sold exclusively for money at the average Net Sales price charged to Third Parties for cash sales in such country during the applicable reporting period (or if there were only *de minimis* cash sales in such country, the average Net Sales price charged to Third Parties for cash sales in all countries in the Territory during the applicable reporting period).

1.71 "**Non-Bankrupt Party**" has the meaning set forth in Section 11.5.

1.72 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.73 "**Patents**" means, collectively, (a) pending patent applications (and patents issuing therefrom), issued patents, regional patents, utility models and designs; and (b) reissues, divisions, substitutions, confirmations, renewals, extensions, provisionals, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, divisionals, or any Supplementary Protection Certificates or restoration of patent terms of or to any patents, patent applications, utility models or designs.

1.74 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.75 "**Product Marks**" has the meaning set forth in Section 7.5(a).

1.76 "**Publication**" has the meaning set forth in Section 10.5.

1.77 "**Pulmaquin**" means Grifols' proprietary inhaled liposomal and Free Ciprofloxacin product, comprising a mixture of Lipoquin® with unencapsulated ciprofloxacin. Pulmaquin® is also known as "Apulmiq®" and "Linhaliq®".

1.78 "**Qualified Bid**" has the meaning set forth in Section 8.4(a).

1.79 "**Regulatory Approval**" means all approvals necessary for the commercial sale of a Licensed Product for any indication in a given country or regulatory jurisdiction in the Territory, which shall include satisfaction of all applicable regulatory and notification requirements, but which shall exclude any pricing and reimbursement approvals.

1.80 "**Regulatory Authority**" means the FDA or any corollary agency involved in granting Regulatory Approval in any other country or jurisdiction in the Territory, including the EMA in the EU.

1.81 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize a Licensed Product in a particular country or jurisdiction.

1.82 "**Remedial Action**" has the meaning set forth in Section 4.5.

1.83 "**Revenue**" has the meaning set forth in Section 7.2(e).

1.84 "**Royalty Term**" has the meaning set forth in Section 6.4(c).

1.85 "**Savara**" has the meaning set forth in the Preamble.

1.86 "**Savara Indemnitees**" has the meaning set forth in Section 9.1.

1.87 "**Savara Sublicense Agreement**" has the meaning set forth in Section 2.2(a).

1.88 "**Submission Date**" means the date that an NDA for a Licensed Product is submitted to a Governmental Authority in the Territory.

1.89 "**Term**" has the meaning set forth in Section 11.1.

1.90 "**Termination Fee**" has the meaning set forth in Section 11.6.

1.91 "**Territory**" means the entire world.

1.92 "**Third Party**" means any Person not including the Parties or the Parties' respective Affiliates.

1.93 "**USA**" means the United States of America, including all possessions and territories thereof.

1.94 "**Valid Claim**" means a claim of a Patent within the Grifols Patents, which claim is pending and has not been finally abandoned or finally rejected or is issued and unexpired and has not been found to be unpatentable, invalid or unenforceable by a court or other authority having jurisdiction, from which decision no appeal is taken, shall be taken or can be taken.

ARTICLE 2
LICENSES

2.1 License to Savara.

(a) Subject to the terms and conditions of this Agreement, Grifols hereby grants to Savara, during the Term, an exclusive, royalty-bearing license, with the right to sublicense, solely as provided in Section 2.2, under the Grifols Technology, to make, have made, use, Develop, import and export, supply, offer for sale, and sell or otherwise Commercialize Licensed Products in the Field and in the Territory.

(b) Savara shall not, and shall ensure that its Affiliates and sublicensees do not, use or practice any Grifols Technology outside the scope of the license granted to it under this Section 2.1.

2.2 Savara Sublicense Rights.

(a) Savara shall have the right to (i) grant sublicenses of the licenses granted in Section 2.1 to its Affiliates or Third Parties, and (ii) allow such Affiliates or Third Parties to grant further sublicenses through multiple tiers, in each case solely as set forth in this Section 2.2 (each such sublicense, a "**Savara Sublicense Agreement**"). Savara shall remain responsible for all of its sublicensees' activities with respect to such sublicenses and any and all failures by its sublicensees to comply with the applicable terms of this Agreement. For the avoidance of doubt, and notwithstanding anything to the contrary in Section 10.2, Savara shall include in each Savara Sublicense Agreement a provision that prohibits such sublicensee from challenging the validity of the Grifols Patents.

(b) Savara shall, within thirty (30) days after granting any Savara Sublicense Agreement, notify Grifols of the grant of such sublicense and provide Grifols a copy of each Savara Sublicense Agreement. Each Savara Sublicense Agreement shall (i) be consistent with the terms and conditions of this Agreement and Savara shall include in such sublicense provisions that require the sublicensee to be, and to require any further sublicensee to be, bound by and subject to all applicable terms and conditions of this Agreement in the same manner and to the same extent as Savara is bound thereby, or (ii) otherwise include terms that are mutually agreed upon by the Parties.

2.3 Third Party Licenses.

(a) **Licensed Product in the same form and formulation as of the Effective Date**. Savara shall be responsible for entering into (and/or maintaining) any necessary Third Party licenses and [***] percent ([***]%) of any related payment obligations and Grifols shall be responsible for [***] percent ([***]%) of such payment obligations, to Third Parties to allow Savara to use the Licensed Rights in connection with the Licensed Product in the same form and formulation existing as of the Effective Date; provided, that Savara, prior to the execution of any such Third Party license, shall provide Grifols a draft of such Third Party license and Grifols shall have the right to provide comments, which Savara shall reasonably consider in good faith. Grifols' payment obligations as provided hereunder shall be satisfied by deducting such amounts from the royalty payments next payable to Grifols pursuant to Section 6.4 (but Savara may not deduct same against Milestone Payments); provided, that any such deduction shall not exceed [***] percent ([***]%) of any royalty payment due and payable to Grifols. Savara may carry forward to future royalty periods any unused deduction due to the [***] percent ([***]%) floor until all deductions Savara is eligible for are exhausted. Savara acknowledges that no Third Party rights are included in the Licensed Rights.

(b) **Changes to the Licensed Product during the Term**. The responsibility, necessity and handling of any Third Party license required as a result of improvements or changes to any Licensed Product or the Development of an Additional Licensed Product, in each case, requested or proposed by Savara and conducted pursuant to an Additional Development Plan, shall lie with Savara, provided that the costs associated with any such requirements shall be the responsibility of Savara.

2.4 Transfer and Assignment of Rights to Savara.

(a) In connection with the license described in Section 2.1(a), Grifols shall (i) transfer (including assignment where appropriate, required by applicable law, or consistent with the Asset Purchase Agreement or this Agreement) (A) all Grifols Technology and (B) all Purchased Assets, as such term is defined in the Asset Purchase Agreement, that are necessary or useful for Savara to exercise its rights under this Agreement, including, without limitation, its rights under Section 2.1(a), in each of (A) and (B) above as acquired from Aradigm pursuant to the Asset Purchase Agreement to Savara, following the closing of the Asset Purchase Agreement, and (ii) shall obtain the consents or approvals necessary for such transfer, including, without limitation, the consents or approvals with respect to Savara to the same extent such consents or approvals were required to be obtained with respect to Grifols as set forth on Schedule 3.02(a)(ix) of the Asset Purchase Agreement.

(b) For the avoidance of doubt, under the license described in Section 2.1(a), all Grifols Know-How acquired from Aradigm, pursuant to the Asset Purchase Agreement, shall be transferred (including execution of all necessary signatures and transfer approvals) to Savara within sixty (60) days of the closing of the Asset Purchase Agreement.

(c) In addition, to the extent permitted by Law and also under the license described in Section 2.1(a), Regulatory Materials, acquired from Aradigm, pursuant to the Asset Purchase Agreement, shall be transferred to Savara within sixty (60) days of the closing of the Asset Purchase Agreement, or as soon as practicable, and if not permitted by law, that a right of reference be granted to Savara to the extent applicable Law permits grant and use of a right of reference.

(d) Also, following closing of the Asset Purchase Agreement, as part of the license described in Section 2.1(a), Grifols shall provide to Savara technology transfer/transition services, at Savara's cost, in regards to any Grifols Technology acquired from Aradigm or any of its contracted sublicensees, subcontractors, distributors, development partners, manufacturing suppliers and other Third Parties, pursuant to the Asset Purchase Agreement.

2.5 Grifols Retained Rights. All rights, licenses, benefits and privileges not expressly granted to Savara hereunder are reserved by Grifols.

ARTICLE 3
DEVELOPMENT

3.1 Development Plan. Attached hereto as Exhibit B is the initial Development Plan, setting forth the activities to be conducted by Savara to Develop a Licensed Product for the Initial Indication, and a detailed budget (the "**Budget**") of the Development Costs allocated to such Development and each such activity, including, but not limited to the status of financing the Development of such Licensed Product for the Initial Indication. From time to time throughout the Development of such Licensed Product for the Initial Indication, Savara may revise the Development Plan in its sole and absolute discretion, to reflect additional or different activities which are appropriate in light of the prior Development, and to reflect any changes in the cost of conducting such revised Development activities, provided it uses Diligent Efforts to Develop Licensed Products.

3.2 Development Responsibility. Savara shall have sole responsibility for Developing (i) a Licensed Product for the Initial Indication in commercially reasonable accordance with the Development Plan and (ii) any Additional Licensed Product for an Additional Indication, elected by Savara pursuant to Section 4.1.

3.3 Development Costs. Savara shall have the sole responsibility for all Development Costs, in connection with any Licensed Product, including a Licensed Product for the Initial Indication and any Additional Licensed Product for an Additional Indication.

3.4 Records and Reports. Savara shall maintain complete, current and accurate records of (i) all work conducted by it, its Affiliates or sublicensees under the Development Plan or any Additional Development Plan; (ii) all data, Know-How and Patents resulting from such work; and (iii) all Development Costs incurred in connection therewith (collectively, the "**Development Records**"). Within ten (10) days of the end of each calendar quarter during the Term, Savara shall provide Grifols with written reports, in a form to be reasonably approved by Grifols, detailing all Development Records for such calendar quarter; provided, that Grifols may request up to two (2) additional Development Records from Savara and Savara shall produce such Development Records in any calendar year. The Parties shall review all such reports on a quarterly basis.

3.5 Subcontracts. Savara may perform any of its Development obligations under this Agreement through its Affiliates and through one or more subcontractors or consultants, provided that (a) Savara remains responsible for the work allocated to such Affiliates, subcontractors and consultants to the same extent it would if it had done such work itself, (b) the Affiliate or subcontractor (as the case may be) undertakes in writing obligations of confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to ARTICLE 11 hereof.

ARTICLE 4
REGULATORY MATTERS

4.1 Regulatory Activities. Savara shall be responsible for conducting all Development activities related to regulatory filings for the Initial Indication and any Additional Indications in the USA and the EU and shall use Diligent Efforts to obtain and support Regulatory Approval for such Initial Indication and any Additional Indications of the Licensed Product in the USA and the EU. Subject to Section 13.2 of this Agreement, Savara shall conduct a new Phase 3 clinical trial (as that term is defined in 21 C.F.R. §312.21(c)) on the Initial Indication and complete such Phase 3 clinical trial – and the results of that Phase 3 clinical trial made available to Grifols – within five (5) years from the Effective Date of this Agreement. Notwithstanding the foregoing, if such Phase 3 clinical trial is "on-going" on the fifth (5th) anniversary of the Effective Date and Savara, in accordance with this Section 4.1, has used Diligent Efforts to conduct such Phase 3 clinical trial, such period shall be extended for as long as is reasonably necessary to complete such Phase 3 clinical trial, with such additional period to not to exceed two (2) years. For the purposes of the preceding sentence, a Phase 3 clinical trial shall be "on-going" if such Phase 3 clinical trial has already concluded the enrollment of subjects in such trial or enrolled at least two hundred (200) subjects in such trial. In addition, Savara shall be responsible, for submitting the NDAs for all Licensed Products in such other countries selected by Savara, provided that Savara shall use Diligent Efforts to submit NDAs to the FDA in the USA and to the EMA in the EU for the Initial Indication in accordance with this Agreement. In all countries in the Territory, Savara shall be solely responsible for all regulatory matters and for maintaining all NDAs and other regulatory approvals. Savara shall use Diligent Efforts to file and, subject to Section 11.6, Savara shall own all right, title and interest in all Regulatory Materials designed to obtain or support such Regulatory Approval. If any Regulatory Authority requires Grifols consent or participation or otherwise seeks to inquire with Grifols with respect to any Regulatory Approval of a Licensed Product, then Savara hereby grants to Grifols effective on the date of Savara's written notification from such Regulatory Authority of such requirement or inquiry, an exclusive, fully-paid license to use the Regulatory Materials in the Territory solely as necessary to respond to such Regulatory Authority.

4.2 Regulatory Reports; Meetings with Regulatory Authorities. Savara shall keep Grifols informed of material regulatory developments relating to Licensed Products in the Territory.

4.3 Regulatory Costs. Savara shall be solely responsible for all costs and expenses incurred by either Party in the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for Licensed Products in the Territory. The costs and expense for such preparation and filing activities conducted by Savara, to the extent such activities are Development activities for the Initial Indication of the Licensed Product in the USA and EU, are to be included as part of the Development Costs.

4.4 Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may affect the Development, Commercialization or regulatory status of a Licensed Product. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

4.5 Remedial Actions. Each Party shall notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, market withdrawal, corrective action or other regulatory or administrative action with respect to a Licensed Product taken by virtue of applicable Laws (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Savara shall, and shall ensure that its Affiliates and sublicensees will, maintain records in accordance with Savara's normal and customary practices, intended to permit the Parties to trace the distribution and use of the Licensed Products. Savara shall have the right to decide whether any Remedial Action with respect to Licensed Products should be commenced and Savara shall, at its expense, control and coordinate all efforts necessary to conduct such Remedial Action.

ARTICLE 5
COMMERCIALIZATION AND SUPPLY

5.1 Commercialization Responsibilities. During the Term, subject to the receipt of Regulatory Approval for a particular Licensed Product or Additional Licensed Product, as applicable, Savara shall be responsible for all aspects of the Commercialization of the Licensed Product for the Initial Indication and any Additional Licensed Products for their applicable Additional Indications in countries within the Territory in which such Licensed Product and/or Additional Licensed Product (as applicable) has received Regulatory Approval. Such Commercialization responsibilities shall include: (a) developing and executing a commercial launch and pre-launch plan including considerations for the distribution of commercial supplies of the Licensed Product and/or Additional Licensed Product (as applicable); (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of such Licensed Product and/or Additional Licensed Product (as applicable); (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of such Licensed Product and/or Additional Licensed Product (as applicable) in the Territory. Savara shall bear all of the costs and expenses incurred in connection with such Commercialization activities.

5.2 **Commercialization Plan**. The strategy for the Commercialization of each Licensed Product and Additional Licensed Product shall be described in a comprehensive plan that describes the pre-launch, launch and subsequent Commercialization activities for such Licensed Product in the Territory, which may include, in Savara's sole but reasonable judgment: (i) the annual anticipated number of detail persons to be used in each of the USA, EU, China and Japan, (ii) the annual anticipated marketing expenses to be incurred in each of the USA, EU, China and Japan, (iii) the annual anticipated number of FTEs to be assigned to Commercialize in each of the USA, EU, China and Japan, and (iv) a report on pricing, advertising, education, planning, marketing, and sales force training (the "**Commercialization Plan**"). Savara shall submit the initial Commercialization Plan to Grifols no later than ninety (90) days after the FDA and EMA Submission Date.

5.3 **Commercial Diligence**. During the Term for each Licensed Product or Additional Licensed Product, as applicable, Savara, except as set forth on Schedule 5.2 shall use Diligent Efforts to Commercialize each Licensed Product for the Initial Indication and any Additional Licensed Products for their respective Additional Indications, throughout the Territory, in each case to the extent that Regulatory Approval has been obtained.

5.4 **Records and Reports**. Savara shall maintain, in accordance with its normal and customary practices, records of all work conducted by it, its Affiliates or sublicensees regarding the Commercialization of Licensed Products (the "**Commercialization Records**"). Savara shall provide written reports on its Commercialization of the Licensed Product, in a form reasonably acceptable to Grifols, detailing all Commercialization work conducted by it, its Affiliates or sublicensees during the previous calendar quarter, in which case such Commercialization Records shall be delivered to Grifols on a calendar quarter basis; provided, that Grifols may request two (2) additional such reports from Savara during any calendar year.

5.5 **Post-Commercialization Trials**. After initiation of Commercialization, Savara shall have the right, but not the obligation, at its sole cost and expense, to support any post-Commercialization trials, such as Phase IV clinical trials and observational studies, as well as any investigator sponsored studies conducted with the any Licensed Product. Notwithstanding the foregoing, if the FDA, EMA or other Governmental Authority requires, as a condition of continued approval of the Licensed Product or Additional Licensed Product, additional clinical studies or other trials, Savara shall have the obligation, at its sole cost and expense, to conduct and support any such clinical studies or trials.

ARTICLE 6
COMPENSATION

6.1 **Equity Investment**. Upon commencement of the Term, Savara shall issue to Grifols one million (1,000,000) shares of Savara's common stock.

6.2 **Upfront Payment**. In connection with this Agreement, Savara agrees to pay to Grifols upon commencement of the Term Three Million Dollars ($3,000,000), which payment shall be made in accordance with the terms of the Letter of Intent.

6.3 Development Milestone Payments. Savara shall notify Grifols within thirty (30) days of the achievement of the following milestone events (each a "**Milestone Event")** and shall make each of the following milestone payments (each, a "**Milestone Payment**") to Grifols upon the achievement of each Milestone Event in connection with the Development of a Licensed Product for the Initial Indication. Savara shall pay to Grifols each such amount within sixty (60) days after Savara receives a properly documented invoice from Grifols in connection with the achievement of the applicable Milestone Event. For clarity, each of the following Milestone Payments are one-time only payments and each Milestone Payment shall be made once upon the first occurrence of the applicable Milestone Event, regardless of the number of Licensed Products that achieve such Milestone Event.

	Milestone Event for Licensed Product	Milestone Payment
1	Approval of the Licensed Product by the FDA if the Licensed Product is the only inhaled antibiotic approved by the FDA for non-CF bronchiectasis (NCFB) on the approval date or if no inhaled antibiotic has been approved by the FDA for NCFB, approval of the Licensed Product for pulmonary infections associated with NCFB if the Licensed Product is the only inhaled antibiotic approved by the FDA for pulmonary infections associated with NCFB on the approval date	[***] Dollars ($[***])
2	Approval of the Licensed Product by the FDA, other than as described in Milestone Event 1 above	[***] Dollars ($[***])
3	Approval of the Licensed Product by the EMA	[***] Dollars ($[***])

In addition, Savara will pay to Grifols the following amounts for the first calendar year in which the annual global Net Sales of a Licensed Product achieves the following levels:

Annual Net Sales	Payment Amount
One Hundred Million Dollars ($100,000,000)	[***] Dollars ($[***])
Three Hundred Million Dollars ($300,000,000)	[***] Dollars ($[***])
Five Hundred Million Dollars ($500,000,000)	[***] Dollars ($[***])

6.4 Royalties.

(a) Licensed Products. In addition to the Milestone Payments and the Annual Net Sales payments set forth in Section 6.3 above, during the Royalty Term, Savara shall pay to Grifols royalties based on the Net Sales by Savara or its sublicensees of all Licensed Products in the Territory. The royalty rate shall begin on January 1 of each calendar year and shall be in the following percentages:

Annual Net Sales of All Licensed Products in the Territory	**Royalty Rate**
For that portion of annual Net Sales of Licensed Products (aggregated across the Territory) less than or equal to Three Hundred Million Dollars ($300,000,000)	[***] percent ([***]%)
For that portion of annual Net Sales of Licensed Products (aggregated across the Territory) greater than Three Hundred Million Dollars ($300,000,000) and less than Five Hundred Million Dollars ($500,000,000)	[***] percent ([***]%)
For that portion of annual Net Sales of Licensed Products (aggregated across the Territory) greater than five hundred million dollars ($500,000,000)	[***] percent ([***]%)

For example, if aggregate annual Net Sales of all Licensed Products in the Territory during any calendar year is One Billion Dollars ($1,000,000,000), then royalties payable by Savara equal [***] Dollars ($[***]) calculated as follows:

Royalties due for Up to Three Hundred Million in Net Sales: ([***]% (royalty rate applicable for such Net Sales amount) x $300 million (Aggregate Net Sales across the Territory subject to royalty rate)) = $[***]

Plus

Royalties due for Between Three Hundred Million-Five Hundred Million in Net Sales: ([***]% (Royalty rate applicable for such Net Sales amount) x $200 million (Aggregate Net Sales across the Territory subject to royalty rate)) = $[***]

Plus

Royalties due for Over Five Hundred Million in Net Sales: ([***]% (royalty rate applicable for such Net Sales amount) x $500 million (Aggregate Net Sales across the Territory subject to royalty rate)) = $[***]

Totaling $[***]

(b) Royalty Term. Royalties on Licensed Products shall be due during the period of time beginning, on a country-by-country and Licensed Product-by-Licensed Product basis, from the effective date of this Agreement, until the later of (i) ten (10) years from the first commercial sale of a Licensed Product in a country; (ii) the expiration of the last Grifols Patent covering that Licensed Product in such country; or (iii) generic introduction of inhaled liposomal ciprofloxacin in such country; provided, that such generic introduction is not caused or effectuated by Savara, its Affiliates, licensees, and sublicensees (the "**Royalty Term**"). For the avoidance of doubt, upon market introduction of any other inhaled ciprofloxacin product, to the extent the Royalty Term has not expired, the royalty rate in the corresponding country will be reduced by [***] percent ([***]%). At the end of the Royalty Term, Savara will have a fully paid-up license for such Licensed Product.

(c) Royalty Step Down for Third Party Payments. If, after the Effective Date, Savara (or its sublicensee) obtains a right or license under any Patent of a Third Party (which right or license includes one or more Patents), where Savara (or its sublicensee) determines that such Patent is reasonably necessary for the making, using, selling, offering for sale or importing of a Licensed Product, then Savara may offset the royalty payments due and payable by Savara to Grifols with respect to the Product in a calendar quarter by [***] percent ([***]%) of the amount of payments paid by Savara (or its sublicensee) to such Third Party for such right or license (but Savara may not deduct same against Milestone Payments). At no point during the Royalty Term will the royalty paid to Grifols be below [***] percent ([***]%) of the royalty rate by tier.

(d) Royalty Reports and Payments. Within thirty (30) days following the end of each calendar quarter, commencing, with respect to Savara's obligations under Section 6.3, with the calendar quarter in which the First Commercial Sale of any Licensed Product is made anywhere in the Territory, Savara shall provide Grifols with a royalty report on a product-by-product basis, which shall include: (i) the amount of gross sales of such applicable Licensed Product in the Territory, (ii) an itemized calculation of Net Sales in the Territory showing deductions provided for in the definition of Net Sales, (iii) a calculation of the royalty payment due on such sales, and (iv) the exchange rate for such country. Such report shall include such other information reasonably requested by Grifols, provided that such information reasonably relates to the sale of Licensed Products, which are the subject of this Agreement, and the calculation of Net Sales. Within thirty (30) days of the delivery of the applicable quarterly report, Savara shall pay in Dollars all royalty amounts due to Grifols in connection with such quarterly report.

6.5 Foreign Exchange. The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be made at the closing exchange rate reported in *The Wall Street Journal* for the last Business Day of the applicable calendar quarter.

6.6 Payment Method; Late Payments. All payments due to Grifols hereunder (including those due to Grifols pursuant to ARTICLE 12) shall be made in Dollars by wire transfer of immediately available funds into an account in the USA designated by Grifols. If Grifols does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due until the date of payment at the per annum rate of ten percent (10%) or the maximum rate allowable by applicable Laws, whichever is lower.

6.7 Records. Savara and its Affiliates and licensees and sublicensees shall maintain complete and accurate records in sufficient detail to permit Grifols to confirm the accuracy of the calculation of royalty payments. Grifols shall have the right to audit such records in accordance with Section 6.8.

6.8 Audits. For a period of two (2) years from the end of the calendar year in which a payment was due hereunder, upon thirty (30) days prior notice, Savara (the "**Audited Party**") shall (and shall require that its Affiliates and licensees and sublicensees) make such records relating to such payment available, during regular business hours and not more often than once each calendar year, for examination by an independent certified public accountant selected by the Grifols (the "**Auditing Party**") and reasonably acceptable to the Audited Party, for the purposes of verifying compliance with this Agreement and the accuracy of the financial reports and/or invoices furnished pursuant to this Agreement. The results of any such audit shall be shared by the auditor with both Parties and shall be considered Confidential Information of both Parties. Any amounts shown to be owed by either Party to the other shall be paid within thirty (30) days from the auditor's report, plus interest (as set forth in Section 6.6) from the original due date. The Auditing Party shall bear the full cost of such audit unless such audit discloses a deficiency in the Audited Party's payments of greater than five percent (5%) (i.e., an under-payment by Savara pursuant to Section 6.3), in which case the Audited Party shall bear the full cost of such audit.

6.9 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made under this Agreement. To the extent that a Party is required to deduct and withhold taxes on any payment to the other Party, the first Party shall deduct and pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the other Party an official tax certificate or other evidence of such withholding sufficient to enable the other Party to claim such payment of taxes. The other Party shall provide the first Party any tax forms that may be reasonably necessary to permit first Party to make any payments made under this Agreement without withholding tax or at a reduced rate of withholding. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. Savara shall require its sublicensees in the Territory to cooperate with Grifols in a manner consistent with this Section 6.9(b).

ARTICLE 7
INTELLECTUAL PROPERTY MATTERS

7.1 Prosecution of Patents.

(a) Savara Prosecuted Patents.

(i) Subject to 7.1(a)(ii) below, as between the Parties, Savara shall have the first right to prepare, file, prosecute and maintain the Grifols Patents in the Territory. The costs of preparation, filing, prosecution and maintenance of Grifols Patents in the countries listed in Schedule 7.1(a)(i)(1) shall be included in Development Costs, and, to the extent any new Patents are developed under this Agreement that are owned or Controlled by Grifols, Savara agrees to file such Patents with the applicable Regulatory Authorities in the countries listed in Schedule 7.1(a)(i)(1) and 7.1(a)(i)2). Savara shall provide Grifols reasonable opportunity to review and comment on such prosecution efforts regarding the Grifols Patents, as set forth in this Section 7.1(a)(i). All such Patents shall be filed with Grifols as the owner. Savara shall provide Grifols with copies of all material communications from any patent office or similar patent authority regarding the Grifols Patents.

(ii) If Savara decides not to prepare or file a Grifols Patent or if it decides to cease the prosecution or maintenance of any Grifols Patent, it shall notify Grifols in writing sufficiently in advance (but in no event less than twenty (20) Business Days before any submission needs to be made) so that Grifols may, at its discretion, assume the responsibility for the prosecution or maintenance of such Patent, at Savara' cost and expense. If Grifols assumes such responsibility, Savara, to the extent Savara has any right, title or interest in such Grifols Patents, shall promptly assign to Grifols all right, title and interest in such Grifols Patent.

(b) **Cooperation**. Grifols shall provide Savara all reasonable assistance and cooperation, at Savara's request and expense, in the patent prosecution efforts provide above in this Section 7.1, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

7.2 Enforcement of Grifols Patents.

(a) **Notification**. If either Party becomes aware of any existing or threatened infringement of the Grifols Patents which infringing activity involves the using, making, importing, offering for sale or selling of Licensed Products or otherwise adversely affects or is reasonably expected to adversely affect the Commercialization of any Licensed Product in the Territory (an "**Infringement**"), it shall promptly notify the other Party in writing to that effect and the Parties shall consult with each other regarding any actions to be taken with respect to such Infringement.

(b) **Actions Controlled by Savara; Grifols' Back-Up Enforcement Right**. Savara, at its sole discretion, shall have the first right, but not the obligation, to bring an appropriate suit or take other action against any Third Party engaged in any Infringement. If, after its receipt or delivery of notice thereof under Section 7.2(a), Savara (i) notifies Grifols that it will not bring any claim, suit or action to prevent or abate such Infringement or (ii) fails to commence a suit to prevent or abate such Infringement within one hundred and eighty (180) days, Grifols shall have the right, but not the obligation, to commence a suit or take action to prevent or abate such Infringement under the Grifols Patents at its own cost and expense. If Savara brings suit or action, it will use counsel reasonably acceptable to Grifols. Recoveries on suits under this Section 7.2(b) shall be handled as provided in Section 7.2(e).

(c) **Collaboration**. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, except as outlined directly above in Section 7.2(b), including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall seek consent of the other Party in any important aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court, which consent shall not be unreasonably withheld or delayed. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) **Settlement**. Savara shall not settle any claim, suit or action under Section 7.2(b) in a manner that would negatively impact the applicable Grifols Patents (e.g., shorten the life of such Patents or narrow their scope) without the prior written consent Grifols.

(e) **Expenses and Recoveries**. The term "**Revenue**" includes all fees, minimum royalties, payments, compensation, or consideration of any kind, including without limitation in-kind payments, forbearance in connection with settlement, equity amounts taken in lieu of cash, or discounts below fair market value of equity received by either Party or its Affiliates, to which entity pays, transfers or otherwise provides the Revenue, or how the Revenue is structured, denominated, or paid, transferred or provided. If the enforcing Party receives Revenue in such claim, suit or action, such Revenue shall be allocated first to the reimbursement of any expenses incurred by the Party which paid for such expenses in such claim, suit or action (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be partially allocated to Grifols in an amount equal to the royalty that would have been payable to Grifols under Section 6.3 if Savara had made Net Sales equivalent to the remaining amount, with the remaining portion of the remaining amount allocated to Savara.

7.3 **Infringement of Third Party Rights in the Territory**. Subject to ARTICLE 9, if any Licensed Product used or sold by Savara, its Affiliates or licensees or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Third Party's Patent granted by a jurisdiction within the Territory (and such alleged infringement is caused by the Grifols Technology and not Savara' use of its own or any Third Party technologies), Savara shall promptly notify Grifols and the Parties shall agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action. Savara shall be responsible for defending such claim (with all of its costs and expenses) and Grifols shall provide necessary assistance to Savara with such defense. All costs and expenses associated with defending such claim, including all payments to such Third Parties, including, without limitation, all payments and royalties paid to such Third Parties required to obtain any license rights under such Third Party's Patents, shall be shared [***] percent ([***]%) by Savara and [***] percent ([***]%) by Grifols. Grifols' payment obligations as provided hereunder shall be satisfied by deducting such amounts from the royalty payments next payable to Grifols pursuant to Section 6.4 (but Savara may not deduct same against Milestone Payments); provided, that any such deduction shall not exceed [***] percent ([***]%) of any royalty payment due and payable to Grifols. Savara may carry forward to future royalty periods any unused deduction due to the [***] percent ([***]%) floor until all deductions Savara is eligible for are exhausted.

7.4 Patent Marking. Savara and its Affiliates and licensees and sublicensees shall mark (or shall use Diligent Efforts to ensure the marking of) each Licensed Product marketed and sold by Savara or its Affiliates or licensees or sublicensees hereunder with appropriate patent numbers or indicia as required by applicable Law.

7.5 Trademarks.

(a) Product Marks. Savara shall have the right to brand the Licensed Products and create all Licensed Product labels using Savara-related trademarks and any other trademarks and trade names it determines appropriate for the Licensed Products, which may vary by country or within a country (collectively, the "**Product Marks**"). Savara shall use commercially reasonable efforts to insure that any Product Mark that it determines appropriate for the Licensed Products will not infringe any other trademark or trade name in the country where Savara wishes to use that Product Mark and that no such Product Mark will infringe any trademark owned by Grifols in any country of the Territory.

(b) Ownership; No Challenge. Absent a default under this Agreement by Savara, Savara shall own all right, title and interest in and to the Product Marks and Grifols acknowledges and affirms the validity and enforceability thereof. Absent a default under this Agreement by Savara, Grifols shall not engage in or support any action, claim or challenge that is inconsistent with the foregoing. Prior to a default under this Agreement by Savara, all use of the Product Marks and the goodwill generated thereby shall inure solely to the benefit of Savara. Absent a default under this Agreement by Savara, Grifols shall not use, adopt, file, register, seek to register, or take any other action to use or establish rights in any mark anywhere in the world which is comprised of, derivative of, a combination with, or otherwise confusingly similar to, any Product Mark. Immediately following a default by Savara under this Agreement, Savara shall assign all right, title and interest in and to the Product Marks to Grifols, Savara acknowledges and affirms the validity and enforceability thereof, and Savara shall not engage in or support any action, claim or challenge that is inconsistent with the foregoing.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES; COVENANTS; EXCLUSIVITY

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as **follows**:

(a) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated;

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date or the date of any required approval by its shareholders, (i) it has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; (ii) it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms; and

(c) **No Conflict**. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not, in any material respect, conflict with, violate, or breach or constitute a default or require any consent that has not been obtained under any contractual obligation or court or administrative order by which such Party is bound.

8.2 **Additional Representations and Warranties of Savara**. Savara represents and warrants that: Attached as Section 8.2 are true, complete and correct copies of unaudited interim balance sheet and related unaudited statement of income and statement of cash flows of Savara at and for the three fiscal periods ended September 30, 2019.

8.3 **Mutual Covenants**.

(a) **No Debarment**. In the course of the Development of the Licensed Products, each Party shall not use any employee or consultant who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

(b) **Compliance**. Each Party and its Affiliates shall comply in all material respects with all applicable Laws in the Development and Commercialization of Licensed Products and performance of its obligations under this Agreement, including the statutes, regulations, guidances, guidelines, and written directives of the FDA, the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Federal Health Care Programs Anti-Kickback Law, 42 US 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 US § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time.

8.4 **Exclusivity**. [***]:

(a) [***];

(b) [***]; or

(c) [***].

8.5 **Bidding**.

(a) [***].

(b) [***].

8.6 Disclaimer. Savara understands that the Compound and Licensed Products are the subject of ongoing clinical research and Development and that Grifols cannot assure the safety or efficacy of any Compound or Licensed Product. In addition, Grifols makes no warranties except as set forth in this Article 9 concerning the Grifols Technology. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL IMPLIED REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY DISCLAIMED. In addition, Grifols acknowledges that any failure by Savara to obtain required additional funding on acceptable terms would adversely impact Savara's ability to support the Development Plan, Regulatory Approval matters, the Commercialization Plan and related other obligations hereunder. Savara agrees to use Diligent Efforts to obtain such funding and report the status of such financing in the Development Plan and any Additional Development Plan, but makes no representation regarding its ability to obtain such funding.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Grifols. Grifols shall indemnify and hold harmless Savara, and its directors, officers, employees, agents, Affiliates and contractors (collectively, the "**Savara Indemnitees**"), from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs (collectively, "**Liabilities**"), resulting from any claims, demands, actions or other proceedings by any Third Party ("**Claims**") to the extent arising out of or relating to an allegation which, if true, would result in (a) the breach of any representation, warranty or covenant by Grifols under this Agreement, or (b) the negligence or willful misconduct of Grifols or its agents, Affiliates and contractors. The foregoing indemnity obligation shall not apply to the extent that (i) the Savara Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Grifols' defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim results from any activity set forth in Section 9.2(a), (b), (c), or (d) for which Savara is obligated to indemnify the Grifols Indemnitees under Section 9.2

9.2 Indemnification by Savara. Savara shall indemnify and hold harmless Grifols, and its directors, officers, employees, agents, Affiliates and contractors (collectively, the "**Grifols Indemnitees**"), from and against all Liabilities to the extent arising out of or relating to the Licensed Products, including, but not limited to Liabilities arising out of or relating to (a) an allegation which, if true, would result in (i) the breach of any representation, warranty or covenant by Savara under this Agreement, (ii) the negligence or willful misconduct of Savara or its agents, Affiliates and contractors, or (iii) the breach of any Aradigm contract, assumed by Grifols pursuant to an the Asset Purchase Agreement, (b) the Development of any Licensed Product, (c) the Commercialization of any Licensed Product, or (d) any products liability claim resulting from the sale of any Licensed Product. The foregoing indemnity obligation shall not apply to the extent that (i) the Grifols Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Savara' defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim results from any activity set forth in Section 9.1(a) or (b) for which Grifols is obligated to indemnify the Savara Indemnitees under Section 9.1.

9.3 Indemnification Procedures. The Party claiming indemnity under this ARTICLE 9 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice, and the Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. Each Party shall not settle or compromise any Claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned. If the Parties cannot agree as to the application of the foregoing Sections 9.1 and 9.2, each may conduct separate defenses of the Claim, and each Party reserves the right to claim indemnity from the other in accordance with this ARTICLE 9 upon the resolution of the underlying Claim.

9.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, INCLUDING LOST PROFITS (BUT EXPRESSLY EXCLUDING ANY MILESTONE PAYMENTS OR ROYALTIES HEREUNDER), ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.1 OR SECTION 9.2 OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 10, OR RELATING TO A PARTY'S BREACH OF REPRESENTATIONS OR WARRANTIES OR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

9.5 Insurance. Within sixty (60) days of the Effective Date Savara shall provide Grifols a certificate of insurance and at all times during the Term of this Agreement and for three (3) years thereafter, obtain and maintain at its own expense the following types of insurance, with limits of liability not less than those specified below:

(a) Commercial general liability insurance against claims for bodily injury and property damage which shall include contractual coverage, with limits of not less than Two Million Dollars ($2,000,000) per occurrence and Two Million Dollars ($2,000,000) in the aggregate.

(b) Products liability insurance against claims based upon products liability which shall include contractual coverage, with limits of not less than Five Million Dollars ($5,000,000) per occurrence and Five Million Dollars ($5,000,000) in the aggregate.

(c) Workers compensation and employers' liability insurance with limits to comply with the statutory requirements of the state(s) in which the Agreement is to be performed. The policy shall include employers' liability for not less than One Million Dollars ($1,000,000) per accident.

(d) Umbrella liability insurance with limits of not less than Four Million Dollars ($4,000,000) per occurrence and Four Million Dollars ($4,000,000) in the aggregate.

All policies shall be issued by insurance companies with an A.M. Best's rating of Class A-:V (or its equivalent) or higher status. Savara shall deliver certificates of insurance evidencing coverage to Grifols promptly after the execution of this Agreement and annually thereafter. All policies provided for herein shall expressly provide that such policies shall not be cancelled, terminated or altered without at least thirty (30) days prior written notice to the insured Party, and each insuring Party shall immediately notify the insured Party in the event that a policy provided for herein is cancelled, terminated or altered.

ARTICLE 10
CONFIDENTIALITY

10.1 Confidentiality. During the Term and for a period of five (5) years thereafter, each Party shall maintain all Confidential Information of the other Party in trust and confidence and shall not, without the written consent of the other Party, disclose any Confidential Information of the other Party to any Third Party or use any Confidential Information of the other Party for any purpose other than as necessary or helpful in connection with the exercise of rights or discharge of obligations under this Agreement. The confidentiality obligations of this Section 10.1 shall not apply to Confidential Information to the extent that the receiving Party can establish by competent evidence that such Confidential Information: (a) is publicly known prior or subsequent to disclosure without breach of confidentiality obligations by such Party or its employees, consultants or agents; (b) was in such Party's possession at the time of disclosure without any restrictions on further disclosure; (c) is received by such receiving Party, without any restrictions on further disclosure, from a Third Party who has the lawful right to disclose it; or (d) is independently developed by employees or agents of the receiving Party without reference to the disclosing Party's Confidential Information.

10.2 Authorized Disclosure. Nothing herein shall preclude a Party from disclosing the Confidential Information of the other Party, solely to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patents as contemplated by this Agreement; (ii) to comply with the requirement of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval (or any pricing and reimbursement approvals) of a Licensed Product; or (iii) for prosecuting or defending litigations as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;

(d) such disclosure is reasonably necessary to comply with applicable Laws, including regulations promulgated by applicable security exchanges, a valid order of a court of competent jurisdiction, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to any of Sections 10.2(a) through 10.2(d), such Party shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

10.3 Return of Confidential Information. Promptly after the termination or expiration of this Agreement for any reason, each Party shall return to the other Party all tangible manifestations of such other Party's Confidential Information at that time in the possession of the receiving Party.

10.4 Publicity; Terms of the Agreement; Confidential Treatment.

(a) The Parties agree that the terms of this Agreement (including without limitation any exhibits hereto) shall be considered Confidential Information of each Party, subject to the special authorized disclosure provisions set forth in Section 10.2 and this Section 10.4.

(b) The Parties have agreed to issue a joint press release on or promptly after the Effective Date in a form to be mutually agreed upon by the Parties. In addition, to the extent required by applicable Laws, including regulations promulgated by applicable security exchanges, each Party shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals in the Territory as they occur, subject to the other Party's consent as to form and substance of such announcement, which shall not be unreasonably withheld or delayed. In relation to the other Party's review and approval of such an announcement, such other Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone has been achieved and triggered a payment hereunder. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 10.4, provided such information remains accurate as of such time.

(c) In addition, the Parties acknowledge that either or both Parties may be obligated to file under applicable law and regulation a copy of this Agreement with the USA Securities and Exchange Commission or similar stock exchange authorities or other governmental authorities. Each Party shall be entitled to make such a required filing; *provided*, *however*, that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof. In the event of any such filing, each Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

10.5 Technical Publication. Neither Party may publish peer reviewed manuscripts or give other forms of public disclosure such as abstracts and media presentations (such disclosure collectively, for purposes of this Section 10.5, "**publication**"), of results of studies carried out under this Agreement, without the opportunity for prior review by the other Party, except to the extent required by applicable Laws. A Party seeking publication shall provide the other Party the opportunity to review and comment on any proposed publication that relates to the Licensed Product at least thirty (30) days (or at least ten (10) days in the case of abstracts and media presentations) prior to its intended submission for publication. The other Party shall provide the Party seeking publication with its comments in writing, if any, within twenty (20) days (or within five (5) days in the case of abstracts and media presentations) after receipt of such proposed publication. The Party seeking publication shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party's reasonable request to remove any and all of such other Party's Confidential Information from the proposed publication. In addition, the Party seeking publication shall delay the submission for a period up to sixty (60) days in the event that the other Party can demonstrate reasonable need for such delay in order to accommodate the preparation and filing of a patent application. If the other Party fails to provide its comments to the Party seeking publication within such twenty (20)-day period (or five (5)-day period, as the case may be), such other Party shall be deemed not to have any comments, and the Party seeking publication shall be free to publish in accordance with this Section 10.5 after the thirty (30)-day period (or ten (10)-day period, as the case may be) has elapsed. The Party seeking publication shall provide the other Party a copy of the publication at the time of the submission. Each Party agrees to acknowledge the contributions of the other Party and its employees in all publications as scientifically appropriate.

10.6 Equitable Relief. Each Party acknowledges that its breach of this Agreement may cause irreparable injury to the other Party for which monetary damages may not be an adequate remedy. Therefore, each Party shall be entitled to seek injunctive and other appropriate equitable relief to prevent or curtail any actual or threatened breach of the obligations under this Agreement by the other Party. The rights and remedies provided to each Party in this Section 10.6 are cumulative and in addition to any other rights and remedies available to such Party at law or in equity.

ARTICLE 11
TERM AND TERMINATION

11.1 Term. This Agreement shall become effective on the date that Grifols closes the Asset Purchase Agreement, following Bankruptcy Court Approval, provided, however, that the Parties shall be bound by the terms and conditions of Sections 8.4 and 8.5 upon execution of this Agreement, and, unless earlier terminated pursuant to this ARTICLE 11, this Agreement shall remain in effect until the Royalty Term has expired in all countries, for all Licensed Products (the "**Term**").

11.2 Termination by Grifols for Patent Challenge. Grifols may terminate this Agreement in its entirety immediately upon written notice to Savara, if Savara or any Savara's Affiliate files a challenge with a Governmental Authority contesting the validity, enforceability or scope of any Grifols Patent anywhere in the world. If a sublicensee of Savara takes the forgoing action, Savara shall terminate the sublicense, however, it being understood that Grifols shall not have the right to terminate this Agreement in such event.

11.3 Termination by Grifols for Lack of Development. Grifols may terminate this Agreement in its entirety immediately upon written notice to Savara, if Savara fails to Develop Licensed Products or execute its Development Plan by failing to allocate material funds, full-time equivalents, and resources over a period of twelve (12) consecutive months, net of any delay due to Force Majeure pursuant to Section 13.2.

11.4 Termination for Breach.

(a) Breach by Grifols. Savara shall have the right to terminate this Agreement in its entirety upon written notice to Grifols, if Grifols materially breaches any of its material obligations under this Agreement, which (for avoidance of doubt) shall include, without limitation, any breach of the obligations under Section 2.1(a) and Section 2.4 hereunder, and, after receiving written notice identifying such material breach in reasonable detail, Grifols fails to cure such material breach within sixty (60) days from the date of such notice, provided, that if such breach is not capable of being cured within such 60-day period, the cure period shall be extended for such amount of time that the Parties may agree in writing is reasonably necessary to cure such breach, so long as (1) Grifols is making commercially reasonable efforts to do so, and (2) the Parties discuss in good faith and agree on an extension within such 90-day period.

(b) Breach by Savara. Grifols shall have the right to terminate this Agreement in its entirety upon written notice to Savara, if Savara materially breaches any of its material obligations under this Agreement, which (for avoidance of doubt) shall include, without limitation, any breach of the obligations under Section 3.1, Section 3.2, Section 3.3, and ARTICLE 4 hereunder, and, after receiving written notice identifying such material breach in reasonable detail, Savara fails to cure such material breach within sixty (60) days from the date of such notice, provided, that if such breach is not capable of being cured within such 60-day period, the cure period shall be extended for such amount of time that the Parties may agree in writing is reasonably necessary to cure such breach, so long as (1) Savara is making commercially reasonable efforts to do so, and (2) the Parties discuss in good faith and agree on an extension within such 90-day period.

(c) If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 11.3, Section 11.4(a), or Section 11.4(b), and such alleged breaching Party provides the other Party notice of such dispute within the applicable cure period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 11.3, Section 11.4(a), or Section 11.4(b) unless and until an arbitrator, in accordance with ARTICLE 12 has determined that the alleged breaching Party has materially breached the Agreement and such breaching Party fails to cure such breach within the applicable cure period (measured as commencing after the arbitrator's decision). It is understood and agreed that during the pendency of such 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.

11.5 Termination for Bankruptcy. To the extent permitted under applicable Laws, if at any time during the Term of this Agreement, an Event of Bankruptcy (as defined below) relating to either Party (the "**Bankrupt Party**") occurs, the other Party (the "**Non-Bankrupt Party**") shall have, in addition to all other legal and equitable rights and remedies available hereunder, the option to terminate this Agreement upon thirty (30) days written notice to the Bankrupt Party. It is agreed and understood that if the Non-Bankrupt Party does not elect to terminate this Agreement upon the occurrence of an Event of Bankruptcy, except as may otherwise be agreed with the trustee or receiver appointed to manage the affairs of the Bankrupt Party, the Non-Bankrupt Party shall continue to make all payments required of it under this Agreement as if the Event of Bankruptcy had not occurred, and the Bankrupt Party shall not have the right to terminate any license granted herein.

(a) The term "**Event of Bankruptcy**" means: (a) filing, in any court or agency pursuant to any statute or regulation of any state or country, (i) a petition in bankruptcy or insolvency, (ii) for reorganization or (iii) for the appointment of (or for an arrangement for the appointment of) a receiver or trustee of the Bankrupt Party or of its assets; (b) with respect to the Bankrupt Party, being served with an involuntary petition filed in any insolvency proceeding, which such petition is not dismissed within thirty (30) days after the filing thereof; (c) proposing or being a party to any dissolution or liquidation when insolvent; or making an assignment for the benefit of creditors.

(b) Without limitation, the Bankrupt Party's rights under this Agreement shall include those rights afforded by 11 US § 365(n) of the United States Bankruptcy Code (the "**Bankruptcy Code**") and any successor thereto.

(c) If the bankruptcy trustee of a Bankrupt Party as a debtor or debtor-in-possession rejects this Agreement under 11 US § 365 of the Bankruptcy Code, the Non-Bankrupt Party may elect to retain its rights licensed from the Bankrupt Party hereunder (and any other supplementary agreements hereto) for the duration of this Agreement and avail itself of all rights and remedies to the full extent contemplated by this Agreement and 11 US § 365(n) of the Bankruptcy Code, and any other relevant Laws.

11.6 Effect of Termination.

(a) **In General**. The termination of this Agreement shall not relieve either Party from liability or damages for any breach of this Agreement.

(b) **Effect of Termination for Breach by Grifols, Expiration of the Term, or Bankruptcy of Grifols**.

(i) **Licensed Rights**. All licenses and rights granted to Savara, under this Agreement, including, but not limited to the license described in 2.1(a), shall be deemed fully paid, perpetual, and irrevocable.

(c) Effect of Termination for Breach By Savara, Patent Challenge by Savara, Bankruptcy of Savara, or Lack of Development.

(i) Licensed Rights. All licenses and rights granted to Savara, under this Agreement, including, but not limited to the license described in Section 2.1(a), shall immediately terminate (except to the extent necessary to allow Savara to sell off its inventory pursuant to Section 12.7(b)(i)). Grifols, in its sole discretion, may elect to assume or terminate any sublicenses granted by Savara pursuant to Section 2.2 (to the extent offered by Savara and assignable).

(ii) Inventory. Savara may sell off all of Savara's inventory of Licensed Products during the twelve (12) month period after the effective date of termination (during which time royalties shall continue to be paid by Savara).

(iii) Regulatory Materials; Data. To the extent permitted by applicable Laws, Savara shall immediately transfer and assign to Grifols all Regulatory Materials (including all right, title and interest in all Regulatory Materials designed to obtain or support any Regulatory Approval, including all NDAs), data and Know-How relating to the Licensed Products and Compound and shall treat the foregoing as Confidential Information of Grifols (and not of Savara) under ARTICLE 11; provided that Savara shall be allowed to retain copies of any such materials that a Regulatory Authority requires Savara to retain under applicable Laws, or that Savara requires pursuant to its internal recordkeeping rules (with such information to be used strictly in accordance with such rules).

(iv) Savara License. Savara shall be deemed to have granted to Grifols, only effective upon termination, an exclusive, fully paid up, worldwide, fully transferable, irrevocable license (with the right to grant sublicenses through multiple tiers) under all Patents, Know-How, and Product Marks (to the extent not assigned under Section 11.5(c)(iii) (A) Controlled by Savara (or its Affiliates) at any time (including after the termination of this Agreement)and (B) actually used or conceived by Savara or any of its Affiliates during the Term (1) for the Development and/or Commercialization of the Licensed Product or (2) at any time as a result of Savara's or any of its Affiliates' in existence during the Term access to Grifols Technology under this Agreement, or (C) Covering the Licensed Product or Compound, in each case to make, have made, use, import, offer for sale and sell Licensed Products. For the avoidance of doubt, all rights of Savara in the intellectual property of Grifols (including, without limitation, as mentioned above, the Product Marks) shall immediately be deemed to be granted or otherwise transferred to Grifols.

(v) Transition Assistance. For a period of one hundred eighty (180) days Savara shall provide such assistance, at no cost to Grifols, as may be reasonably necessary for Grifols to continue Developing and/or Commercializing Licensed Products throughout the Territory, to the extent Savara is then performing or having performed such activities, including by using good faith efforts to assign or amend, as appropriate, upon the request of Grifols, any agreements or arrangements with Third Party vendors to Develop and/or Commercialize Licensed Products. To the extent that any such contract between Savara and a Third Party is not assignable to Grifols, Savara shall reasonably cooperate with Grifols to arrange with any such Third Party to continue to provide such services for a reasonable time after termination. Savara shall not knowingly, during any notice period prior to the termination of this Agreement or during any transition period after termination, take any action that could reasonably be expected to have a material adverse impact on the further Development and Commercialization of any Licensed Product.

11.7 Survival. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: ARTICLE 1, Sections 6.7, 6.8, 6.9(a), ARTICLE 9, ARTICLE 10, 11.6, ARTICLE 12, 13.1, 13.3, 13.4, 13.7, 13.8, 13.9, 13.10, 13.11, and 13.12.

ARTICLE 12
DISPUTE RESOLUTION

12.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this ARTICLE 12 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

12.2 Internal Resolution. With respect to all disputes arising between the Parties under this Agreement, including any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within thirty (30) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Officers of the Parties for attempted resolution by good faith negotiations within thirty (30) days after such notice is received, including at least one (1) in-person meeting of the Executive Officers within twenty (20) days after such notice is received.

12.3 Arbitration. If the Executive Officers of the Parties are not able to resolve such dispute referred to them under Section 12.2 within such thirty (30) day period, then subject to Section 13.4, such dispute shall be settled by binding arbitration in accordance with the then current rules of commercial arbitration of the American Arbitration Association ("**AAA**"). A single arbitrator with experience in the development and commercialization of drugs and diagnostics shall be appointed by each of the Parties, and the two arbitrators appointed by the Parties shall appoint the third arbitrator with experience in the development and commercialization of drugs and diagnostics. The place of arbitration shall be Los Angeles, California. The arbitrator's fees and expenses shall be shared equally by the Parties. Each Party shall bear and pay its own expenses incurred in connection with any dispute resolution under this Section 12.3. The proceedings, including any outcome, shall be confidential. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrator hereunder or pending the arbitrator's decision of the dispute subject to arbitration.

12.4 Patent and Trademark Disputes. Notwithstanding Section 12.3, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Covering the manufacture, use, importation, offer for sale or sale of any Licensed Product or of any trademark rights relating to any Licensed Product shall be submitted to a court of competent jurisdiction in the country in which such Patent or trademark rights were granted or arose.

12.5 Equitable Relief. Nothing in this ARTICLE 12 shall prevent either Party from seeking equitable or other relief in a court of competent jurisdiction. All rights and remedies provided to each Party in this Agreement are cumulative and in addition to any other rights and remedies available to such Party at law or in equity.

ARTICLE 13
MISCELLANEOUS

13.1 Entire Agreement; Amendment. This Agreement, together with the exhibits attached hereto, which are hereby incorporated herein, represents the entire agreement and understanding between the Parties with respect to its subject matter and supersedes and terminates any prior and/or contemporaneous discussions, representations or agreements, whether written or oral, of the Parties regarding the subject matter hereto, and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. Amendments or changes to this Agreement shall be valid and binding only if in writing and signed by duly authorized representatives of the Parties.

13.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including an act of God, clinical hold, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). If a force majeure persists for more than ninety (90) days, then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure, and if the force majeure prevents Savara from performing its obligations under the Development Plan for a period of more than one hundred and five (105) days, Grifols shall have the right to terminate this Agreement pursuant to Section 11.4(b).

13.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 13.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Grifols:

Grifols, S.A.
Avinguda de la Generalitat, 152
Parc empresarial Can Sant Joan
08174 Sant Cugat del Vallès
Barcelona, Spain
Facsimile: +34.93.571.0267
Attention: Victor Grifols
Raimon Grifols

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

Osborne Clarke S.L.P.
Avenida Diagonal, 477
Planta 20
Torre de Barcelona
08036
Barcelona, Spain
Facsimile: +34.93.571.0267
Attention: Tomás Dagá

and

Arent Fox LLP
Gas Company Tower
555 West 5th Street
48th Floor
Los Angeles, CA 90013
Attn: Aram Ordubegian, Esq.
David C. Meyer, Esq.

If to Savara:

Savara, Inc.
6836 Bee Cave Road
Building 3, Suite 200
Austin, TX 78746
Phone: 512-851-1360
Attn.: Kate McCabe

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

Wilson Sonsini Goodrich & Rosati, P.C.
Attn: John E. Wehrli, Esq.
12235 El Camino Real, Suite 200
California, U.S.A. 92130

13.4 No Strict Construction; Headings. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

13.5 Assignment. Neither Party may assign this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, except that (i) either Party may assign this Agreement without the prior consent of the other Party to its Affiliate; provided that, as between Savara and its assignee, on the one hand, and Grifols, on the other hand, Savara shall remain the primary obligor with respect to its and its assignee's obligations under this Agreement, and (ii) Savara may assign this Agreement to any purchaser of all or substantially all of the business or assets of Savara to which this Agreement relates, or of all of its capital stock, or to any successor corporation or entity resulting from any merger or consolidation of Savara with or into such corporation or entity, provided, that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by all obligations of Savara under this Agreement. Notwithstanding the foregoing, Grifols may assign without Savara's consent its rights to royalties received under this Agreement. Any permitted assignment shall be binding on the successors of the assigning Party. Any attempted or purported assignment in violation of this Section 13.5 shall be null and void.

13.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates (and, for the avoidance of doubt, Savara may sublicense its rights and obligations under this Agreement to any of its wholly-owned subsidiaries). Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

13.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.8 Severability. If any provision of this Agreement is found by a court of competent jurisdiction to be unenforceable, then such provision shall be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it shall be severed from the remainder of this Agreement. The remainder of this Agreement shall remain in full force and effect, unless the severed provision is essential and material to the rights or benefits received by either Party. In such event, the Parties shall negotiate, in good faith, and substitute a valid and enforceable provision or agreement that most nearly implements the Parties' intent in entering into this Agreement.

13.9 **No Waiver**. No provision of this Agreement can be waived except by the express written consent of the Party waiving compliance. Except as specifically provided for herein, the waiver from time to time by either Party of any of its rights or its failure to exercise any remedy shall not operate or be construed as a continuing waiver of the same or of any other of such Party's rights or remedies provided in this Agreement.

13.10 **Independent Contractors**. For all purposes under this Agreement, Savara and Grifols and their respective Affiliates are independent contractors with respect to each other, and shall not be deemed to be an employee, agent, partner or legal representative of the other Party. This Agreement does not grant any Party or its employees, consultants or agents any authority (express or implied) to do any of the following without the prior express written consent of the other Party: create or assume any obligation; enter into any agreement; make any representation or warranty; serve or accept legal process on behalf of the other Party; settle any claim by or against the other Party; or bind or otherwise render the other liable in any way.

13.11 **Governing Law**. This Agreement shall be governed by the laws of the state of Delaware, without regard to its choice of law provisions that would require the application of the laws of a different jurisdiction. The Parties hereby irrevocably submit to the jurisdiction of the state and federal courts sitting in the State of Delaware for the adjudication of disputes arising out of or relating to this Agreement.

13.12 **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together shall constitute the same legal instrument.

[Signature page follows]

In Witness Whereof, the Parties have executed this agreement by their duly authorized officers as of the Effective Date.

Savara, Inc.		**Grifols S.A.**	
By:	/s/ Rob Neville	By:	/s/ Lafmin Morgan
Name:	Rob Neville	Name:	Lafmin Morgan
Title:	CEO	Title:	Chief Commercial Officer

Exhibit A

Patent List

[Intentionally omitted. The exhibit will be provided to the Securities and Exchange Commission upon request.]

Exhibit B

Development Plan

[***]

AMENDMENT TO LICENSE AND COLLABORATION AGREEMENT

This AMENDMENT TO LICENSE AND COLLABORATION AGREEMENT (this "**Amendment**"), dated as of February 18, 2020, by and among Grifols, S.A., a company (*sociedad anónima*) organized under the laws of Spain having a principal place of business at Avinguda de la Generalitat, 152, Parc empresarial Can Sant Joan, 08174 Sant Cugat del Vallés, Barcelona, Spain ("**Grifols**") and Savara Inc., a Delaware corporation, and its affiliates (collectively, "**Savara**").

WHEREAS, Grifols and Savara entered into a License and Collaboration Agreement, dated as of January 7, 2020 (the "**License Agreement**"); and

WHEREAS, the parties now desire to make certain modifications to the License Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein and for other good and valuable consideration, the parties hereby agree that the License Agreement shall be, and it hereby is, amended as follows:

1. Upfront Payment. Section 6.2 of the License Agreement is hereby amended and restated in its entirety to read as follows:

"6.2 Upfront Payment. In connection with this Agreement, Savara agrees to pay to Grifols upon the commencement of the Term Three Million Two Hundred Forty-Seven Thousand Dollars ($3,247,000), which payment shall be made in accordance with the terms of (i) that certain Escrow Agreement dated February 18, 2020 by and among Savara, Grifols and Citibank, N.A., as escrow agent, and (ii) that certain letter agreement dated February 18, 2020 between Savara and Grifols."

2. Defined Terms. All capitalized terms not otherwise defined in this Amendment shall have the meanings given to them in the License Agreement.

3. Counterparts. This Amendment may be executed in any number of counterparts, each such counterpart being deemed to be an original instrument, and all such counterparts shall together constitute the same instrument.

4. Governing Law. This Amendment shall be governed by the laws of the State of Delaware, without regard for choice-of-law provisions.

5. Miscellaneous. Except as specifically amended by the terms of this Amendment, all other terms and conditions of the License Agreement are and shall remain in full force and effect for all purposes.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

SAVARA INC.

By: /s/ David L. Lowrance

Name: David L. Lowrance

Title: CFO

GRIFOLS S.A.

By: /s/ Lafmin Morgan

Name: Lafmin Morgan

Title: Chief Commercial Officer

SECOND AMENDMENT TO LICENSE AND COLLABORATION AGREEMENT

This SECOND AMENDMENT TO LICENSE AND COLLABORATION AGREEMENT (this "**Second Amendment**"), dated as of March 31, 2020, by and among Grifols, S.A., a company (*sociedad anónima*) organized under the laws of Spain having a principal place of business at Avinguda de la Generalitat, 152, Parc empresarial Can Sant Joan, 08174 Sant Cugat del Vallés, Barcelona, Spain ("**Grifols**") and Savara Inc., a Delaware corporation, and its affiliates (collectively, "**Savara**").

WHEREAS, Grifols and Savara entered into a License and Collaboration Agreement, dated as of January 7, 2020 and amended February 18, 2020 (the "**License Agreement**"); and

WHEREAS, the parties now desire to make certain modifications to the License Agreement as set forth in this Second Amendment.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein and for other good and valuable consideration, the parties hereby agree that the License Agreement shall be, and it hereby is, amended as follows:

1. Force Majeure. Section 13.2 of the License Agreement is hereby amended and restated in its entirety to read as follows:

"13.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). If a force majeure persists for more than ninety (90) days, then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure, and if the force majeure prevents Savara from performing its obligations under the Development Plan for a period of more than one hundred and five (105) days, Grifols shall have the right to terminate this Agreement pursuant to Section 11.3(b), provided, however, that Grifols shall not have such right to terminate this Agreement for twelve (12) months due to a force majeure caused by the COVID-19 pandemic, including, without limitation, due to any action or inaction, promulgation, restriction, or change in law by any Governmental Authority in response to the COVID-19 pandemic and delays in the supply chain or interruptions to the labor force and commercial activities substantially necessary for a Party's timely performance under this Agreement reasonably caused by the COVID-19 pandemic."

2. Defined Terms. All capitalized terms not otherwise defined in this Second Amendment shall have the meanings given to them in the License Agreement.

3. Counterparts. This Second Amendment may be executed in any number of counterparts, each such counterpart being deemed to be an original instrument, and all such counterparts shall together constitute the same instrument.

4. Governing Law. This Second Amendment shall be governed by the laws of the State of Delaware, without regard for choice-of-law provisions.

5. Miscellaneous. Except as specifically amended by the terms of this Second Amendment, all other terms and conditions of the License Agreement are and shall remain in full force and effect for all purposes.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Second Amendment as of the date first above written.

SAVARA INC.

By: /s/ Rob Nevile

Name: Rob Neville

Title: Chief Executive Officer

GRIFOLS S.A.

By: /s/ Lafmin Morgan

Name: Lafmin Morgan

Title: Chief Commercial Officer

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 7, 2020

/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 7, 2020

/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, 2020, 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.

May 7, 2020

/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, 2020, 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 7, 2020

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