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 June 30, 2019

OR

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

For the transition period from _____ to _____

Commission File Number 001-32157

Savara Inc.

(Exact name of registrant as specified in its charter)

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

(512) 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 August 8, 2019, the registrant had 41,197,636 shares of common stock, $0.001 par value per share, outstanding.

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 16,830	$ 24,301
Short-term investments	94,902	86,529
Prepaid expenses and other current assets	2,436	2,514
Total current assets	114,168	113,344
Property and equipment, net	454	522
In-process R&D	11,274	11,372
Goodwill	19,432	26,918
Other non-current assets	2,002	131
Total assets	$ 147,330	$ 152,287
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,440	$ 3,879
Accrued expenses and other current liabilities	4,612	3,375
Total current liabilities	9,052	7,254
Long-term liabilities:		
Debt facility	24,822	24,530
Contingent consideration	—	12,214
Other long-term liabilities	657	70
Total liabilities	34,531	44,068
Stockholders' equity:		
Common stock, $0.001 par value, 200,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 38,903,830 and 35,146,096 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	40	36
Additional paid-in capital	276,317	237,702
Accumulated other comprehensive income	212	200
Accumulated deficit	(163,770)	(129,719)
Total stockholders' equity	112,799	108,219
Total liabilities and stockholders' equity	$ 147,330	$ 152,287

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 10,464	$ 9,268	$ 20,483	$ 17,807
General and administrative	4,211	2,486	6,974	4,254
Impairment of acquired IPR&D	—	—	—	21,692
Impairment of goodwill	7,420	—	7,420	—
Depreciation and amortization	59	153	197	260
Total operating expenses	22,154	11,907	35,074	44,013
Loss from operations	(22,154)	(11,907)	(35,074)	(44,013)
Other income, net:				
Interest income (expense), net	31	(113)	11	(217)
Foreign currency exchange gain	110	155	51	94
Tax credit income	115	277	1,079	1,201
Change in fair value of financial instruments	(41)	(6)	(118)	(62)
Total other income	215	313	1,023	1,016
Loss before income taxes	(21,939)	(11,594)	(34,051)	(42,997)
Income tax benefit	—	—	—	4,555
Net loss	$ (21,939)	$ (11,594)	$ (34,051)	$ (38,442)
Net loss per share:				
Basic and diluted	$ (0.57)	$ (0.37)	$ (0.91)	$ (1.23)
Weighted average common shares outstanding:				
Basic and diluted	38,440,647	31,433,494	37,235,209	31,376,425
Other comprehensive loss:				
Gain (loss) on foreign currency translation	91	(856)	(134)	(515)
Unrealized gain on short-term investments	120	37	146	13
Total comprehensive loss	$ (21,728)	$ (12,413)	$ (34,039)	$ (38,944)

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

Savara Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity
Periods Ended June 30, 2019 and 2018
(In thousands, except share amounts)
(Unaudited)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
Balance on December 31, 2018	**35,146,096**	**$ 36**	**$ 237,702**	**$ 200**	**$ (129,719)**	**$ 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**	**$ 1**	**$ (141,831)**	**$ 101,804**
Issuance of common stock upon at the market offerings, net	1,870,500	2	19,035	—	—	19,037
Issuance of common stock upon settlement of contingent liability	1,105,216	1	12,477	—	—	12,478
Issuance of common stock for settlement of RSUs	13,125	—	—	—	—	—
Issuance of common stock upon cashless exercise of warrants	11,119	—	—	—	—	—
Issuance of common stock upon exercise of stock options	73,630	1	60	—	—	61
Stock-based compensation	—	—	1,147	—	—	1,147
Foreign exchange translation adjustment	—	—	—	91	—	91
Unrealized gain on short-term investments	—	—	—	120	—	120
Net loss incurred	—	—	—	—	(21,939)	(21,939)
Balance on June 30, 2019	**38,903,830**	**$ 40**	**$ 276,317**	**$ 212**	**$ (163,770)**	**$ 112,799**

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

Savara Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity (Continued)
Periods Ended June 30, 2019 and 2018
(In thousands, except share amounts)
(Unaudited)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
Balance on December 31, 2017	**30,509,522**	**$ 32**	**$ 186,522**	**$ 958**	**$ (68,203)**	**$ 119,309**
Issuance of common stock upon at the market offerings, net	46,900	—	493	—	—	493
Issuance of common stock for settlement of RSUs	11,250	—	—	—	—	—
Net issuance of common stock upon cashless exercise of stock options	28,655	—	—	—	—	—
Issuance of common stock upon exercise of stock options	6,000	—	3	—	—	3
Issuance of common stock upon exercise of warrants	2,039	—	18	—	—	18
Stock-based compensation	—	—	412	—	—	412
Foreign exchange translation adjustment	—	—	—	341	—	341
Unrealized loss on short-term investments	—	—	—	(24)	—	(24)
Net loss incurred	—	—	—	—	(26,848)	(26,848)
Balance on March 31, 2018	**30,604,366**	**$ 32**	**$ 187,448**	**$ 1,275**	**$ (95,051)**	**$ 93,704**
Issuance of common stock for settlement of RSUs	13,125	—	—	—	—	—
Net issuance of common stock upon cashless exercise of stock options	87,099	—	—	—	—	—
Issuance of common stock upon exercise of stock options	24,521	—	30	—	—	30
Issuance of common stock upon exercise of warrants	84	—	1	—	—	1
Common stock issued for purchase of assets	107,579	—	995	—	—	995
Stock-based compensation	—	—	392	—	—	392
Foreign exchange translation adjustment	—	—	—	(856)	—	(856)
Unrealized loss on short-term investments	—	—	—	37	—	37
Net loss incurred	—	—	—	—	(11,594)	(11,594)
Balance on June 30, 2018	**30,836,774**	**$ 32**	**$ 188,866**	**$ 456**	**$ (106,645)**	**$ 82,709**

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

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

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (34,051)	$ (38,442)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization including right-of-use assets	539	260
Impairment of acquired IPR&D	—	21,692
Impairment of goodwill	7,420	—
Changes in fair value of financial instruments	118	62
Change in fair value of contingent consideration	264	(3)
Noncash interest (income) / expense	(69)	54
Acquired IPR&D	—	995
Foreign currency loss	(51)	(94)
Amortization of debt issuance costs	292	223
Accretion on discount to short-term investments	(688)	(278)
Stock-based compensation	2,147	804
Benefit for deferred taxes	—	(4,555)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	115	(281)
Non-current assets	(838)	—
Accounts payable and accrued expenses and other current liabilities	1,141	(444)
Long-term liabilities	(103)	(13)
Net cash used in operating activities	$ (23,764)	$ (20,020)
Cash flows from investing activities:		
Purchase of property and equipment	(132)	(65)
Purchase of available-for-sale securities, net	(92,198)	(24,724)
Maturities of available-for-sale securities	70,600	39,500
Sale of available-for-sale securities, net	14,129	6,513
Net cash provided (used) by investing activities	$ (7,601)	$ 21,224
Cash flows from financing activities:		
Issuance of common stock upon exercise of warrants	$ —	$ 19
Issuance of common stock upon at the market offerings, net	23,927	493
Proceeds from exercise of stock options	67	33
Capital lease obligation principal payments	(42)	(258)
Net cash provided by financing activities	$ 23,952	$ 287
Effect of exchange rate changes on cash and cash equivalents	(58)	(8)
Increase (decrease) in cash and cash equivalents	$ (7,471)	$ 1,483
Cash and cash equivalents beginning of period	24,301	22,121
Cash and cash equivalents end of period	$ 16,830	$ 23,604
Noncash transaction:		
Common stock issued for IPR&D, net	$ —	$ 995
Settlement of contingent consideration	$ 12,478	$ —
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,058	$ 685

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

1. Description of Business and Basis of Presentation

Description of Business

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

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

Basis of Presentation

The interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") as defined by the Financial Accounting Standards Board ("FASB"). These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2018. Certain prior period amounts have been reclassified for consistency with current period presentation.

Unaudited Interim Financial Information

The interim condensed consolidated financial statements included in this document are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of June 30, 2019, and its results of operations for the three and six months ended June 30, 2019 and 2018, and cash flows for the six months ended June 30, 2019 and 2018. The results of operations for interim periods shown in this report are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The December 31, 2018 consolidated balance sheet was derived from audited financial statements but does not include all disclosures required by U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2018.

2. Summary of Significant Accounting Policies

Liquidity

As of June 30, 2019, the Company had an accumulated deficit of approximately $163.8 million. The Company also had negative cash flow from operations of approximately $23.8 million during the six months ended June 30, 2019. The cost to further develop and obtain regulatory approval for any drug is substantial and, as noted below, the Company may have to take certain steps to maintain a positive cash position. Accordingly, the Company will need additional capital to further fund the development of, and seek regulatory approvals for, its product candidates and begin to commercialize any approved products.

Currently, the Company is primarily focused on the development of respiratory drugs and believes such activities will result in the Company's continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of the Company's product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of the Company's product candidates, if approved, fail to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash and cash equivalents on hand and through a combination of equity offerings, debt financings, government or other third-party funding, and other collaborations and strategic alliances. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders.

While the Company had cash and cash equivalents of $16.8 million and short-term investments of $94.9 million as of June 30, 2019, the Company intends to continue to raise additional capital as needed through the issuance of additional equity and potentially through borrowings, and strategic alliances with partner companies. However, if such financings are not available timely and at adequate levels, the Company will need to reevaluate its operating plans. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Principles of Consolidation

The interim condensed consolidated financial statements of the Company are stated in U.S. dollars and are prepared using U.S. GAAP. These financial statements include the accounts of the Company and its wholly owned subsidiaries. The financial statements of the Company's wholly owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency is reported in "Accumulated other comprehensive income." All intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Management's estimates include those related to the accrual of research and development and general and administrative costs, certain financial instruments recorded at fair value, stock-based compensation, contingent consideration prior to its settlement in May 2019 (See Note 10), 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" within stockholders' equity.

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

Concentration of Credit Risk

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

Accrued Research and Development Costs

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

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

Business Combinations

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

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

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized, but assessed for impairment on an annual basis or more frequently if impairment indicators exist. 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. 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. In June 2019, the Company determined that the results from its phase 3 study for the use of Molgradex for the treatment of aPAP required a current assessment for impairment of both its IPR&D and goodwill. Upon completion of the aforementioned qualitative and quantitative impairment testing of its IPR&D and quantitative impairment testing of its goodwill, the Company concluded that there was no impairment to its IPR&D; however, goodwill was impaired resulting in a write-down of $7.4 million in the carrying value of goodwill from $26.8 million as of March 31, 2019 to $19.4 million as of June 30, 2019. If the Company experiences further material declines in our stock price, additional goodwill impairment may occur. In addition, for the six months ended June 30, 2019, the Company experienced a minimal decrease in the carrying value of goodwill and a decrease of approximately $0.1 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 June 30, 2019. Under Danish tax law, Denmark remits a research and development tax credit equal to 22% of qualified research and development expenditures, not to exceed established thresholds. As of June 30, 2019, 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, 2018 and is recorded in "Prepaid expenses and other current assets" and expected to be received in the fourth quarter of 2019. The remaining portion of the Danish tax credit of $0.8 million, which was generated during the six months ended June 30, 2019, is recorded in "Other non-current assets" and is expected to be received in the fourth quarter of 2020.

The Company also recognized tax credit income for the six months ended June 30, 2019 as provided by the Australian Taxation Office for qualified research and development expenditures incurred through our subsidiary, Savara Australia Pty. Limited. Under Australian tax law, Australia remits a research and development tax credit equal to 43.5% of qualified research and development expenditures, not to exceed established thresholds. As of June 30, 2019, credits totaling $0.3 million had been generated but not yet received and such amount is recorded in "Prepaid expenses and other current assets" with expectation of receipt in the first half of the year ending December 31, 2020.

Leases

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02") as codified in Accounting Standards Codification ("ASC") No. 842 ("ASC 842"). ASU 2016-02, 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 10). The Company has also elected the package of practical expedients, applied by class of underlying asset, permitted in ASU 2018-11. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC 842, (b) whether classification of the operating leases would be different in accordance with ASC 842, and (c) whether the unamortized initial direct costs before transition adjustments (as of the period of adoption) would have met the definition of initial direct costs in ASC 842 at lease commencement, and the Company did not separate lease and non-lease components.

As a result of the adoption of the new lease accounting guidance using the effective date transition method, on January 1, 2019, the Company recognized (a) a lease liability of approximately $1.4 million, which represents the present value of the remaining lease payments, as of the date of adoption, of approximately $1.5 million, discounted using the Company's incremental borrowing rate of 8.5%, and (b) a right-of-use asset of approximately $1.4 million. The adoption of the new standard did not result in any adjustment to the Company's retained earnings as of January 1, 2019. The adoption of this standard did not have a material impact on the Company's condensed consolidated balance sheets, cash used/provided from operating, investing, or financing 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.

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, contingent consideration, prior to its settlement and full satisfaction in May 2019, related to the acquisition of certain assets, liabilities, and subsidiaries of Serenova A/S, formerly Serendex Pharmaceuticals A/S ("Serenova"), through the Company's Danish subsidiary, Savara ApS (see Notes 7 and 10), for which any change is reflected in "General and administrative" expense through May 27, 2019, and foreign exchange derivatives not designated as hedging instruments.

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

Revenue Recognition

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

Milestone Revenue

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

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

Net Loss per Share

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

Stock-Based Compensation

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

Manufacturing and Other Commitments and Contingencies

The Company is subject to various manufacturing royalties and payments related to its product candidate, Molgradex. Under a manufacture and supply agreement with the active pharmaceutical ingredients ("API") manufacturer, 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.

Pursuant to a license agreement (see Note 12) between the Company and a Japanese licensee regarding the development and commercialization of Molgradex for the treatment of aPAP in Japan, the Company shall fund the licensee fifty percent (50%), up to a maximum of approximately $0.8 million, of the external costs associated with specific regulatory and filing activities to be conducted by the licensee. As of June 30, 2019, no costs have been incurred.

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

The Company is also subject to certain contingent milestone payments, disclosed in the following table, payable to the manufacturer of the nebulizer used to administer Molgradex. In addition to these milestones, the Company will owe a royalty to the manufacturer of the nebulizer based on net sales. The royalty rate ranges from three and one half percent (3.5%) to five percent (5%) depending on the device technology used by the Company to administer the product.

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

	June 30, 2019
Molgradex API manufacturer:	
Achievement of certain milestones related to validation of API and regulatory approval of Molgradex	$ 3,350
Molgradex nebulizer manufacturer:	
Achievement of various development activities and regulatory approval of nebulizer utilized to administer Molgradex	7,730
Molgradex Japanese licensee:	
Co-development and regulatory costs	750
Medical education and research foundation:	
First commercial sale in the U.S. of Molgradex in treatment of NTM	500
Total manufacturing and other commitments	**$ 12,330**

The milestones and co-developement 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 resonably estimable, as of June 30, 2019.

Income Taxes

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

Recent Accounting Pronouncements

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

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

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

In April 2019, the FASB issued ASU 2019-04, "Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments." The Company has reviewed ASU 2019-01 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):

	June 30, 2019	December 31, 2018
R&D tax credit receivable	$ 1,134	$ 1,263
Prepaid clinical trial costs	280	561
VAT receivable	583	421
Prepaid insurance	261	162
Deposits and other	178	107
Total prepaid expenses and other current assets	**$ 2,436**	**$ 2,514**

4. Accrued expenses and other current liabilities

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

	June 30, 2019	December 31, 2018
Accrued contracted research and development costs	$ 2,835	$ 2,044
Accrued general and administrative costs	336	371
Accrued compensation	706	643
Foreign currency exchange derivative	41	26
Deferred revenue	—	250
Lease liability	689	—
Other	5	41
Total accrued expenses and other current liabilities	**$ 4,612**	**$ 3,375**

5. Short-term Investments

Short-term Investments in Available-for-Sale Securities

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

As of June 30, 2019:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 28,326	$ 34	$ —	$ 28,360
Asset backed securities	5,767	17	—	5,784
Corporate securities	30,443	64	—	30,507
Commercial paper	30,251	—	—	30,251
Total short-term investments	**$ 94,787**	**$ 115**	**$ —**	**$ 94,902**

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

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

There were no significant realized gains or losses related to investments for the six months ended June 30, 2019 and June 30, 2018.

6. Debt Facility

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

Silicon Valley Bank has been granted a perfected first priority lien in all of our assets with a negative pledge on our intellectual property. The Loan Agreement, as amended, contains customary affirmative and negative covenants, including among others, covenants limiting our ability and our subsidiaries' ability to dispose of assets, permit a change in control, merge or consolidate, make acquisitions, incur indebtedness, grant liens, make investments, make certain restricted payments and enter into transactions with affiliates, in each case subject to certain exceptions.

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

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

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

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

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

Summary of Carrying Value

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

	As of June 30, 2019	
	Short-term	**Long-term**
Principal payments to lender and end of term charge	$ —	$ 25,236
Debt issuance costs	—	(221)
Debt discount related to warrants	—	(193)
Carrying Value	$ —	$ 24,822

The carrying value of the debt facility approximates fair value.

7. Fair Value Measurements

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

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

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

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

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

The fair value of these instruments as of June 30, 2019 and December 31, 2018 was as follows (in thousands):

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of June 30, 2019:			
Cash equivalents:			
U.S. Treasury money market funds	$ 13,577	$ —	$ —
Short-term investments:			
U.S. government securities	$ 28,360	$ —	$ —
Asset backed securities	$ —	$ 5,784	$ —
Corporate securities	$ —	$ 30,507	$ —
Commercial paper	$ —	$ 30,251	$ —
Liabilities:			
Foreign exchange derivatives not designated as hedging instruments	$ —	$ 41	$ —
As of December 31, 2018:			
Cash equivalents:			
U.S. Treasury money market funds	$ 14,710	$ —	$ —
Commercial paper	$ —	$ 4,411	$ —
Corporate securities	$ —	$ 2,371	$ —
Short-term investments:			
U.S. government securities	$ 15,965	$ —	$ —
Asset backed securities		$ 8,588	
Corporate securities	$ —	$ 19,954	$ —
Commercial paper	$ —	$ 42,022	$ —
Liabilities:			
Contingent consideration	$ —	$ —	$ 12,214
Foreign exchange derivatives not designated as hedging instruments	$ —	$ 26	$ —

Pursuant to the acquisition of certain assets, liabilities, and subsidiaries of Serenova A/S through Savara's wholly-owned Danish subsidiary, Savara ApS, on July 15, 2016, Savara agreed to pay the seller, in addition to a set amount of shares of Savara's common stock, (i) $5.0 million upon receipt of marketing approval of Molgradex by the European Medicines Agency, (ii) $15.0 million upon receipt of marketing approval of Molgradex by the FDA, and (iii) $1.5 million upon receipt of marketing approval of Molgradex by the Japanese Pharmaceuticals and Medical Devices Agency (the "Contingent Milestone Payments"). The Company estimated the likelihood of approval in each region, separately, based on the product candidate's current phase of development and utilizing published studies of clinical development success rates for comparable non-oncology orphan drugs. The present value of the potential cash outflows from the probability weighted Contingent Milestone Payments was then estimated by taking into consideration that the Contingent Milestone Payments are similar to a business expense of the Company and would be senior to any Company debt obligations. The resulting weighted average present value factor was then applied to discount the probability adjusted Contingent Milestone Payments for each region to derive the fair value of the Contingent Milestone Payments. On May 27, 2019, the Company settled the Contingent Milestone Payments in full (see Note 10).

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 six months ended June 30, 2019 and year ended December 31, 2018:

	Contingent Consideration
As of December 31, 2017	**$ 11,948**
Change in fair value	266
Balance at December 31, 2018	**$ 12,214**
Change in fair value	219
Settlement of contingent liability	(12,433)
Balance at June 30, 2019	**$ —**

The Company records changes in fair value of the contingent consideration in general and administrative expense. The Company also accounted for the time value of money related to the Contingent Milestone Payments from December 31, 2018 to May 27, 2019 in its assessment. Accordingly, the related contingent consideration liability was remeasured to $12.4 million on May 27, 2019 prior to its settlement (See Note 10).

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 six months ended June 30, 2019 and year ended December 31, 2018.

8. Derivative Financial Instruments

In the normal course of business, the Company is exposed to the impact of foreign currency fluctuations. The Company seeks to limit these risks by following risk management policies and procedures, including the use of derivatives. The Company's derivative contracts, which are not designated as hedging instruments, principally address short-term foreign currency exchange. The estimated fair value of the derivative contracts was based upon the relative exchange rate as of the balance sheet date. Accordingly, any gains or losses resulting from variances between this exchange rate and the exchange rate at the contract inception date were recognized in "Other income, net" in the condensed consolidated statements of operations and comprehensive loss. As of June 30, 2019, there was an asset of approximately $3.1 million consisting of unsettled forward exchange contracts to purchase foreign currency and a corresponding liability of approximately $3.1 million consisting of forward exchange contract obligations, resulting in a minimal net derivative financial instrument, recorded at their estimated fair value in "Accrued expenses and other current liabilities."

9. Shareholders' Equity

Common Stock Sales Agreement

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

During the six months ended June 30, 2019, the Company sold 2,517,926 shares of common stock under the Sales Agreement, for net proceeds of approximately $23.9 million.

Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue 201 million shares of common and preferred stock, consisting of 200 million shares of common stock with $0.001 par value and one million shares of preferred stock with $0.001 par value. The following is a summary of the Company's common stock at June 30, 2019 and December 31, 2018.

	June 30, 2019	December 31, 2018
Common stock authorized	200,000,000	200,000,000
Common stock outstanding	38,903,830	35,146,096

The Company's shares of common stock reserved for issuance as of June 30, 2019 and December 31, 2018 were as follows:

	June 30, 2019	December 31, 2018
Warrants acquired in merger	718,373	750,840
Warrants converted pursuant to merger	72,869	72,869
April 2017 SVB Warrants	24,725	24,725
June 2017 SVB Warrants	41,736	41,736
December 2018 SVB Warrants	11,332	11,332
Pre-funded warrants	775,000	775,000
Stock options outstanding	3,295,666	3,077,264
Issued and nonvested RSU's	130,000	156,250
Total shares reserved	**5,069,701**	**4,910,016**

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of June 30, 2019:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
314,446	$	52.50	November 2019
403,927	$	29.40	February 2021
72,869	$	8.98	June 2021
775,000	$	0.01	October 2024
24,725	$	9.10	April 2027
41,736	$	5.39	June 2027
11,332	$	8.824	December 2028
1,644,035			

10. Commitments and Settlement

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 six months ended June 30, 2019, it is not reasonably certain the Company will exercise the extension options inherent in the lease. Our annual rent is approximately $0.1 million, paid over monthly installments, subject to annual increases equal to the Danish consumer price index, or approximately 2% annually.

On March 23, 2017, we sublet office space located in San Diego, California with rentable office space of approximately 13,707 square feet, which previously served as a predecessor's corporate headquarters, to a third party as the Company no longer had an ongoing need for this facility. The term of the sub-sublease commenced on July 1, 2017 and expires on May 31, 2020, coterminous with a sublease agreement dated June 19, 2014 with the sublessor. As of June 30, 2019, annual rent under the sub-sublease is approximately $0.5 million, payable in monthly installments.

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

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of June 30, 2019 (in thousands):

Year ending December 31,		
2019	$	397
2020		478
2021		184
2022		67
Total future minimum lease payments	**$**	**1,126**
Less imputed interest		(80)
Total	**$**	**1,046**

	For the three months ended June 30, 2019	**For the six months ended June 30, 2019**
Lease cost:		
Operating lease cost	$ 372	$ 741
Sublease income	(153)	(304)
Total lease cost	**$ 219**	**$ 437**
Other information:		
Operating cash flows from operating leases	$ 194	$ 388
Weighted-average remaining lease term (in months) - operating leases	22.7	22.7
Weighted-average discount rate - operating leases	8.5%	8.5%

As of June 30, 2019, the carrying value of the right-of-use assets for the operating leases was $1.0 million, which is reflected in "Other non-current assets," and the carrying value of the lease liabilities for operating leases was $1.0 million, of which $0.7 million related to the current portion of the lease liabilities is recorded in "Accrued expenses and other current liabilities," and $0.3 million related to the non-current portion of the lease liabilities is recorded in "Other long-term liabilities."

Contingent Milestone Payment Settlement

On May 27, 2019, the Company, through its wholly-owned subsidiary, Aravas Inc. ("Aravas"), entered into an amendment to the Business Transfer Agreement, dated May 13, 2016 (the "BTA"), between Aravas and Serenova. Prior to this amendment, the terms of the BTA provided for an aggregate of $21.5 million in cash payments to Serenova upon the achievement of certain Contingent Milestone Payments (See Note 7). This amendment modifies the BTA to provide for the issuance of 1,105,216 shares of the Company's common stock, which represents the equivalent of approximately $12.5 million in shares of the Company's common stock based on the volume weighted-average trading price of the Company's common stock for the ten trading days ending May 23, 2019 in lieu of the Contingent Milestone Payments. This amendment further provides that Serenova will not sell, contract to sell, or otherwise transfer or dispose of the common stock, as issued under this amendment, until the earlier of (i) marketing approval of the Company's Molgradex product by the U.S. Food and Drug Administration or (ii) twelve months following the date of this amendment.

Risk Management

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

Employment Agreements

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

11. Stock-Based Compensation

A. Equity Incentive Plan

2008 Stock Option Plan

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

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

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

2015 Omnibus Incentive Option Plan

The Company operates the 2015 Omnibus Incentive Plan (the "2015 Plan"), which was amended and approved by stockholders in June 2018. The 2015 Plan provides for the grant of incentive and non-statutory stock options, as well as share appreciation rights, restricted shares, restricted stock units, performance units, shares and other stock-based awards. Share-based awards are subject to terms and conditions established by our board of directors or the compensation committee of our board of directors. As of June 30, 2019, the number of shares of our common stock available for grant under the 2015 Plan was 1,272,893 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 six months ended June 30, 2019 and 2018:

	Six months ended June 30, 2019			Six months ended June 30, 2018		
	Stock Options	RSUs	Total	Stock Options	RSUs	Total
Outstanding as of December 31	**3,077,264**	**156,250**	**3,233,514**	**1,916,832**	**86,875**	**2,003,707**
Granted	339,125	—	339,125	31,720	120,000	151,720
Exercised	(97,223)	(26,250)	(123,473)	(154,766)	(24,375)	(179,141)
Forfeited	(23,500)	—	(23,500)	(102,500)	—	(102,500)
Outstanding as of June 30	**3,295,666**	**130,000**	**3,425,666**	**1,691,286**	**182,500**	**1,873,786**

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 and six months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended		Six Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Research and development	$ 545	$ 145	$ 996	$ 373
General and administrative	602	247	1,151	431
Total stock-based compensation	**$ 1,147**	**$ 392**	**$ 2,147**	**$ 804**

12. License Agreement

The Company entered into a license agreement on May 12, 2016, as amended on June 4, 2018 (the "License Agreement"), with a licensee under which the licensee received an exclusive right to import, market, sell, distribute and promote Molgradex in Japan for the treatment of aPAP. In return, the licensee will pay the Company marketing and regulatory-based milestone payments and sales-based royalties. In October 2018, the Company achieved a milestone payment pursuant to the License Agreement resulting in the receipt of $0.3 million from the licensee. As of June 30, 2019, the Company has determined that it has not met all of the performance obligations under the License Agreement and, accordingly, has recorded the milestone payment as deferred revenue in "Other long-term liabilities" in the Company's condensed consolidated balance sheet until such time the performance obligations are met.

13. Net Loss per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding during the period. For periods in which the Company generated a net loss, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.

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

	Six Months Ended	
	June 30, 2019	June 30, 2018
Awards under equity incentive plan	3,295,666	1,691,286
Nonvested restricted shares and restricted stock units	130,000	190,595
Warrants to purchase common stock	869,035	890,170
Total	**4,294,701**	**2,772,051**

The following table reconciles basic earnings per share of common stock for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended		Six Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Net loss	$ (21,939)	$ (11,594)	$ (34,051)	$ (38,442)
Net loss attributable to common stockholders	(21,939)	(11,594)	(34,051)	(38,442)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	(21,939)	(11,594)	(34,051)	(38,442)
Weighted average common shares outstanding, basic and diluted	38,440,647	31,433,494	37,235,209	31,376,425
Basic and diluted EPS	**$ (0.57)**	**$ (0.37)**	**$ (0.91)**	**$ (1.23)**

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Any statements contained herein that involve risks and uncertainties, such as Savara's plans, objectives, expectations, intentions, and beliefs should be considered forward-looking statements. Savara's actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" in this Quarterly Report on pages 33 through 53.

Overview

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

Together with our wholly-owned subsidiaries, including Aravas Inc., Savara ApS, Drugrecure A/S, and Savara Australia Pty. Limited, we operate in one segment with our principal offices in Austin, Texas, USA. Since inception, we have devoted substantially all of our efforts and resources to identifying and developing our product candidates, recruiting personnel, and raising capital. We have incurred operating losses and negative cash flow from operations and have no product revenue from inception to date as we have not yet commenced commercial operations. From our inception to June 30, 2019, we have raised net cash proceeds of approximately $233.2 million from public offerings of common stock, private placements of convertible preferred stock, and debt financings.

We have never been profitable and have incurred operating losses in each year since inception. Our net losses were $34.1 million for the six months ended June 30, 2019, which included an impairment charge to our goodwill of $7.4 million, and $61.5 million for the year ended December 31, 2018, which included an impairment charge of $21.7 million on certain acquired in-process research and development ("IPR&D"). As of June 30, 2019, we had an accumulated deficit of $163.8 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

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

As of June 30, 2019, we had cash of $16.8 million and short-term investments of $94.9 million. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

Recent Events

IMPALA Phase 3 Study Results

On June 12, 2019, we announced the results of the IMPALA Phase 3 pivotal study of Molgradex ("IMPALA") for the treatment of aPAP. 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 what 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). Additionally, when we correlate improvement in either A-aDO2 or DLCO (both measures of gas exchange) with improvement in the clinical endpoints, we saw statistically significant correlations across the endpoints. Meaning, improvements in the clinical endpoints move in synch with gas exchange improvement. Adverse event frequencies were similar between the treatment arms and placebo.

With the clinically meaningful improvement in SGRQ, and the significant correlation between improved oxygenation and improved clinical endpoints, we remain encouraged by the results of IMPALA and the Molgradex/aPAP program will continue. We are preparing to meet with the FDA and European Medicines Agency ("EMA") to discuss the best regulatory path forward and anticipate filing for breakthrough therapy designation in the U.S. We are currently preparing a briefing package for discussion in October 2019 with the regulatory agencies, and in parallel, will be compiling the learnings from IMPALA to inform the scope and study design of an additional Phase 3 study should that be required.

Goodwill Impairment

In accordance with Accounting Standards Codification and our accounting policies regarding acquired IPR&D and goodwill impairment testing (refer to our policy as subsequently discussed below in "Critical Accounting Policies and Estimates"), we determined that the results from IMPALA on June 12, 2019 required a reassessment of both our acquired IPR&D and goodwill. Upon completion of the qualitative and quantitative impairment testing of our IPR&D and quantitative impairment testing for our goodwill, we concluded that there was no impairment to our IPR&D; however, goodwill was impaired resulting in a write-down of $7.4 million in the carrying value. If the Company experiences further material declines in our stock price, additional goodwill impairment may occur.

ENCORE Study

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

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

Contingent Liability Settlement

On May 27, 2019, the Company, through its wholly-owned subsidiary, Aravas Inc. ("Aravas"), entered into an amendment to the Business Transfer Agreement, dated May 13, 2016 (the "BTA"), between Aravas and Serenova A/S ("Serenova"), formerly Serendex Pharmaceuticals A/S. Prior to this amendment, the terms of the BTA provided for an aggregate of $21.5 million in cash payments to Serenova upon the achievement of certain contingent milestones ("Contingent Milestone Payments"). This amendment modifies the BTA to provide for the issuance of 1,105,216 shares of the Company's common stock, which represents the equivalent of approximately $12.5 million in shares of the Company's common stock based on the volume weighted-average trading price of the Company's common stock for the ten trading days ending May 23, 2019 in lieu of the Contingent Milestone Payments. This amendment further provides that Serenova will not sell, contract to sell, or otherwise transfer or dispose of the common stock, as issued under this amendment, until the earlier of (i) marketing approval of the Company's Molgradex product by the U.S. Food and Drug Administration or (ii) twelve months following the date of this amendment.

GEMA

On April 26, 2019, the Company, through its wholly-owned subsidiary Savara ApS, entered into a manufacture and supply agreement (the "New Supply Agreement") (See Note 2 of the condensed consolidated financial statements in this report) with GEMABIOTECH SAU ("GEMA") pursuant to which GEMA will supply the active pharmaceutical ingredient ("API") for our Molgradex product. The New Supply Agreement supersedes the prior supply agreement with GEMA. Under the New Supply Agreement, GEMA shall manufacture and supply the API exclusively for us for commercial sale and continue to supply the API to us for clinical studies and research and development activities. The New Supply Agreement obligates us to remit up to $5.0 million in various milestone payments related to GEMA's completion of requirements for the commercial process and regulatory approvals, as well as Mogradex's marketing approval in specified jurisdictions.

Additionally, if we successfully commercialize a product containing the API in a country, we must pay GEMA a single-digit percentage royalty on annual net sales in that country until the earlier of (i) ten (10) years after first receipt of marketing approval in that country or (ii) the date a biosimilar of such product is first sold in such country.

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

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

Patheon

On June 26, 2019, the Company, through our wholly-owned subsidiary, Savara ApS, executed a master manufacturing services agreement ("Manufacturing Agreement") with Patheon UK Limited ("Patheon") that governs the general terms under which Patheon, or one of its affiliates, will provide manufacturing services to us for the drug products specified by us from time to time. We expect to enter into one or more related product agreements (each a "Product Agreement") pursuant to the Manufacturing Agreement to govern the terms and conditions of Patheon's manufacture of commercial supplies of Molgradex. The Manufacturing Agreement stipulates that we utilize Patheon for a certain minimum percent of our commercial requirements for a product under a Product Agreement. Under the Manufacturing Agreement, we shall supply Patheon both a long-term and rolling forecast of our commercial volume requirements along with monthly purchase orders for the product. Upon acceptance and delivery of the product, Patheon will invoice us for production and service costs, subject to consumer price index increases. The Manufacturing Agreement will continue until December 31, 2024, unless terminated earlier by one of the parties, and will automatically renew for successive terms of two years each, if there is a Product Agreement in effect, unless we provide twelve months notice of termination prior to the end of the then current term or Patheon provides twenty-four months notice prior to the end of the then current term.

Common Stock Sales Agreement

During the three and six months ended June 30, 2019, we sold 1,870,500 shares and 2,517,926 shares of our common stock, respectively, under our Common Stock Sales Agreement, as amended (the "Sales Agreement"), with H.C. Wainwright & Co., LLC, as sales agent, resulting in net proceeds of $19.0 million and $23.9 million, respectively.

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 June 30, 2019 and 2018 and the six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Product candidates:				
AeroVanc	$ 5,349	$ 4,232	$ 8,653	$ 7,271
Molgradex	5,115	3,996	$ 11,800	8,777
Other	—	1,040	$ 30	1,759
Total research and development expenses	**$ 10,464**	**$ 9,268**	**$ 20,483**	**$ 17,807**

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 marketing functions, and professional and consulting fees for accounting, legal, investor relations, business development, commercial strategy and research, human resources, and information technology services. Other 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

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

Accounting Standards Update ("ASU") 2017-04, "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment," outlines an impairment model providing the Company the option to implement a one-step method for determining impairment of goodwill, thereby simplifying the subsequent measurement of goodwill by eliminating Step 2 (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," provides us a two-step impairment process with the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more-likely-than not (that is, a likelihood of more than 50%) that our acquired IPR&D is impaired. If we choose to first assess qualitative factors and we determine that it is more-likely-than not acquired IPR&D is not impaired, we are not required to take further action to test for impairment.

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

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

Share-based Compensation Expenses

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

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

Revenue

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

Milestone Revenue

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

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

Results of Operations — Comparison of Three Months Ended June 30, 2019 and 2018

	Three Months Ended June 30,		Dollar
	2019	2018	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 10,464	$ 9,268	$ 1,196
General and administrative	4,211	2,486	1,725
Impairment of goodwill	7,420	—	7,420
Depreciation	59	153	(94)
Total operating expenses	22,154	11,907	10,247
Loss from operations	(22,154)	(11,907)	(10,247)
Other income, net	215	313	(98)
Net loss before income taxes	(21,939)	(11,594)	(10,345)
Income tax benefit	—	—	—
Net loss	**$ (21,939)**	**$ (11,594)**	**$ (10,345)**

Research and development

Research and development expenses increased by $1.2 million, or 12.9% to $10.5 million for the three months ended June 30, 2019 from $9.3 million for the three months ended June 30, 2018. The increase was primarily due to approximately $1.1 million in increased AeroVanc study costs related to Phase 3 activities and $1.1 million in increased development costs associated with the development of Molgradex, which was offset by $1.0 million in expense in the form of common stock issued in connection with an asset purchase in the second quarter of 2018.

General and administrative

General and administrative expenses increased by $1.7 million, or 69.4%, to $4.2 million for the three months ended June 30, 2019 from $2.5 million for the three months ended June 30, 2018. The increase was primarily due to increased personnel costs and other legal, accounting, insurance, commercial strategy, business development, and operating activities.

Impairment of Goodwill

During the quarter ended June 30, 2019, we recognized a $7.4 million impairment charge to the carrying value of our goodwill following the results of our IMPALA Phase 3 study of Molgradex for the treatment of aPAP.

Results of Operations — Comparison of Six Months Ended June 30, 2019 and 2018

	Six Months Ended June 30, 2019	2018	Dollar Change
		(in thousands)	
Operating expenses:			
Research and development	$ 20,483	$ 17,807	$ 2,676
General and administrative	6,974	4,254	2,720
Impairment of IPR&D	—	21,692	(21,692)
Impairment of goodwill	7,420	—	7,420
Depreciation	197	260	(63)
Total operating expenses	35,074	44,013	(8,939)
Loss from operations	(35,074)	(44,013)	8,939
Other income	$ 1,023	$ 1,016	$ 7
Net loss before income taxes	(34,051)	(42,997)	8,946
Income tax benefit	$ —	$ 4,555	$ (4,555)
Net loss	**$ (34,051)**	**$ (38,442)**	**$ 4,391**

Research and development

Research and development expenses increased by $2.7 million, or 15.0%, to $20.5 million for the six months ended June 30, 2019 from $17.8 million for the six months ended June 30, 2018. The increase was primarily due to $3.0 million in increased development costs associated with the development of Molgradex, including the commencement of the ENCORE study, and an increase of $1.4 million in AeroVanc study costs related to Phase 3 activities, which was offset by $1.0 million in expense in the form of common stock issued in connection with to an asset purchase in the second quarter of 2018 and $0.7 million recognized during the six months ended June 30, 2018 related to milestone and development costs of an ancillary study acquired in a merger, which is no longer a part of our product pipeline.

General and administrative

General and administrative expenses increased by $2.7 million, or 63.9%, to $7.0 million for the six months ended June 30, 2019 from $4.3 million for the six months ended June 30, 2018 and was primarily due to increased personnel costs and other legal, accounting, insurance, commercial strategy, business development, and operating activities.

Impairment of IPR&D and goodwill

During the six months ended June 30, 2019, we recognized a $7.4 million impairment charge to the carrying value of our goodwill following the results of our IMPALA Phase 3 study of Molgradex for the treatment of aPAP. Additionally, during the six months ended June 30, 2018, we recognized a $21.7 million impairment charge against the full carrying value of acquired IPR&D related to an ancillary drug candidate previously assumed by us due to unfavorable results from the Phase 2 study that demonstrated a failure of this drug candidate to meet the endpoints of the study and limited effectiveness of the compound in patients. We are no longer supporting or pursuing this drug candidate**.**

Income tax benefit

There was no income tax benefit for the six months ended June 30, 2019 resulting in a $4.6 million decrease, or 100.0%, from $4.6 million for the six months ended June 30, 2018. The decrease was due to a $4.6 million tax benefit recorded during the first quarter of 2018 related to the reversal of a deferred tax liability resulting from the impairment of acquired IPR&D of an ancillary drug candidate assumed by us in a merger.

Liquidity and Capital Resources

As of June 30, 2019, we had $16.8 million in cash, $94.9 million in short-term investments and an accumulated deficit of $163.8 million. We entered into a loan and security agreement with Silicon Valley Bank during the year ended December 31, 2017, which was amended December 2018, under which we have drawn a total of $25.0 million and $20.0 million remains available upon the Company's request prior to September 30, 2019, subject to certain conditions. We continue to sell our common stock through "at the market offerings" under the Sales Agreement and have raised net proceeds of $26.2 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.

We have used and intend to use the net proceeds from these offerings for working capital and general corporate purposes, which include, but are not limited to, the funding of clinical development of and pursuing regulatory approval for our product candidates, the initiation of Molgradex pre-commercialization activities, and general and administrative expenses.

Cash Flows

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

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Cash used in operating activities	$ (23,764)	$ (20,020)
Cash provided (used) by investing activities	(7,601)	21,224
Cash provided by financing activities	23,952	287
Effect of exchange rate changes	(58)	(8)
Net increase (decrease) in cash	**$ (7,471)**	**$ 1,483**

Cash flows from operating activities

Cash used in operating activities for the six months ended June 30, 2019 was $23.8 million, consisting of a net loss of $34.1 million, which was partially offset by noncash charges of $10.0 million, mainly comprised of impairment of goodwill, 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 a net increase in assets and liabilities of approximately $0.3 million. The change in our net operating assets and liabilities was primarily due to an increase in accrued liabilities primarily related to research and development costs for both AeroVanc and Molgradex.

Cash flows from investing activities

Cash used in investing activities for the six months ended June 30, 2019 and was primarily the result of the purchase of short-term investments.

Cash flows from financing activities

Cash provided by financing activities for the six months ended June 30, 2019 was primarily related to net proceeds of $23.9 million from the “at the market offerings” under the Sales Agreement.

Future Funding Requirements

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

As of June 30, 2019, we had cash, cash equivalents, and short-term investments of $111.7 million. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through the issuance of additional equity and potentially through borrowings, grants and strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

On June 26, 2019, through our wholly-owned subsidiary, Savara ApS, we executed the Manufacturing Agreement with Patheon that governs the general terms under which Patheon, or one of its affiliates, will provide manufacturing services to us for the drug products specified by us from time to time. Additionally, on April 26, 2019, through our wholly-owned subsidiary, Savara ApS, we entered into the New Supply Agreement with GEMA, which replaces and supersedes all previous agreements with GEMA. Under the New Supply Agreement, GEMA will manufacture and supply us with the API for our Molgradex product, and we are obligated, in addition to paying an agreed upon price per vial of API supply, to pay certain milestone payments and royalties. Other than the agreements with Patheon and GEMA, there were no other material changes outside of the ordinary course of business in our contractual obligations during the six months ended June 30, 2019 from those disclosed in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations - Contractual Obligations and Other Commitments" of our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 13, 2019.

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We have market risk exposure related to our cash, cash equivalents, and short-term investment securities. Such interest-earning instruments carry a degree of interest rate risk; however, we have not been exposed, nor do we anticipate being exposed, to material risks due to changes in interest rates. A hypothetical 1% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. Additionally, our investment securities are fixed income instruments denominated and payable in U.S. dollars and have short-term maturities, typically less than twelve months, and typically carry credit ratings of "A" at a minimum by two of three Nationally Recognized Statistical Rating Organizations, specifically Moody's, Standard & Poor's or Fitch. As such, we do not believe that our cash, cash equivalents and short-term investment securities have significant risk of default or illiquidity.

We also have interest rate exposure as a result of our loan and security agreement with Silicon Valley Bank. As of June 30, 2019, the outstanding gross principal amount of the secured term loan was $25.0 million. The loan agreement bears interest at the prime rate reported in The Wall Street Journal, plus a spread of 3.0%. Changes in the prime rate may therefore affect our interest expense associated with our secured term loan. If a 10% change in interest rates from the interest rates on June 30, 2019 were to have occurred, this change would not have had a material effect on our interest expense obligations with respect to outstanding borrowed amounts.

We have ongoing operations in Denmark and pay those vendors in local currency (Danish Krone) or Euros. We seek to limit the impact of foreign currency fluctuations through the use of derivative instruments, short-term foreign currency forward exchange contracts not designated as hedging instruments. We also have ongoing operations in Australia as a result of the expansion of Molgradex for the treatment of NTM lung infection and pay our respective vendors in Australian Dollars. We did not recognize any significant exchange rate losses during the six months ended June 30, 2019 and 2018. A 10% change in the Krone-to-dollar, Euro-to-dollar, Australian dollar-to-dollar, or Krone-to-Australian dollar exchange rate on June 30, 2019 would not have had a material effect on our results of operations or financial condition.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2019. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2019 these disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

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

Risks Related to Our Capital Requirements and Financial Condition

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

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

For the six months ended June 30, 2019, we incurred a net loss of $34.1 million, and net cash used in operating activities was $23.8 million. At June 30, 2019, our cash, cash equivalents and short-term investment securities were $111.7 million, and working capital was $105.1 million. At June 30, 2019, we had an accumulated deficit of $163.8 million. We expect to continue to incur substantial operating losses for the next several years as we seek to advance our product candidates through clinical development, global regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, one of our product candidates is approved by the Food and Drug Administration ("FDA") or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve.

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

Since our Aravas subsidiary was formed in 2007, most of our resources have been dedicated to the development and acquisition of our product candidates, Molgradex and AeroVanc. Under our current operating plan, we believe that our existing capital resources will be sufficient to fund our planned operations into 2021. However, we may raise additional capital, including through our "at the market offering" program to fund new studies, programs, or acquisitions, or to address changes in our existing development programs. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidates and there is no certainty that we will be able to raise the necessary capital on reasonable terms or at all.

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

- the number, size, complexity, results, and timing of our drug development programs;
- the timing and terms of any collaborative or other strategic arrangement that we may establish;
- the number of clinical and nonclinical studies necessary to demonstrate acceptable evidence of the safety and efficacy of our product candidates;

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

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

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

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

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

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

As of June 30, 2019, we had goodwill and IPR&D of approximately $30.7 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 and IPR&D for impairment annually, or more frequently if an event or change in circumstances indicates that the asset may be impaired. If an impairment is identified, we would be required to record an impairment charge with respect to the impaired asset to our condensed statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations. We will continue to evaluate our intangible assets for potential impairment in accordance with our accounting policies.

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

Risks Related to Our Business Strategy and Operations

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

The success of our business is dependent on our ability to advance the clinical development of Molgradex for the treatment of patients with aPAP, treatment of patients with NTM lung infection, and its expansion into NTM lung infection with people living with CF, and AeroVanc for the treatment of MRSA infection in the lungs of CF patients.

The 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 what 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). Additionally, when we correlate improvement in either A-aDO2 or DLCO (both measures of gas exchange) with improvement in the clinical endpoints, we saw statistically significant correlations across the endpoints. Meaning, improvements in the clinical endpoints move in synch with gas exchange improvement. Adverse event frequencies were similar between the treatment arms and placebo.

We are preparing to meet with the FDA and EMA to discuss the best regulatory path forward and anticipate filing for breakthrough therapy designation in the U.S. We are currently preparing a briefing package for discussion in October 2019 with the regulatory agencies, and in parallel, will be compiling the learnings from IMPALA to inform the scope and study design of an additional Phase 3 study should that be required. However, any regulatory progress or success, including the potential filing or approval of a Biologics License Application ("BLA"), is not known at this time and remains subject to rejection from the FDA, EMA, or other regulatory authorities. Likewise, the commencement and success of an additional Phase 3 study, if necessary, is also currently not known.

The Molgradex studies for (i) the treatment of NTM lung infection, designated as OPTIMA, and the treatment of NTM lung infection in people living with CF, designated ENCORE, are in Phase 2a development. The AeroVanc Phase 3 study, designated as AVAIL, started in the U.S. and Canada in the third quarter of 2017. We expect to announce topline results from AVAIL in late 2020 or early 2021 subject to enrollment.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process as demonstrated by the 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of August 8, 2019, we had 41 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.

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

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

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

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

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

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

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

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

We have set goals for accomplishing certain objectives material to the successful development of our product candidates. The actual timing of these events may vary due to many factors, including delays or failures in our nonclinical testing, clinical studies, and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. From time to time we create estimates for the completion of enrollment of or announcement of data from clinical studies of our product candidates. However, predicting the rate of enrollment or the time from completion of enrollment to announcement of data for any clinical study requires us to make significant assumptions that may prove to be incorrect. As an example, we have experienced enrollment delays in our AeroVanc program. 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 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 information technology ("IT") providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber-attacks, or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion by computer hackers, foreign governments, or cyber-terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider's operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in loss or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed or could fail. We have experienced and may continue to experience attempts to breach our security and attempts to introduce malicious software into our information technology systems; however, to date and to our knowledge, such attacks have not resulted in any material damage to us.

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

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

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

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

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

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

Risks Related to Drug Development and Commercialization

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

Pharmaceutical products are subject to stringent regulatory requirements covering quality, safety, and efficacy. The burden of proof is on the manufacturer, such as 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. Failure to complete a clinical study of a product candidate or an unsuccessful result of a clinical study could have a material adverse effect on our business.

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

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

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

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

- inability to raise sufficient funding to initiate or continue a clinical study;
- delays in obtaining regulatory approval to commence a clinical study;
- delays in identifying and reaching agreement on acceptable terms with prospective CROs, clinical study sites, and investigators, which agreements can be subject to extensive negotiation and may vary significantly among study sites;
- delays in obtaining regulatory approval in a prospective country;
- delays in obtaining ethics committee approval to conduct a clinical study at a prospective site;
- delays in reaching agreements on acceptable terms with prospective CMOs or other vendors for the production and supply of clinical trial material and, if necessary, drug administration devices, which agreements can be subject to extensive negotiation;
- delays in the production or delivery of sufficient quantities of clinical trial material or drug delivery devices from our CMOs and other vendors to initiate or continue a clinical study;
- delays due to product candidate recalls as the result of stability failure, excessive product complaints, or other failures of the product candidate during its use or testing;

- invalidation of clinical data caused by premature unblinding or integrity issues;
- invalidation of clinical data caused by mixing up of the active drug and placebo through randomization or manufacturing errors;
- delays on the part of our CROs, CMOs, and other third-party contractors in developing procedures and protocols or otherwise conducting activities in accordance with applicable policies and procedures and in accordance with agreed upon timelines;
- delays in identifying and hiring or engaging, as applicable, additional employees or consultants to assist in managing clinical study-related activities;
- delays in recruiting and enrolling individuals to participate in a clinical study, which historically can be challenging in orphan diseases;
- delays caused by patients dropping out of a clinical study due to side effects, concurrent disorders, difficulties in adhering to the study protocol, unknown issues related to different patient profiles than in previous studies, such as the reduced age limit required for inclusion into the AeroVanc Phase 3 study, or otherwise;
- delays in having patients complete participation in a clinical study, including returning for post-treatment follow-up;
- delays resulting from study sites dropping out of a trial, providing inadequate staff support for the study, problems with shipment of study supplies to clinical sites, or focusing its staff's efforts on enrolling studies that compete for the same patient population;
- suspension of enrollment at a study site or the imposition of a clinical hold by the FDA or other regulatory authority following an inspection of clinical study operations at study sites or finding of a drug-related serious adverse event;
- 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, or for personal reasons, or without reason, or by patients who fail to return for or complete post-treatment follow-up.

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

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

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

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

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

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

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

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

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

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

We received guidance from the FDA on the requirements to initiate clinical studies in the U.S. and on the clinical study requirements to achieve BLA approval for Molgradex. Based on the guidance, we amended our ongoing Phase 3 clinical study to include more patients, and amended our endpoint hierarchy and statistical analyses to be used for U.S. approval purposes. The clinical study results were released on June 12, 2019 and did not meet all of the statistical goals and protocol end points. Accordingly, the FDA may not view the results as sufficient or conclusive to provide persuasive evidence of efficacy across multiple clinical endpoints. Instead, they may require additional clinical studies and/or other costly studies, including an additional Phase 3 study, which would require us to expend substantial additional resources and would significantly extend the timeline for clinical development prior to market approval, or result in failure to complete the clinical development of Molgradex.

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

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

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including Molgradex and AeroVanc. Regardless of any guidance the FDA or foreign regulatory agencies may provide a drug's sponsor during its development, the FDA or foreign regulatory agencies retain complete discretion in deciding whether to accept an NDA or BLA or the equivalent foreign regulatory approval submission for filing or, if accepted, 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 any of a variety of reasons, including a decision related to the safety or efficacy data, manufacturing controls or systems, or for any other issues that the agency may identify related to the development its product candidates. Even if one or more Phase 3 clinical studies are successful in providing statistically significant evidence of the efficacy and safety of the investigational drug, the FDA or foreign regulatory agencies may not consider efficacy and safety data from the submitted studies adequate scientific support for a conclusion of effectiveness and/or safety and may require one or more additional Phase 3 or other studies prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and competitors may bring products to market before us, which could impair our ability to generate revenues from the product candidates, or even seek approval, if blocked by a competitor's Orphan Drug exclusivity, which would have a material adverse effect on our business, financial condition, and results of operations.

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

Even if the FDA or foreign regulatory agencies grant approvals for our product candidates, the conditions or scope of the approval(s) may limit successful commercialization of the product candidates and impair our ability to generate substantial sales revenue. For example, the FDA may approve label claims for AeroVanc with age restrictions and/or treatment duration limitations, or Molgradex with restrictions for use only by patients unresponsive to the current standard of care. They may limit the label of Molgradex or AeroVanc to a subset of patients based on a review of which patient groups had the greatest efficacious response in clinical studies. Such label restriction may be undesirable and may limit successful commercialization. The FDA or foreign regulatory agencies may also only grant marketing approval contingent on the performance of costly post-approval nonclinical or clinical studies, or subject to warnings or contraindications that limit commercialization. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMP, GCP, international conference on harmonization regulations, and GLP, which are regulations and guidelines that are enforced by the FDA or foreign regulatory agencies for all 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, or health maintenance organizations, or the medical community in general, will accept or utilize any of our products, if approved. If our product candidates are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or remain profitable. In addition, our efforts to educate the medical community and third-party payers regarding benefits of our products may require significant resources and may never be successful.

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

Our success will depend on our ability to:

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

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

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

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

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

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

We may rely on trademarks, trade names, and brand names to distinguish our products, if approved for commercial sale, from the products of our competitors. We intend to seek approval for new names for AeroVanc and Molgradex that meet the FDA's and foreign regulatory requirements. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks, in which case we may expend substantial resources to defend our proposed or approved trademarks and may enter into agreements with third parties that may limit our use of our trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. For example, we filed a trademark for the name "Savara" and were challenged. We decided to terminate 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 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. The potential use and potential therapeutic benefits of systemically administered GM-CSF for systemic NTM disease have been described in case reports in the literature, and therefore the use of an inhaled form of GM-CSF may be considered to lack novelty and an inventive step, and thereby to be unpatentable.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Industry

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

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

The industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology, and pharmaceutical) are highly competitive and subject to rapid and significant change. Developments by others may render potential application of any of our product candidates in a particular indication obsolete or noncompetitive, even prior to completion of its development and approval for that indication. If successfully developed and approved, we expect our product candidates will face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical, and human resources than us, and may be better equipped to develop, manufacture, market, and distribute products. Many of these companies operate large, well-funded research, development, and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us and prevent us from competing due to their orphan drug protections. Smaller companies may also prove to be significant competitors,

particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, heightened awareness on the part of academic institutions, government agencies, and other public and private research organizations of the potential commercial value of their inventions have led them to actively seek to commercialize the technologies they develop, which increases competition for investment in our programs. Competitive products may be more effective, easier to dose, or more effectively marketed and sold than ours, which would have a material adverse effect on our ability to generate revenue.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Common Stock

Our stock price is expected to continue to be volatile.

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

- 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, 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, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

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

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

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

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

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

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Index

Exhibit Number	Description
10.1	Amendment dated May 27, 2019 to the Business Transfer Agreement Between Savara Inc. and Serendex Pharmaceuticals A/S, dated May 13, 2016, between Savara Inc. and Serendex Pharmaceuticals A/S.
10.2*	Master Manufacturing Services Agreement, dated June 26, 2019, between Savara ApS and Patheon UK Limited.
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: August 8, 2019

By: /s/ Dave Lowrance

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

Date: August 8, 2019

By: /s/Robert Neville

Robert Neville
Chief Executive Officer
(Principal Executive Officer)

Exhibit 10.1

AMENDMENT TO THE
BUSINESS TRANSFER AGREEMENT BETWEEN
SAVARA INC. AND SERENDEX PHARAMCEUTICALS A/S

This amendment **("Amendment")** to the Business Transfer Agreement, dated May 13, 2016 (the **"Agreement"),** between Aravas Inc., formerly Savara Inc. **("Savara"),** and Serenova A/S, formerly Serendex Pharmaceuticals A/S **("Serenova"),** is made effective as of May [27], 2019 **("Amendment Effective Date")** by and between Savara and Serenova. Savara and Serenova shall be referred to each as a **"Party"** and collectively as the **"Parties."**

WHEREAS, pursuant to the Agreement, Savara agreed to purchase and Serenova agreed to sell, transfer and assign to Savara, all of its assets and subsidiaries, certain of its contracts, and certain of its employees and liabilities (the **"Acquired Assets");**

WHEREAS, as consideration for the Acquired Assets, Savara agreed to provide Serenova with (i) shares of Savara common stock and (ii) Contingent Milestone Payments (as defined in the Agreement); and

WHEREAS, the Parties now desire to amend the Agreement to adjust certain provisions related to the Contingent Milestone Payments as set forth below.

NOW, THEREFORE, in consideration of the recitals set forth above, the mutual covenants, terms and conditions set forth below, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE I.
DEFINITIONS

Unless otherwise defined in this Amendment, initially capitalized terms used herein shall have the meanings given to them in the Agreement.

ARTICLE II.
AMENDMENTS TO THE AGREEMENT

As of the Amendment Effective Date, the Agreement is hereby amended or modified as follows:

The Parties agree that in lieu of Savara paying the Contingent Milestone Payments set forth in Section 7.3 of the Agreement, it shall, through its parent company, provide for the issuance to Serenova, within five business days of the Amendment Effective Date, 1,105,216 shares of common stock of Savara Inc. (the **"Shares"),** which represents the equivalent of Twelve Million Five Hundred Thousand Dollars ($12,500,000) in shares of Savara Inc. common stock based on the volume weighted-average trading price of Savara Inc. common stock for the ten trading days ending May 23, 2019. Following issuance of the Shares, Savara shall have no further obligation regarding the Contingent Milestone Payments. Serenova further agrees that, until the date on which

the United States Food and Drug Administration grants marketing approval of the Product or such later date if required for compliance with applicable securities laws, Serenova will not sell, offer to sell, contract to sell, or otherwise transfer or dispose of the Shares (this period will last for a maximum of 12 months from the agreement is signed). For the avoidance of doubt, this restriction will have no effect on any shares of Savara Inc. held by Serenova prior to the Amendment Effective Date.

ARTICLE III.
SERENOVA REPRESENTATIONS AND WARRANTIES

In respect of the acquisition of the Shares, Serenova represents and warrants to Savara that the following statements are true and correct as of the date hereof:

3.1 Purchase for Own Account. The Shares to be issued to Serenova hereunder will be acquired for investment for Serenova's own account, not as a nominee or agent, and not with a view to the public resale or distribution thereof in violation of the Securities Act of 1933 (as amended) (the **"Securities Act"**), and Serenova has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the Securities Act. Serenova has not been formed for the specific purpose of acquiring the Shares.

3.2 Disclosure of Information. Serenova has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the Shares. Serenova further has had an opportunity to ask questions and receive answers from the issuer regarding the terms and conditions of the offering of the Shares and to obtain additional information necessary to verify any information furnished to Serenova or to which Serenova had access.

3.3 Investment Experience. Serenova understands that the acquisition of the Shares involves substantial risk. Serenova acknowledges that it is able to fend for itself, can bear the economic risk of Serenova's investment in the Shares and has such knowledge and experience in financial or business matters that Serenova is capable of evaluating the merits and risks of investment in the Shares and protecting its own interests in connection with this investment.

3.4 Accredited Investor Status. Serenova is an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act

3.5 Restricted Securities. Serenova understands that the Shares are characterized as "restricted securities" under the Securities Act and that such securities may be resold without registration under the Securities Act only in certain limited circumstances. Serenova is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act. Serenova understands that the issuer is under no obligation to register any of the Shares.

3.6 Legend. Serenova understands and acknowledges that upon the issuance thereof, and until such time as the same is no longer required under applicable requirements of the Securities Act, certificates or electronic book entries representing the Shares shall bear the following legend:

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"). SUCH SHARES MAY NOT BE SOLD, TRANSFERRED, PLEDGED, OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SHARES UNDER THE SECURITIES ACT, UNLESS, IN THE OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER, SUCH REGISTRATION IS NOT REQUIRED."

ARTICLE IV.
GENERAL

4.1 No Other Modifications. Except as specifically set forth in this Amendment, the terms and conditions of the Agreement shall remain in full force and effect. No waiver, alteration or modification of any of the provisions of this Amendment shall be binding unless made in writing and signed by the Parties by their respective officers thereunto duly authorized. The waiver by either Party of a breach or a default of any provision of this Amendment by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

4.2 Miscellaneous. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This Amendment, once executed by a Party may be delivered via electronic means of transmission and shall have the same force and effect as if it were executed and delivered by the Parties in the presence of one another. This Amendment shall be governed by and construed in accordance with the laws of Denmark.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date indicated above.

ARAVAS INC.

By: /s/ Rob Neville
Name: Rob Neville
Title: CEO
Date: 5/27/2019

SERENOVA A/S

By: /s/ Michael Aslo-Petersen
Name: Michael Aslo-Petersen
Title: CEO
Date: 26th May 2019

By: /s/ Hans Ole Svendsen
Name: Hans Ole Svendsen
Title: Chairman of the board
Date: 26th May 2019

By: /s/ Lorenz Jorgensen
Name: Lorenz Jorgensen
Title: Member of the board
Date: 26th May 2019

ACKNOWLEDGED:

SAVARA INC.

By: /s/ Rob Neville
Name: Rob Neville
Title: CEO
Date: 5/27/2019

Exhibit 10.2

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.

Master Manufacturing Services Agreement

Effective Date: 26 June 2019

PARTIES

PATHEON UK LIMITED
a company existing under the laws of the United Kingdom, with its principal place of business at Kingfisher Drive, Swindon, SN3 5BZ, United Kingdom ("**Patheon**"),

- and -

SAVARA APS
a company existing under the laws of Denmark, with its principal place of business at Slotsmarken 17, 1 th., DK-2970 Hørsholm, Denmark ("**Client**").

Table of Contents

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

With effect from the date stated at the start of this Agreement (the "**Effective Date**"), the parties have agreed to the following terms:

1. Structure of Agreement and Interpretation

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon in the business of performing manufacturing services may perform Manufacturing Services for Client or any Affiliate of Client. This master form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of Product through Patheon's global network of manufacturing sites by entering into specific Product Agreements without having to re-negotiate the general terms and conditions that apply.

1.2 Product Agreements.

This Agreement is structured so that Product Agreements may be entered into by the parties (or their Affiliates) for the manufacture of Product at any Patheon manufacturing site. Each Product Agreement will be governed by and will incorporate the terms and conditions of this Agreement, except to the extent that the parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be substantially in the general form, and contain the information referred to, in Appendix 1.

1.3 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party; or

(b) a business entity which is controlled by a party, either directly or indirectly; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party;

For this definition, "control" means the lawful right to determine (by ownership of shares or otherwise) the election of the majority of directors (or equivalent managers) of a business entity;

"**Annual Volume**" means, for the purpose of the Price, Patheon's assumed minimum volume of Product to be manufactured in any Year as set out in the "Annual Volume Forecast" section of Schedule A of the applicable Product Agreement;

"**API**" means the active materials listed in the applicable Product Agreement (references to "Active Materials" or "Active Pharmaceutical Ingredient" in documents forming part of this Agreement or of a Product Agreement will mean "API");

"**API Credit Value**" means the value of the API for certain purposes of this Agreement, as set out in the applicable Product Agreement;

"**Applicable Laws**" means: (i) for Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (ii) for Client and the Product, the Laws of all jurisdictions where Product is manufactured, distributed, and marketed as these are agreed by the parties in the Product Agreement;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal, with competent jurisdiction over a party, the Manufacturing Services, or the relevant Product (or its use);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in Patheon's resident jurisdiction, Client's resident jurisdiction, or the jurisdiction where the Manufacturing Site is located;

"**Capital Equipment Agreement**" means the separate agreement that the parties may enter into that addresses the rights and responsibilities of the parties regarding capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"**cGMPs**" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) Commission Directive (EU) 2017/1572 (art. 2); and

(c) Division 2 of Part C of the Food and Drug Regulations (Canada);

together with current final industry-accepted Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"**Client Intellectual Property**" means Intellectual Property (i) generated, acquired or derived by Client, or any developments thereof generated, acquired or derived by Client, at any time separate and apart from the performance of Manufacturing Services, or (ii) by Patheon while performing any Manufacturing Services which Intellectual Property is specific to, or dependent upon, the Product;

"**Client-Supplied Components**" means those Components supplied or to be supplied by or on behalf of Client as identified in Schedule A of a Product Agreement;

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture or package Product in accordance with the Processing Instructions, other than the API;

"**Confidential Information**" has the meaning specified in Section 11.1;

“**DEA**” means the Drug Enforcement Administration of the United States Department of Justice;

“**Deficient Product**” has the meaning specified in Section 6.1(a);

“**Disclosing Party**” has the meaning specified in Section 11.1;

"**EMA**" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Order**" has the meaning specified in Section 5.1(d);

"**Health Canada**" means the department of the Canadian Government known as Health Canada and includes, among other relevant branches, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

“**Initial Product Term**” has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"**Invention**" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means, at a point in time, all inventories of Components and work-in-process under Patheon’s care or control used for the manufacture or packaging of Product;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

“**Local Currency**” has the meaning specified in Appendix 4;

“**Long Term Forecast**” has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, as set out in the relevant Product Agreement, for the manufacture of Product for distribution in the Territory;

"**Manufacturing Site**" means the facility identified in a Product Agreement where the Manufacturing Services will be performed;

“**Minimum Market Requirement**” has the meaning specified in Section 2.1;

"**Minimum Order Quantity**" means, for each manufacturing campaign ordered, the minimum number of units or batches of a Product that Client must purchase, as set out in Schedule A of the applicable Product Agreement;

"**Obsolete Stock**" has the meaning specified in Section 5.2(b);

"**Patheon Competitor**" means a business that derives greater than 50% of its revenues from performing contract pharmaceutical or biopharmaceutical development or commercial manufacturing services;

"**Patheon Intellectual Property**" means Intellectual Property generated or derived by Patheon or its Affiliates before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, the Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products or drug delivery systems unrelated to the specific requirements of the Product;

"**Price**" means the fees to be charged by Patheon for:

(a) performing the Manufacturing Services;

(b) the cost of Components (other than Client-Supplied Components); and

(c) any separate cost items and other fees,

as set out in Schedule A of the applicable Product Agreement;

"**Processing Instructions**" means the agreed file, for each Product, which contains documents relating to the Product, including, without limitation:

(a) quality control testing methods for API and Components;

(b) manufacturing instructions, directions, and processes;

(c) any storage requirements for the API, Components, or Product;

(d) all environmental, health and safety information for the Product including material safety data sheets; and

(e) the finished Product quality control testing methods, packaging instructions and shipping requirements for the Product;

"**Product**" means a product listed in Schedule A of a Product Agreement;

"**Product Agreement**" means the agreement between Patheon and Client (or their applicable Affiliates) substantially in the form set out in Appendix 1 under which Patheon will perform Manufacturing Services;

"**Product Claims**" has the meaning specified in Section 6.1(a);

"**Quality Agreement**" means a separate agreement that sets out the quality assurance standards for the Manufacturing Services;

“**Recall**” has the meaning specified in Section 6.2(a);

“**Recipient**” has the meaning specified in Section 11.1;

“**Regulatory Approval**” has the meaning specified in Section 7.5(a);

"**Regulatory Authority**" means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical or biopharmaceutical products, including the Products, in the Territory;

“**Release Date**” means in relation to each batch of Product the scheduled date by which the Product will be released by Patheon’s quality department (by confirmation or certification) as agreed in the Quality Agreement and made available for shipment, and as confirmed by Patheon in a Firm Order;

“**Representatives**” means, a party’s directors, officers, employees, advisers, agents, consultants, subcontractors, service partners or professional advisors;

“**Rolling Forecast**” has the meaning specified in Section 5.1(b);

"**Technical Dispute**" has the meaning specified in Appendix 2;

"**Territory**" means the geographic area described in a Product Agreement where Product manufactured by Patheon will be distributed by or on behalf of Client;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**VAT**" has the meaning specified in Section 13.14; and

"**Year**" means in the first year of this Agreement or a Product Agreement, the time from the Effective Date up to and including December 31 of the same calendar year, and after that will mean a calendar year.

1.4 Interpretation.

The division of this Agreement into Sections, Subsections, Appendices and Schedules, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Schedule refers to the specified Section, Appendix or Schedule to this Agreement. In this Agreement, the term "**this Agreement**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix or Schedule of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

2. Patheon's Manufacturing Services

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services as set out in the relevant Product Agreement for the Price and in accordance with the Quality Agreement. Subject to the preceding sentence, Patheon will convert API and Components into Product, and provide supportive Manufacturing Services such as quality assurance (for example quality controls, analytical testing, and stability programs), primary and secondary packaging, and any other related Manufacturing Services as agreed between the parties.

Unless otherwise agreed in a Product Agreement, Patheon will manufacture [***]% of Product offered for sale by Client or its Affiliates (the "**Minimum Market Requirement**"). The Minimum Market Requirement will be automatically reduced five Years after the effective date of a Product Agreement to [***]% of Client's requirements for Product in those countries in the Territory that are member states of the European Economic Area.

2.2 Subcontracting.

Patheon may subcontract the Manufacturing Services under a Product Agreement to any of its Affiliates, as agreed in the Product Agreement. Patheon will remain exclusively liable to Client for any breach of this Agreement or negligence by its Affiliates in the course of performing: (i) subcontracted Manufacturing Services under a Product Agreement; or (ii) obligations under the Quality Agreement. Patheon may also arrange for non-Affiliate subcontractors to perform specific services arising under any Product Agreement with the prior written consent of Client ("**Third Party Subcontractors**"). Patheon will be liable to Client for the failure by any Third Party Subcontractor to perform any part of the subcontracted services. But Patheon's liability for Third Party Subcontractors will remain subject to all limitations on Patheon's liability as set out in this Agreement. Patheon will have no liability arising from the performance of services by Third Party Subcontractors: (i) that are chosen by Client; (ii) that are suppliers or service providers not validated and utilized by Patheon; or (iii) to the extent that the Third Party Subcontractor is following the direct instructions of Client.

3. Client's Obligations

3.1 Payment.

Client will pay Patheon the applicable Price in accordance with Sections 4 and 5. All cost items that are not included in the Price (as specified in the applicable Product Agreement) are subject to additional fees to be paid by Client.

3.2 Processing Instructions.

Before the start of commercial manufacturing of Product under this Agreement, Client will give Patheon a copy of the Processing Instructions, which must be accompanied by the applicable API, Component and finished product specifications (if applicable, precisely matching the specifications approved by the applicable Regulatory Authority). If the Processing Instructions or accompanying documents received are amended or no longer reflect those currently approved by the Regulatory Authority, then Client will give Patheon a copy of the revised documents (if applicable, precisely matching the revised specifications approved by the applicable Regulatory Authority). Upon acceptance of the revised Processing Instructions and accompanying documents, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance. At Patheon's request, Client will provide evidence of the executed original documents submitted by or on behalf of Client to the Regulatory Authority.

3.3 API and Components.

(a) Client will at its sole cost and expense deliver the API and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2010). Client's obligation will include obtaining the release of the API and any Client-Supplied Components from the applicable customs agency and Regulatory Authority. Unless otherwise agreed in writing, Client or Client's designated broker will be the "**Importer**" or "**Importer of Record**" (or equivalent, as understood under Applicable Laws) for API, Client-Supplied Components, drug products and intermediates imported to the Manufacturing Site, and Client is responsible for compliance with Applicable Laws (and the cost of compliance) relating to that role. For API or Client-Supplied Components which may be subject to import or export to or from the United States, Client agrees that its vendors and carriers will comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism.

(b) Unless otherwise agreed in writing between the parties, the API and any Client-Supplied Components must be delivered by the Client to the Manufacturing Site at least 45 days before the scheduled manufacture date for Product covered by a Firm Order in sufficient quantity to enable Patheon to manufacture the agreed quantities of Product. Patheon reserves the right to refuse to store any quantity of API in excess of the amount necessary for the Firm Order, at its sole discretion at any time. If Client fails to deliver the API or Client-Supplied Components within the agreed time period and, making commercially reasonable efforts, Patheon is unable to manufacture Product on the scheduled date because of the delay, the Firm Order will be considered cancelled by Client and Section 5.1(e) will apply.

(c) Patheon will control the unloading of API and Client-Supplied Components arriving at the Manufacturing Site and Client will comply and ensure that its carrier complies with all related directions of Patheon. The API and Client-Supplied Components will be held by Patheon on behalf of Client as set out in this Agreement. The API and Client-Supplied Components will at all times remain the property of Client. Any API and Client-Supplied Components received by Patheon will only be used by Patheon to perform the Manufacturing Services.

(d) Client will ensure that: (i) all delivered API meets the specifications for that API; and (ii) all shipments of API are accompanied by the required documentation as specified in the applicable Quality Agreement.

(e) If Client asks Patheon to qualify an additional supplier for the API or any Component, the parties must agree on the scope of work to be performed by Patheon and the additional fees to be paid by Client. For any API or any Component, this work at a minimum will include: (i) laboratory testing to confirm the API or Component meets existing specifications; (ii) manufacture of an experimental batch of Product that will be placed on three months accelerated stability; and (iii) manufacture of full-scale validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale).

(f) Patheon will promptly advise Client if it encounters API or Component supply problems, including delays or delivery of non-conforming API or Components from a Client designated additional supplier. The parties will cooperate to reduce or eliminate any supply problems from these additional suppliers. If supply problems persist, Patheon may suspend the Manufacturing Services affected by the problems until it is satisfied that the Client has resolved the problems with its supplier or appointed an alternative supplier. Client will qualify or certify (as appropriate) all Client designated additional suppliers on an annual basis at its expense and will provide Patheon with copies of the relevant annual reports. If Patheon agrees to certify or qualify a Client designated additional supplier on behalf of Client, it will do so for an additional fee payable by Client.

3.4 Packaging and Artwork.

Client will be responsible for the cost of artwork development and approval of all artwork. Client will be responsible for changes to labels, product inserts, and other packaging for the Product, including obtaining all required approvals. Client will be responsible for the cost of labelling obsolescence as contemplated in Section 5.2. Patheon's name will not appear on the label or anywhere else on the Product unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name. At least 150 days prior to the Release Date of Product for which new or modified artwork is required, Client will provide at no cost to Patheon and in accordance with the applicable specifications, final camera ready artwork for all packaging Components to be used in the manufacture of the Product. Client will be responsible for the costs associated with complying with any and all regulatory requirements for the labeling and tracking of the manufactured Product, including product serialisation, product data transfer and anti-counterfeiting requirements in the Territory.

4. Price and Price Adjustments

4.1 First Year Pricing.

The Price for each Product will be listed in Schedule A of a Product Agreement and may be adjusted under this Section 4.

4.2 Annual Price Adjustments.

Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Inflation. Patheon may adjust the Price for inflation in accordance with Appendix 4.

(b) Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than the Local Currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated in accordance with Appendix 4 after all other annual Price adjustments under this Section 4.2 have been made.

(c) Pricing Basis. Client acknowledges that the Price in any Year is agreed based upon the applicable Minimum Market Requirement, Annual Volume, and Minimum Order Quantity for that Year. Patheon may adjust the Price if it reasonably concludes, or is notified by Client, that the Minimum Market Requirement, Annual Volume or Minimum Order Quantity will not be ordered in a Year.

(d) Tier Pricing. If the Pricing is divided into Annual Volume tiers, unless otherwise agreed in a Product Agreement, Client will be invoiced during the Year based at the lowest volume tier. Within 30 days after the end of each Year or on termination of the Product Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by Client during the Year at the actual applicable Pricing tiers. If the reconciliation shows an overpayment, Patheon will issue a credit to Client for the amount of the overpayment within 60 days after the end of the Year or will reimburse the overpayment within 60 days after termination. The parties will work together in good faith to resolve any disagreement over the reconciliation.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about October 1 but no later than December 1 of each Year (unless otherwise agreed in writing) a letter stating the adjusted Pricing under a Product Agreement to be effective for Product to be delivered on or after January 1 of the next Year including any Firm Orders accepted by Patheon before that date. Any omitted adjustment in a Year does not waive Patheon's right to apply that adjustment cumulatively with the next permitted adjustment.

4.3 Price Adjustments at any Time.

The Prices may be adjusted by Patheon at any time upon written notice to Client as follows:

(a) Extraordinary Increases in Component Costs. If the cost of a Component increases cumulatively by at least [***]% since the last annual adjustment as a result of market factors outside of Patheon's control, then Patheon will be entitled to adjust the Price proportionately and as otherwise agreed in the Product Agreement. The revised Price will become effective with the first use of the higher cost Component in the manufacture of the Product. For a Price adjustment under this Section 4.3(a), Patheon will deliver to Client a revised Schedule A to the Product Agreement.

(b) Changes. The scope of the Manufacturing Services is set by the agreed Processing Instructions, the Regulatory Approvals, the Quality Agreement and any assumptions, inclusions, exclusions and other parameters set out in the applicable Product Agreement. Changes to the scope of the Manufacturing Services and related changes to the Price must be agreed in writing by the parties (using a "**Change of Scope**" agreement, or similar, setting out the agreed activities and costs of implementation) and are subject to the change control provisions of the Quality Agreement. Where Patheon requests a change to the Manufacturing Services, the change will be implemented following written approval of Client, which Client will not unreasonably withhold, condition or delay.

5. Purchasing Product

5.1 Orders and Forecasts.

(a) Long Term Forecast. On or before June 1 of each Year, Client will give Patheon a non-binding written forecast of Client's volume requirements for the Product for each of the next [***] ("**Long Term Forecast**"). If Patheon foresees any capacity constraint affecting any portion of the Long Term Forecast, it will notify Client and the parties will agree on a revised Long Term Forecast within Patheon's expected capacity. If Patheon confirms it is unable to meet the Client's Long Term Forecast (neither at the Manufacturing Site set forth in the relevant Product Agreement nor at any other facility within the Patheon network), then Client is free to have the Product manufactured elsewhere without penalty, upon prior written notice thereof to Patheon.

(b) Rolling Forecast. Before each Product Agreement is executed, Client will give Patheon a written forecast of the volume of Product that Client expects to order in each of the next [***] (the "**Rolling Forecast**"). The Rolling Forecast must be reasonably consistent with the Long Term Forecast. Client will provide an updated Rolling Forecast: (i) on or before [***]; and (ii) if at any time it determines that the total forecast volumes estimated in the most recent Rolling Forecast have changed by more than [***]%. Each updated Rolling Forecast supersedes all previous Rolling Forecasts.

(c) Orders. On or before [***], Client will issue a new purchase order for any required Product. Each purchase order must meet the Minimum Order Quantity and specify the purchase order number, quantities by Product type, and requested release dates for the Product (which must occur at least 90 days after the first day of the next month).

(d) Acceptance of Purchase Orders. To the extent that a purchase order covers Product that is forecast in the Rolling Forecast, Patheon will accept the purchase order by sending an acknowledgement to Client, including the confirmed Release Dates. Subject to Section 5.1(f), if Patheon fails to acknowledge receipt of a purchase order within ten Business Days, the purchase order will be considered accepted by Patheon. An accepted purchase order will be binding on the parties (a "**Firm Order**"), except that either party may request to change any Release Date beyond 90 days after the first day of the next month. The parties will negotiate in good faith and agree on any requested alternative release date. Neither party may unreasonably reject an alternative release date requested under this Section 5.1(d), but, if the parties cannot agree, the original Release Date confirmed by Patheon will apply.

(e) Cancellation or Postponement. Patheon will determine the manufacturing schedule of all Product covered by Firm Orders. If Client cancels or reduces a Firm Order, or wishes to postpone the applicable Release Date (subject to Section 5.1(d)), Client will remain liable to pay Patheon [***]% of the Price for the Firm Order.

(f) Capacity Reservation. In advance of each Year of a Product Agreement, Patheon will use the Rolling Forecast to reserve its manufacturing capacity in that Year for Product as follows:

(i) for the first Year, by reference to the first Rolling Forecast;

(ii) for the second Year, if the Effective Date of the Product Agreement occurs after June 1, by reference to the first Rolling Forecast; and

(iii) in all other cases, by reference to the Rolling Forecast applicable at June 1 of the previous Year,

the relevant forecast for the Year being the "**Yearly Forecast Volume**".

At the end of each Year, if the aggregate actual volume of Product ordered by Client with a confirmed Release Date within the Year, taking into account any Product paid for but not ordered, ("**Actual Yearly Volume**") is less than [***]% of the Yearly Forecast Volume, then Patheon may invoice and Client will pay Patheon [***]% of the Price for the shortfall of Product below the tolerance during the Year in an amount calculated as follows:

Amount Due to Patheon=[***]

If the quantity of Product requested by Client in [***] (in purchase orders received by Patheon) exceeds the [***], Patheon shall not be obliged to supply such excess quantities, but it will use commercially reasonable efforts to supply the additional Product volumes depending on the relevant available capacity at the Manufacturing Sites at the time of such request. Patheon will not be considered to have accepted any purchase order for additional Product volumes without written confirmation.

(g) Controlled Substance Quota Requirements (if applicable). Client will give Patheon the information set out below for obtaining any required DEA or equivalent agency quotas ("**Quota**") needed to perform the Manufacturing Services. Patheon will be responsible for routine management of Quota information in accordance with Applicable Laws. The parties will cooperate to communicate the information and to assist each other in Regulatory Authority information requirements related to the Product as follows: (i) by April 1 of each Year for the applicable Product, Client will provide to Patheon the next Year's annual Quota requirements for the Product; (ii) by August 1 of each Year, Client will provide to Patheon any changes to the next Year's Quota requirements; (iii) Client will pro-actively communicate any changes to the Quota requirements for the then-current Year in sufficient time to allow Patheon to file and finalize Regulatory Authority filings supporting the changes; (iv) upon Patheon receiving the necessary forecast information from Client in order to request additional Quota, Patheon will submit to the applicable Regulatory Authority, on a timely basis, all filings necessary to obtain Quotas for API and will use commercially reasonable efforts to secure sufficient Quota from the applicable Regulatory Authority so as to achieve Release Dates for Product as set out in applicable purchase orders and forecasts submitted to Patheon by Client or its designee; and (v) Patheon will not be responsible for any Regulatory Authority's refusal or failure to grant sufficient Quota for reasons beyond the reasonable control of Patheon (including where Client fails to provide the required information in accordance with this Section 5.1(g)).

5.2 Obsolete Stock.

(a) Client understands and acknowledges that Patheon will rely on purchase orders, Firm Orders, the Long Term Forecast and the Rolling Forecast in ordering the Components (other than Client-Supplied Components) required to meet anticipated Firm Orders. Patheon may purchase the Components in sufficient volumes, and reasonably in advance of the expected use of the Component (taking into account lead times), to meet the production requirements for Products covered by anticipated Firm Orders or to meet the production requirements of any longer period agreed to by the parties.

(b) Client will reimburse Patheon for the cost of Components ordered by Patheon in relation to Firm Orders or under Section (a) that are not used in the Manufacturing Services within six months after the forecasted month for which the purchases have been made or if the Components have expired or are rendered obsolete due to changes in any forecast, Processing Instructions, GMP, artwork or Applicable Laws during the period (collectively, "**Obsolete Stock**"). This reimbursement will include Patheon's cost to purchase and destroy the Obsolete Stock (plus a [***] handling fee). If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

5.3 Storage.

If: (i) Client fails to take possession or arrange for the destruction of Obsolete Stock within 30 days of receipt of written notice from Patheon identifying the Obsolete Stock; (ii) any equipment (other than existing Patheon equipment) is stored at the Manufacturing Site at any time prior to its use in the Manufacturing Services; or (iii) Product is not collected by Client within 30 days of the Release Date notified by Patheon, Client will pay Patheon [***], per month after that for storing the Obsolete Stock, equipment or Product. Storage fees for Obsolete Stock or Product which contain controlled substances or require refrigeration will be charged at [***] per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship Product held by it longer than 30 days to Client at Client's expense on 14 days' written notice to Client. If Patheon is unable to store any material due to capacity constraints, Patheon may use an Affiliate or qualified third party to store (outside the Manufacturing Site) any material under this Agreement. After the limited storage periods stated above, Client will assume all risk of loss or damage to materials and Client will be responsible for having appropriate insurance coverage in place for this risk.

5.4 Invoices and Payment.

For shipments of Product, Patheon will issue invoices to Client on or after the Release Date of the Product. Otherwise, Patheon will issue invoices for Manufacturing Services on completion or as agreed in the Product Agreement. Patheon will also submit to Client, with each shipment of Product, a duplicate copy of the invoice covering the shipment. Invoices will be sent by email to the email address given by Client to Patheon in writing. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within 30 days of the date of the invoice. If any portion of an invoice is disputed, Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue at 1.5% per month. Patheon may, on giving 30 days' notice to Client, suspend all Manufacturing Services, including release and shipment of Product, until all undisputed past due invoices have been paid in full. Patheon will have no liability to Client for losses caused by this suspension, including without limitation, losses due to delayed Product delivery or Product shortages.

5.5 Delivery and Shipping.

Delivery of Product and any other materials will be made EXW (Incoterms 2010) from Patheon's Manufacturing Site unless otherwise agreed in a Product Agreement. Subject to Section 8.3, risk of loss or of damage to Product will remain with Patheon until Patheon loads the Product onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. But if Client fails to collect Product within one month after it has been released for shipment by Patheon, Client will assume all risk of loss or damage to the released Product. Patheon may, in accordance with Client's instructions and as agent for Client, at Client's risk, arrange for shipping (to Client or any third party nominated by Client) to be paid by Client. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight activity under this Agreement.

6. Product Claims and Recalls

6.1 Product Claims.

(a) Rejection. Client may reject any manufactured Product that it reasonably considers (by reference to the results of the agreed release testing) to be deficient based on documentation provided by Patheon or Client's own inspection or testing of delivered Product.

(b) Product Claims.

(i) Client may claim a remedy (a "**Product Claim**") for any portion of any batch of Product for which Patheon did not perform the Manufacturing Services in accordance with the agreed Processing Instructions, cGMPs, or Applicable Laws ("**Deficient Product**"). Client will inspect Product manufactured by Patheon, or batch documentation provided by Patheon, upon receipt and will give Patheon written notice of all Product Claims within 30 days after receipt (or, in the case of any deficiency not reasonably susceptible to discovery upon receipt, within 30 days after discovery by Client, but not after the expiration date of the Product). If Client fails to provide a Product Claim within the applicable 30 day period, then the Product will be considered to have been accepted by Client on the 30th day. Patheon will have no liability for any deficiency for which it has not received notice within the applicable 30 day period.

(ii) Without prejudice to Section 10.3, this Section 6 sets out the only liability of Patheon for Deficient Products. Patheon will provide a remedy for Product Claims as specified in this Section 6 and Section 10.2, but Patheon will have no obligation for any Product Claims to the extent the Deficient Product was caused by: (i) deficiencies in the Processing Instructions, specifications, the safety, efficacy, or marketability of the Product or its distribution; (ii) a defect in the API or an incorporated Component that was not reasonably discoverable by Patheon using the test methods set out in the Processing Instructions; (iii) actions of Client or third parties occurring after the Product is delivered by Patheon; (iv) packaging design or labelling defects or omissions for which Patheon has no responsibility; (v) any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws; or (vi) any other breach by Client of its obligations under this Agreement. If after a full investigation as set out in the Quality Agreement and this Section 6.1(b)(ii), it is determined that Patheon manufactured Product in accordance with the agreed Processing Instructions, but a batch or portion of batch of Product is not released, Client will pay Patheon the Price for the Product. Patheon will prepare an annual reconciliation of API as set forth in Appendix 3, and Patheon's only liability for API loss is set out in Appendix 3.

(c) Determination of Deficiency. Upon receipt of a Product Claim, Patheon will have ten days to advise Client by notice in writing whether it disagrees with the contents of the Product Claim. If the parties fail to agree within ten days after Patheon's notice to Client as to whether any Product identified in the Product Claim is Deficient Product, the parties will investigate the matter in accordance with the Quality Agreement. If, after joint testing or investigation has been performed, the parties still cannot agree on the root cause, the provisions of Appendix 2 will apply and, after the required negotiation, the dispute will be handled as a Technical Dispute.

(d) Shortages and Price Disputes. Claims for shortages in the amount of Product shipped by Patheon or a Price dispute will be dealt with by reasonable agreement of the parties. Any claim for a shortage or a Price dispute will be considered waived by Client if it has not been presented within 30 days of the date of the relevant invoice.

6.2 Product Recalls and Returns.

(a) Records and Notice. The parties will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in accordance with the Quality Agreement. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action: (i) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); (ii) by any Regulatory Authority to detain or destroy any of the Product; or (iii) by either party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

(b) Recalls. If: (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled; (ii) a court of competent jurisdiction orders a Recall; or (iii) Client determines that any Product should be Recalled or that a "**Dear Doctor**" letter is required relating the restrictions on the use of any Product, then Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws.

(c) Recalled Product. To the extent that a Recall results from, or arises from Deficient Product, Patheon will be responsible for the reasonable documented out-of-pocket expenses of the Recall and, at Client's election, will as per Section 10 either (i) use its commercially reasonable efforts to replace the Deficient Product with replacement Products as soon as reasonably practical or (ii) refund 100% of the Price paid for the Deficient Product. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense. Patheon's only liability for API loss is set out in Appendix 3.

6.3 Disposition of Deficient Product.

Client will not dispose of any damaged, returned, or Deficient Product for which it intends to assert a Product Claim against Patheon without Patheon's prior written authorization to do so. Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of return and disposition of any Deficient Products. In all other circumstances, Client will bear the cost of return and disposition, including all applicable fees for Manufacturing Services.

7. Co-operation and Regulatory Affairs

7.1 Governance.

Each party will without delay upon execution of this Agreement or a Product Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet on a frequency agreed between the parties to review the current status of the business relationship, including review of key performance indicators such as API delivery, on-time delivery, right first time, and attainment of the Minimum Market Requirement, and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to any restrictions in the Quality Agreement, each party may communicate with any Regulatory Authority responsible for granting Regulatory Approval for the Product and any other relevant Authority regarding the Product if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of the Authority or Applicable Laws. Otherwise, the parties will consult each other in relation to regulatory communications relating to the Product in accordance with the Quality Agreement.

7.3 Records.

Patheon will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, Applicable Laws, cGMP and the Quality Agreement. Copies of the records and samples will be retained as and for the period specified in the Quality Agreement. Patheon reserves the right to destroy or return to Client, at Client's sole expense, any document or samples for which the retention period has expired if Client fails to arrange for destruction or return within 30 days of receipt of notice from Patheon.

7.4 Audits.

Subject to the limits agreed in the Quality Agreement, Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Product is manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. If Client wishes to audit Patheon beyond the agreed limits, except where the audit is required due to Patheon's material breach, Client will pay to Patheon a fee of [***] for each additional audit day and [***] per audit day for each additional auditor. Under no circumstances will: (a) Client have a right of access to Patheon's financial records; or (b) any Patheon Competitor be permitted access to the Manufacturing Site.

7.5 Regulatory Filings.

(a) Regulatory Authority Documentation. Client will provide copies of all relevant documents relating to Regulatory Authority approval for the commercial manufacture, distribution and sale of the Product ("**Regulatory Approval**") to Patheon on request and as required under the Quality Agreement. Patheon will review and verify the accuracy of these documents in accordance with the Quality Agreement. Client is not entitled to submit Regulatory Approvals referring to Patheon or its Affiliates or the Services until approved by Patheon.

(b) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any regulatory information given by Client is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed.

(c) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under this Section 7.5 or the Quality Agreement within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents. Client's breach of this requirement will be considered a material breach of this Agreement.

(d) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Product in accordance with Applicable Laws and the monitoring and management of post-marketing complaints and queries at its cost (including, without limitation, the cost of assistance required of Patheon under the Quality Agreement). Unless required by Applicable Law, neither party will be obliged to exchange with the other party any information or data which it compiles in carrying out pharmacovigilance obligations or activities.

(e) No Patheon Responsibility. Except as otherwise agreed in the Quality Agreement, Patheon will not assume any responsibility for: (a) the submission, accuracy or cost of any application for Regulatory Approval or related documentation (or the success of those applications); (b) any activity that is required by Applicable Laws for Regulatory Approval (including pharmacovigilance and complaints handling, and preparation and submission of any regular quality or other update); or (c) any dealings with the relevant Regulatory Authority on behalf of Client for Regulatory Approval. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the Products which Patheon considers unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss in good faith appropriate mutually acceptable actions, including fee/cost sharing, or termination of all or any part of this Agreement or a Product Agreement. Patheon will be not be obliged to undertake these activities or to pay for the fees or costs until the parties reach agreement on scope and fees for Patheon's assistance.

7.6 Release.

The parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations relating to the Manufacturing Services. Nothing in this Agreement will remove or limit the authority of the relevant quality function (as specified by the Quality Agreement) to determine whether the Product will be released for sale or distribution.

7.7 Withdrawal on Completion.

No later than 90 days following completion or permanent cessation of the Manufacturing Services at the applicable Manufacturing Site, Client will: (a) ensure that any regulatory filings relating to the Product are withdrawn or amended to remove all references to the Manufacturing Site and, as applicable, Patheon or its Affiliates and their facilities (except in an historic context); and (b) provide to Patheon written confirmation of its compliance with this Section 7.7. If this time is not sufficient to meet the requirements of certain Regulatory Authorities, despite Client's best efforts, then Patheon may agree to extend the period based on the written reassurances of Client.

8. Term and Termination

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31 of the fifth Year of the Agreement (the "**Initial Term**"), unless terminated earlier by one of the parties. This Agreement will automatically renew after the Initial Term for successive terms of two Years each if there is a Product Agreement in effect, unless Client gives written notice of its intention to terminate this Agreement at least 12 months prior to the end of the then current term or Patheon gives written notice to Client of its intention to terminate this Agreement at least 24 months prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect. Each Product Agreement will have an initial term from the Effective Date of the Product Agreement until December 31 of the Year agreed to by the parties in the Product Agreement (each, an "**Initial Product Term**"). Unless otherwise agreed in a Product Agreement, Product Agreements will automatically renew after the Initial Product Term for successive terms of two Years each unless Client gives written notice of its intention to terminate the Product Agreement at least 18 months prior to the end of the then current term or Patheon gives written notice to Client of its intention to terminate the Product Agreement at least 18 months prior to the end of the then current term.

8.2 Termination for Cause.

(a) Either party may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of this Agreement or the Product Agreement within 60 days (the "**Remediation Period**") following receipt of a written notice of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to provide notice of termination of this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for a period of 90 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be considered to have waived the breach described in the Breach Notice. The right to terminate a Product Agreement under this Section 8.2(a) does not extend to any other Product Agreements where there has been no material breach of those other Product Agreements.

(b) Either party may immediately terminate this Agreement or a Product Agreement upon written notice to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy or insolvency is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that permanently prevents Client from selling the Product in the Territory.

(d) Client may terminate a Product Agreement upon six months' prior written notice if it intends to no longer order Manufacturing Services for a Product due to the Product's discontinuance in the market.

(e) Patheon may terminate this Agreement or any Product Agreement upon six months' prior written notice if Client assigns under Section 13.4 any of its rights under this Agreement or a Product Agreement to an assignee that, in the reasonable opinion of Patheon acting in good faith, is: (i) unlikely to be able to meet the financial obligations of this Agreement or a Product Agreement; (ii) a Patheon Competitor; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations (as supported by reasonable evidence of late or unpaid invoices or material disputes).

(f) Patheon may terminate this Agreement or any Product Agreement if payment in full of overdue, undisputed invoices is not received within 30 days following the date of suspension of Manufacturing Services by Patheon under Section 5.4.

(g) If Client forecasts zero volume for six successive months during the term of a Product Agreement (excluding the registration period), then Patheon may terminate the Product Agreement by providing 30 days prior written notice to Client. Within that period, Client may either: (i) withdraw the zero forecast and re-submit a reasonable volume forecast, after which Patheon will withdraw the termination notice; or (ii) negotiate other terms and conditions on which the Product Agreement will remain in effect.

8.3 Obligations on Termination.

If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured or packaged in accordance with this Agreement under a Firm Order, at the Price in effect at the time the Firm Order was released;

(b) Client will purchase all Inventory that was purchased (or will be purchased under existing unfulfilled orders for Components), maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory);

(c) Client, at its own expense, will remove from the Manufacturing Site, within 30 days following the completion, termination, or expiration of the Product Agreement, all unused API and Client-Supplied Components, all applicable Inventory (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove Client Property within the 30 day period, Client will pay Patheon [***] per pallet, per month, one pallet minimum (except that Client will pay [***] per pallet, per month, one pallet minimum, for any of Client Property that contains controlled substances, requires refrigeration or other special storage requirements) after that for storing Client Property and will assume any third party storage charges invoiced to Patheon regarding Client Property (which Patheon may incur at its discretion). Patheon may ship Client Property to Client or to an external warehouse at Client's risk and expense. Patheon will invoice Client for these storage charges as set out in Section 5.3 of this Agreement. If Client fails to remove Client Property within 30 days following the completion, termination, or expiration of the Product Agreement, Client will assume all risk of loss or damage to the stored Client Property and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction; and

(d) any completion, termination or expiration of this Agreement or a Product Agreement will not affect any prior outstanding obligations or payments due nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. Completion, termination or expiration of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Sections 5.1(e), 5.1(f), 5.4, 5.5, 8.3, 10, 11, 12, 13.14, 13.15 and 13.16, all of which survive any completion, termination or expiration, as well as any other provisions that are by implication or otherwise intended to survive any completion, termination or expiration. Where Patheon has agreed to provide stability services beyond the final supply of Product, the relevant provisions of this Agreement will survive for the agreed duration of those stability services.

8.4 Technology Transfer.

Following termination of a Product Agreement for any reason, or at Client's request within six months before the end of the term of the Product Agreement, Patheon will provide assistance to transfer part or all of Client's manufacturing process, know-how and analytical testing methodology for the Product to Client ("**Technology Transfer**") to assist Client to manufacture the Product. Patheon will also disclose to Client any Patheon Intellectual Property that is reasonably required to manufacture the Product. Patheon will, upon request of Client, prepare a written proposal to perform the Technology Transfer. Client will pay the agreed fees for the Technology Transfer performed by Patheon.

9. Representations, Warranties and Covenants

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.

9.2 Client Warranties.

(a) Non-Infringement. Client covenants, represents, and warrants that:

(i) the Processing Instructions and specifications for the Product are its or its Affiliate's property and that Client may lawfully disclose the Processing Instructions and specifications to Patheon for use in accordance with this Agreement;

(ii) any Client Intellectual Property used by Patheon in performing the Manufacturing Services (A) is Client's or its Affiliate's unencumbered property, (B) may be lawfully used as directed by Client and agreed in this Agreement, and (C) does not infringe and will not infringe any Third Party Rights;

(iii) the performance of the Manufacturing Services by Patheon or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or any Product Agreement does not and will not infringe any Third Party Rights; and

(iv) there are no actions or other legal proceedings involving Client or its Affiliates that concerns the infringement of Third Party Rights related to any of the Processing Instructions or specifications, or any of the API or Client-Supplied Components, or the sale, use, or other disposition of Product made in accordance with the Processing Instructions.

(b) Quality and Compliance. Client covenants, represents, and warrants that:

(i) the Processing Instructions and specifications for the Product conforms to all applicable cGMPs and Applicable Laws;

(ii) the Product, if labelled and manufactured in accordance with the Processing Instructions and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Product, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption; and

(iii) on receipt by Patheon, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled in accordance with Applicable Laws and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws;

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights;

(c) it will not in the performance of its obligations under this Agreement use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b); and

(d) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Federal Food, Drug, and Cosmetic Act.

9.4 Permits.

(a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Product, Processing Instructions or specifications, including, without limitation, all marketing and post-marketing approvals, and any specific approvals referred to in the Quality Agreement.

(b) Patheon will maintain at all relevant times when performing the Manufacturing Services all required governmental permits, licenses, approval, and authorities.

9.5 No Warranty.

PATHEON MAKES NO WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET OUT IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCT.

10. Liability and Remedies

10.1 Consequential and Other Damages.

Except with respect to [***], under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, indemnity, breach of statutory duty, or otherwise for: (i) any (direct or indirect) delay, penalty, loss of profits, of anticipated savings, of business, of goodwill, or of use of the Product or costs of any substitute services; or (ii) any reliance damages, including but not limited to costs or expenditures incurred to evaluate the viability of entering into this Agreement or to prepare for performance under this Agreement; or (iii) for any other liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Remedies for Deficient Product. If Client makes a Product Claim under Section 6.1 and the parties agree the Product is Deficient Product, or the Product is determined to be Deficient Product under Section 6, Patheon will promptly, at Client's election, either:

(i) replace the Product at Patheon's cost (after which Patheon may invoice for the replacement) if Patheon is able to manufacture the replacement Product at the Manufacturing Site and contingent upon the receipt from Client of all API and Client-Supplied Components required for the manufacture of the replacement Product; or

(ii) refund 100% of the Price paid for the Deficient Product (by credit or offset against other amounts due to Patheon under the Product Agreement).

Except for the indemnity set out in Section 10.3 and any claim for expenses related to a Recall under Section 6.2(c), the remedies described in this Section 10.2 will be Client's sole remedy in contract, tort, negligence, equity or otherwise, for Deficient Product.

(b) API. Except as expressly set out in Appendix 3, under no circumstances whatsoever will Patheon be liable to Client in contract, tort, negligence, indemnity, breach of statutory duty, or otherwise for any loss or damage to the API. Patheon's maximum aggregate liability for loss of or damage to the API will not exceed on a per Product basis [***]% of revenues (being payments of the Price) received by Patheon for that Product under the applicable Product Agreement during the previous Year (or, in the case of the first Year, the expected revenue for that Product if the agreed Yearly Forecast Volumes were ordered).

(c) Maximum Liability. Except with respect to a breach of the obligations of Section 11 or Section 12 , in any Year, in addition to the specific remedies under Section 10.2(a) for Deficient Product and for any Recall, Patheon's maximum aggregate liability to Client under or in connection with this Agreement or any Product Agreement (however arising, including contract, tort, negligence, indemnity, breach of statutory duty, losses of API, or otherwise) will not exceed on a per Product basis [***]% of revenues (being payments of the Price) received by Patheon for that Product under the applicable Product Agreement during the previous Year (or, in the case of the first Year, the expected revenue for that Product if the agreed Yearly Forecast Volumes were ordered), unless otherwise agreed in the relevant Product Agreement. Notwithstanding the foregoing, the said maximum aggregate liability will not apply in the event of Patheon's recklessness or wilful misconduct.

(d) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement will act to exclude or limit either party's liability for personal injury or death caused by the negligence of either party or fraudulent misrepresentation.

10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify Client, its officers and employees, against all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) for any claim (i) of infringement of any Third Party Rights solely and specifically related to the use of the Patheon Intellectual Property, (ii) of personal injury or property damage to the extent that the injury or damage is the result of a failure by Patheon, its officers, employees, or Affiliates to perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws, or is the result of the negligence or wilful misconduct of Patheon, its officers, employees or Affiliates, except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Client, its officers, employees, or Affiliates.

(b) If a claim occurs, Client will: (i) promptly notify Patheon of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Patheon in the defense of the claim; and (iv) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify Patheon, its officers and employees, against all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) for (i) any claim of infringement of any Third Party Rights in the Products or that relates to the manufacture of the Product by a proprietary process disclosed by Client or to Patheon’s use of Client’s Intellectual Property to perform the Manufacturing Services, or any portion of them, or (ii) any claim of personal injury or property damage to the extent that the injury or damage arises other than from a breach of this Agreement or the relevant Product Agreement by Patheon , including, without limitation, any representation or warranty contained in this Agreement, or is the result of negligence or wilful misconduct of Patheon, its officers, employees or Affiliates, except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Patheon, its officers, employees, or Affiliates.

(b) If a claim occurs, Patheon will: (i) promptly notify Client of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Client in the defense of the claim; and (iv) permit Client to control the defense and settlement of the claim, all at Client's cost and expense.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Section 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Product. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Product because Client has developed and holds the marketing approval for the Product, Client requires Patheon to manufacture and label the Product strictly in accordance with the Processing Instructions, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Product.

10.6 Validation Batches.

Where Product is manufactured by Patheon (or any of its Affiliates) under a separate pharmaceutical development or technology transfer agreement (the "**Development Agreement**") and then released by Patheon for commercial sale or distribution by Client, the performance of the applicable pharmaceutical development or technology transfer services including the manufacture of the Product will be governed by the terms of the Development Agreement and will not be subject to the terms and conditions of this Agreement. The terms of this Agreement and the applicable Product Agreement will apply to any Product after release by Patheon.

11. Confidentiality

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients and its clients' confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing Confidential Information will be considered Confidential Information. Samples or materials provided under this Agreement as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. A party's rights and obligations under this Section 11 will apply to any Confidential Information that is disclosed by or received by that party's Representatives. For the purposes of this Section 11, a party receiving Confidential Information under this Agreement (including through its Representatives) is a "**Recipient**", and a party disclosing Confidential Information under this Agreement (including through its Representatives) is the "**Disclosing Party**". The existence, parties to, and terms of this Agreement or of any Product Agreement will be considered Confidential Information.

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality in this Section 11 will not apply to the extent that Confidential Information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, if the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party for the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information is not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information are covered by exceptions in this Section 11.3, unless the combination itself is covered by any of those exceptions.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure and limit the required disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out in this Agreement. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party will use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within 30 days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form or is of a nature reasonably understood to be confidential or proprietary.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies, summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement. Client will not unreasonably require the return of Confidential Information that is necessary or useful to perform the Manufacturing Services.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Section 11 and agree that the non-breaching party will be entitled to seek specific performance, injunctive or other equitable relief to prevent breaches of this Section 11 and to specifically enforce Section 11 in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Section 11 but will be in addition to any and all other remedies available at law or in equity.

12. Intellectual Property

12.1 Inventions.

(a) For the term of this Agreement, Client grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) All Client Intellectual Property will be the exclusive property of Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Unless Patheon identifies in advance any specific Patheon Intellectual Property that will be subject to a separate licensing agreement between the parties, Patheon grants to Client a non-exclusive, perpetual, paid-up, royalty-free, transferable license of the Patheon Intellectual Property used by Patheon in the manufacture of the Product for use in relation to manufacturing that Product only.

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be considered to be improvements or other modifications of the Product, processes or technology owned or otherwise controlled by the party.

12.2 Intellectual Property.

Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13. Miscellaneous

13.1 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years after that. This insurance will have policy limits of not less than: (i) EURO 5,000,000/USD 5,000,000 for each occurrence for personal injury or property damage liability; and (ii) EURO 5,000,000/USD 5,000,000 in the aggregate per annum for product and completed operations liability. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of 30 days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will without delay notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.2 Independent Contractors.

The parties are independent contractors and this Agreement and any Product Agreement does not create between the parties any other relationship such as, by way of example only, that of employer and employee, principal and agent, joint-venturers, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.3 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement will be considered a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.4 Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement, and Client will remain liable under this Agreement. Any partial assignment will be subject to Patheon's cost review of the assigned Product and Patheon may terminate this Agreement or any Product Agreement or any assigned part of them, on 12 months' prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time. Client will reimburse Patheon for any costs incurred by Patheon in connection with the partial assignment including any expenses incurred by Patheon for any due diligence audits in connection with the partial assignment.

(c) Despite the preceding provisions of this Section 13.4, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business to which this Agreement relates, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound by the obligations of this Agreement owed to that party.

13.5 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, cyber-attacks, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order, regulation, or enforcement decision of any government entity (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.5 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement.

13.6 Additional Product and Services.

Additional Product may be added to, or existing Product deleted from, any Product Agreement by amendment to the Product Agreement including its Schedules as applicable. If Client requests services other than those expressly set out in this Agreement or in any Product Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), or any cost items that are specifically excluded from the Price, Patheon will provide a written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be agreed in writing by the parties.

13.7 Notices.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted under this Agreement will be sufficient if made or given to the other party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or email addresses set out below:

If to Client:

Savara ApS
c/o Savara Inc.
6838 Bee Cave Road, Building III, Suite 200
Austin, Texas 78746 USA
Attention: Chief Financial Officer
Email address: dave.lowrance@savarapharma.com

If to Patheon:

Patheon UK Limited
Kingfisher Drive, Swindon, SN3 5NZ, United Kingdom
Attention: Legal Director
Email address: EULegalServices@Patheon.com

or to any other addresses or email addresses given to the other party in accordance with the terms of this Section 13.7. Notices or written communications made or given by personal delivery, or email will be considered to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt (supported by reasonable written evidence), whichever is sooner.

13.8 Severability.

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.9 Entire Agreement.

This Agreement, together with its Appendices, the applicable Product Agreement, Capital Equipment Agreement (if any), and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter of the Agreement and supersedes all previous written or oral negotiations, commitments, representations, agreements, transactions, or understandings concerning the subject matter of this Agreement. The basis of the parties' agreement is set out expressly and they have not been induced by or relied on any statement or representation that is not set out in this Agreement. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, and the Quality Agreement (except that the Quality Agreement will prevail in relation to quality matters).

13.10 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by the parties will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of a party to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

13.11 No Third Party Benefit or Right.

Nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement (except that Patheon Affiliates acting as subcontractors under this Agreement may enforce Sections 10.1 and 10.2). The rights of the parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any other person.

13.12 Execution in Counterparts.

This Agreement and any Product Agreement may be executed in two or more counterparts, by original or electronic (including "**pdf**") signature, each of which will be considered an original, but all of which together will constitute one and the same instrument.

13.13 Use of Name.

Neither party may use the other party's name, trademarks or logo or any variations of them, alone or with any other word or words, without the prior written consent of the other party. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.14 Taxes.

(a) VAT.

Any payment due to Patheon under this Agreement in consideration for the provision of Manufacturing Services to Client by Patheon is exclusive of value added taxes ("**VAT**"), turnover taxes, sales taxes or similar taxes, including any related interest and penalties (together referred to as "**Transaction Tax**"). If any Transaction Tax is payable on a Manufacturing Service supplied by Patheon to Client under this Agreement, this Transaction Tax will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) Client.

If any Transaction Tax on the supplies by Patheon is payable by Client under a reverse charge or withholding procedure (i.e., shifting of liability, accounting or payment requirement to recipient of supplies), Client will ensure that Patheon will not effectively be held liable for this Transaction Tax by the relevant taxing authorities or other parties.

Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to Client are issued in a way to meet the requirements for deduction of input VAT by Client, if Client is permitted by law to do so.

Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of Transaction Tax resulting from payments made under this Agreement, this recovery to be for the benefit of the Party bearing the Transaction Tax.

If Patheon is acting as Client's buying agent, Patheon will always charge to Client the Transaction Tax in the relevant territory in addition to the amount paid by Patheon to supplier.

For the avoidance of doubt, reference to the Manufacturing Services in this Section also includes any element (or the entirety) of the Manufacturing Services characterized as a supply of goods by Patheon, its subcontractors or any tax authority for Transaction Tax purposes.

(b) Duties.

Client will bear the cost of all duties, levies, tariffs and similar charges (and any related interest and penalties) (together "**Duties**") however designated, arising from the performance of the Manufacturing Services by Patheon, including (without limitation) those imposed as a result of the shipping of materials (including drug substance, materials, components and finished Product) to, from or between Patheon sites. If these Duties are incurred by Patheon, then Patheon will be entitled to invoice Client for these Duties at the time that they are incurred.

(c) Withholding Tax.

Where any sum due to be paid to Patheon hereunder is subject to any withholding or similar tax, Client will pay the withholding or similar tax to the appropriate Government Authority without deduction from or offset of the amount then due to Patheon. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate or enable the recovery of any tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Client to Patheon under this Agreement.

Patheon will provide Client any tax forms that may be reasonably necessary in order for Client not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.

Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, or similar obligations resulting from payments made under this Agreement, this recovery to be for the benefit of the Party bearing the withholding tax.

(d) No Offset. Any Transaction Tax, Duty, Withholding Tax or other tax that Client pays, or is required to pay, but which Client believes should properly be paid by Patheon under this Agreement may not be offset against sums due by Client to Patheon whether due under this Agreement or otherwise.

13.15 Governing Law and Jurisdiction.

This Agreement and any Product Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with them or their subject matter or formation are governed by the laws of (i) the State of Delaware if the applicable Patheon party is registered in the United States or (ii) England if the applicable Patheon party is registered outside the United States, in each case without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. Both parties hereby submit to the exclusive jurisdiction of the courts in the applicable location. The parties further expressly agree that the UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

13.16 Dispute Resolution.

All disputes that arise under or in connection with this Agreement will be resolved in accordance with Appendix 2.

[Signature page to follow]

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON UK LIMITED		SAVARA APS	
By:	/s/ Mark Newton	By:	/s/ Rob Neville
Name:	Mark Newton	Name:	Rob Neville
Title:	Dir GCS	Title:	CEO
Date:	26 June 2019	Date:	May 31, 2019

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: August 8, 2019

/s/ Robert Neville

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

Exhibit 31.2

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

I, David Lowrance, certify that:

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

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

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

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

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: August 8, 2019

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

Exhibit 32.1

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

In connection with the Quarterly Report of Savara Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Neville, principal executive officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

August 8, 2019

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

In connection with the Quarterly Report of Savara Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Lowrance, principal financial officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

August 8, 2019

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