# 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, 2017

OR

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

For the transition period from \_\_\_\_\_\_ to \_

Commission File Number 001-32157

# Savara Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

900 South Capital of Texas Highway, Las Cimas IV, Suite 150

Austin, TX

(Address of principal executive offices)

84-1318182 (I.R.S. Employer Identification No.)

> 78746 (Zip Code)

(512) 614-1848

(Registrant's telephone number, including area code)

N/A

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	X
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.  $\Box$ 

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

As of August 9, 2017, the registrant had 24,203,464 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, 2017		
Assets				
Current assets:				
Cash and cash equivalents	\$	61,133	\$	13,373
Grants and award receivable				400
Prepaid expenses and other current assets		2,541		840
Total current assets		63,674		14,613
Property and equipment, net		672		793
In-process R&D		33,071		10,477
Goodwill		28,222		3,051
Other non-current assets		131		
Total assets	\$	125,770	\$	28,934
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		- ,	-	
Current liabilities:				
Accounts payable	\$	1,932	\$	536
Accrued expenses	Ψ	5,487	Ψ	2,477
Current portion of capital lease obligation		719		442
Total current liabilities		8,138		3,455
Long-term liabilities:		0,150		5,455
Accrued interest on convertible promissory notes				151
Debt facility		14,579		151
Convertible promissory notes		14,579		3,448
		_		979
Put option derivative liability		11 (95		
Contingent consideration		11,685		9,708
Deferred tax liability		11,180		2,305
Capital lease obligation, net of current portion		297		579
Warrant liability		100		303
Other long-term liabilities	-	122		20
Total liabilities		46,001		20,948
Redeemable convertible preferred stock:				
Series A redeemable convertible preferred stock, \$0.001 par value, 0 and 1,799,906				
shares authorized, issued, and outstanding, as of June 30, 2017 and				2 2 2 2
December 31, 2016, respectively		_		3,232
Series B redeemable convertible preferred stock, \$0.001 par value, 0 and 6,000,000				
shares authorized as of June 30, 2017 and December 31, 2016, respectively; 0 and 5,675,387 shares issued and outstanding as of June 30, 2017 and				
December 31, 2016; respectively				17,301
Series C redeemable convertible preferred stock, \$0.001 par value; 0 and 8,000,000		_		17,301
shares authorized as of June 30, 2017 and December 31, 2016, respectively;				
0 and 4,452,582 shares issued and outstanding as of June 30, 2017 and				
December 31, 2016, respectively		_		23,328
Total redeemable convertible preferred stock				43,861
Stockholders' equity (deficit):				45,001
Common stock, \$0.001 par value, 500,000,000 and 27,000,000 shares authorized as of				
June 30, 2017 and December 31, 2016, respectively; 24,203,464 and 3,162,573				
shares (after giving effect to the Exchange Ratio and Reverse Stock Split) issued and				
outstanding as of June 30, 2017 and December 31, 2016, respectively		26		5
Additional paid-in capital		134,222		3,117
Accumulated other comprehensive income (loss)		404		(591)
Accumulated deficit		(54,883)		(38,406)
Total stockholders' equity (deficit)		79,769		(35,875)
	¢	125,770	\$	
Total liabilities, redeemable convertible preferred stock, and stockholder's equity (deficit)	\$	123,770	Φ	28,934

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,				onths Ended une 30,	
	 2017	2016		2017		2016
Grant and award revenue	\$ —	\$ —	\$	—	\$	
Operating expenses:						
Research and development	4,164	1,290		7,111		2,552
General and administrative	5,088	608		6,924		953
Depreciation	 91	85		181		170
Total operating expenses	9,343	1,983		14,216		3,675
Loss from operations	(9,343)	(1,983)		(14,216)		(3,675)
Other income (expense):						
Interest expense	(516)	(7)		(761)		(17)
Foreign currency exchange loss	(122)	(84)		(154)		(72)
Loss on extinguishment of debt	(1,816)	—		(1,816)		
Change in fair value of financial instruments	(177)	23		(237)		36
Total other income (expense)	(2,631)	(68)		(2,968)		(53)
Loss before income taxes	(11,974)	(2,051)		(17,184)		(3,728)
Income tax benefit	470	_		707		
Net loss	\$ (11,504)	\$ (2,051)	\$	(16,477)	\$	(3,728)
Accretion of redeemable convertible preferred stock	(554)	(2)		(578)		(26)
Deemed dividend on beneficial conversion feature	(404)	_		(404)		_
Net loss attributable to common stockholders	\$ (12,462)	\$ (2,053)	\$	(17,459)	\$	(3,754)
Other comprehensive income:						
Gain (loss) on foreign currency translation	851	—		995		
Total Comprehensive Loss	\$ (10,653)	\$ (2,051)	\$	(15,482)	\$	(3,728)
Net loss per share:						
Basic and diluted	\$ (0.90)	\$ (1.97)	\$	(2.06)	\$	(3.63)
Weighted average common shares outstanding	 					
Basic and diluted	 13,807,861	1,043,984	_	8,465,053		1,034,553

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

# Savara Inc. and Subsidiaries Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) Period Ended June 30, 2017 (In thousands, except share amounts) (Unaudited)

Redeemable Convertible Preferred Stock     Stockholders' Equity (Deficit)       Redeemable     Redeemable     Redeemable     Stockholders' Equity (Deficit)       Convertible Series A     Convertible Series B     Convertible Series C     Convertible Series C       Preferred Stock     Preferred Stock     Preferred Stock     Additional       Number of     Number of     Number of     Number of       Shares     Amount     Shares     Amount	
Number of Number of Number of Paid-In Accumulated Comprehens	Total
	01)  e(25.975)
Balance on December 31, 2016 1,799,906 \$ 3,232 5,675,387 \$ 17,301 4,452,582 \$ 23,328 \$ 43,861 3,162,573 \$ 5 \$ 3,117 \$ (38,406) \$ (5	<u>91)</u> <u>3(35,675)</u>
Repurchase of forfeited restricted           common stock	
Accretion of redeemable convertible preferred stock - 22 - 460 - 96 578 - (578) -	- (578)
Issuance of common stock upon           exercise of warrants	— 384
Conversion of convertible notes into common stock	— 10,045
Conversion of redeemable convertible preferred stock to common stock as effected for the reverse	11.100
merger exchange ratio (1,799,906) (3,254) (5,675,387) (17,761) (4,452,582) (23,424) (44,439) 7,034,102 7 44,431 -	- 44,438
Reclassification of warrant liability       —       —       —       —       —       370       —         Beneficial conversion feature       —       —       —       —       —       404       —	- 370 - 404
Beneficial conversion feature — — — — — — — — — — 404 — Business combination upon	- 404
Merger           3,639,189         4         35,842            Issuance of common stock upon	— 35,846
public offering, net closing costs 9,034,210 9 39,513	- 39,522
Issuance of detachable warrants with debt instrument	- 359
Issuance of common stock upon At The Market sales, net	— 100
Issuance of common stock for settlement of RSUs 72,361	
Issuance of common stock upon cashless exercise of 14.70	
stock options            4,679              Stock-based compensation	236
Stock-based compensation	- 236
	95 995
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	(16,477)
	04 \$ 79,769

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,			
		2017		2016	
Cash flows from operating activities:					
Net loss	\$	(16,477)	\$	(3,728)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation		181		170	
Changes in fair value of financial instruments		237		(36)	
Change in fair value of contingent consideration		1,977		_	
Noncash interest		400		26	
Loss on extinguishment of debt		1,816			
Foreign currency gain/(loss)		154		72	
Amortization of debt issuance costs		204			
Stock-based compensation		236		112	
Changes in operating assets and liabilities:					
Grant and award receivable		400		—	
Tax refund receivable		(666)		—	
Prepaid expenses and other current assets		(817)		(180)	
Deferred rent		(7)		16	
Accounts payable and accrued expenses		1,847		233	
Net cash used in operating activities	\$	(10,515)	\$	(3,315)	
Cash flows from investing activities:					
Cash acquired through Merger	\$	3,442	\$	_	
Purchase of property and equipment		(60)		(5)	
Net cash used in investing activities	\$	3,382	\$	(5)	
Cash flows from financing activity:					
Proceeds from debt facility	\$	14,894	\$		
Proceeds from convertible promissory note		3,569			
Issuance of common stock upon exercise of warrants		385		_	
Issuance of common stock upon public offering		39,522			
Repayment of long-term debt		(3,567)		_	
Issuance of common stock upon at the market offerings, net		100			
Proceeds from exercise of stock option				1	
Proceeds from issuance of Series C preferred stock, net				776	
Capital lease obligation principal payments		(5)		(81)	
Net cash provided by financing activities	\$	54,898	\$	696	
Effect of exchange rate changes on cash and cash equivalents	Ψ	(5)	Ψ		
Increase / (Decrease) in cash and cash equivalents	\$	47,760	\$	(2,624)	
Cash and cash equivalents beginning of period	ψ	13,373	φ	16,683	
Cash and cash equivalents beginning of period	¢		\$	14,059	
Cash and cash equivalents end of period	\$	61,133	Þ	14,039	
Non-cash transactions:					
Extinguishment and derecognition of put options		2,202		—	
Conversion of convertible notes into common stock		8,249			
Shares issued in connection of business combination and assumed equity awards		35,846		_	
Accretion of Series A redeemable convertible preferred stock		22		3	
Accretion of Series B redeemable convertible preferred stock		460		12	
Accretion of Series C redeemable convertible preferred stock		96		11	
Beneficial conversion feature		404			

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

#### Savara Inc. and Subsidiaries Notes to Condensed Consolidated Financial Statements (Unaudited)

#### 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 a clinical stage specialty pharmaceutical company focusing on the development and commercialization of product candidates for patients with rare respiratory diseases, including cystic fibrosis (CF), and pulmonary alveolar proteinosis (PAP). Our lead clinical stage product candidate, Molgradex, is an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF), intended for the treatment of PAP. Our other lead clinical stage product candidate, AeroVanc, is an inhaled formulation of vancomycin, intended for the treatment of persistent methicillin-resistant Staphylococcus aureus (MRSA) lung infection in CF patients. The Company and its wholly owned subsidiaries, Aravas Inc. and Sarara ApS, operate in one segment with its principal offices in Austin, Texas.

On April 27, 2017, Savara completed its business combination with Mast Therapeutics, Inc. ("Mast"), a publicly held company, in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated January 6, 2017 (the "Merger"). In connection with and immediately prior to the effective time of the Merger, Mast implemented a reverse stock split at a ratio of one new share for every 70 shares of its common stock outstanding (the "Reverse Stock Split"). Under the terms of the Merger Agreement, each outstanding share of Savara common stock was then converted into Mast common stock at a ratio of approximately .5860 of a Savara share (the "Exchange Ratio"). No fractional shares were issued and instead, shareholders received cash for the value of their fractional shares. Immediately following the effective date of the Merger, Mast's preexisting equity holders owned approximately 23% of the combined company, and Savara's preexisting equity holders owned approximately 77%.

Accordingly, all operations presented in the accompanying financial statements and notes to the financial statements represent the historical activity of Savara, the private company prior to the Merger.

The accompanying financial statements and notes to the consolidated financial statements also give retroactive effect to the common stock Exchange Ratio and Reverse Stock Split of the Merger for all periods presented, including common stock warrants and common stock-based compensation awards.

Following the Merger, Mast was renamed "Savara Inc." and began trading on The Nasdaq Capital Market under the symbol "SVRA." Prior to the Merger, Mast was traded on the New York Stock Exchange under the symbol "MSTX."

The combined company's pipeline includes:

- Molgradex
- AeroVanc
- Aironite, a sodium nitrite solution for intermittent inhalation via nebulization, which is being developed for the treatment of heart failure with preserved ejection fraction (HFpEF).

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 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, 2016.

# 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, 2017, and its results of operations for the six months ended June 30, 2017 and 2016, and cash flows for the six months ended June 30, 2017 and 2016. The results of operations for the three and six months ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other future annual or interim period. The December 31, 2016 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, 2016.

# 2. Summary of Significant Accounting Policies

# Liquidity

As of June 30, 2017, the Company had an accumulated deficit of approximately \$54.9 million. The Company also had negative cash flow from operations of approximately \$10.5 million during the six months ended June 30, 2017. 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.

The Company is currently focused primarily 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, fails to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash and cash equivalents on hand and through a combination of equity offerings, debt financings, government or other third-party funding, and other collaborations and strategic alliances. The Company or its stockholders.

While the Company has cash and cash equivalents of \$61.1 million as of June 30, 2017, we intend to continue to raise additional capital 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 condensed consolidated financial statements of the Company are stated in U.S. dollars and are prepared using U.S. GAAP. These financial statements include the accounts of the Company and its wholly owned subsidiaries. The financial statements of the Company's wholly owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency is reported in Accumulated Other Comprehensive Income. All intercompany transactions and accounts have been eliminated in consolidation.

# Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Management's estimates include those related to the accrual of research and development costs, the valuation of preferred and common shares, certain financial instruments recorded at fair value, stock-based compensation, and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Accordingly, actual results could be materially different from those estimates.

# **Risks and Uncertainties**

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

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of drug candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology and market acceptance of the Company's products. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

# Cash and Cash Equivalents

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

#### **Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents. 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 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. 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 all available information and, in some cases, assumptions with respect to the timing and amount of future revenue and expenses associated with an asset.

#### Goodwill and Acquired In-Process Research and Development (IPR&D)

Goodwill and acquired IPR&D are not amortized but are tested annually for impairment or more frequently if impairment indicators exist. The Company adopted accounting guidance related to annual and interim goodwill and acquired IPR&D impairment tests 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 reporting unit is more likely than not less than the carrying amount, a quantitative impairment test is required. The Company experienced a \$.1 million and \$.4 million increase in the carrying value of goodwill and IPR&D, respectively, related to Savara ApS, from the acquisition date, July 15, 2016, which was due to foreign currency translation. Additional goodwill and IPR&D were recorded with respect to the Merger.

# Tax Refund Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS for the post-acquisition period in 2016 and the six months ended June 30, 2017. 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, 2017, the credits had not yet been received and a receivable of \$1.1 million was recorded on the balance sheet in prepaid expenses and other current assets. The portion of the total Danish tax credit related to the post-acquisition period in 2016 of approximately \$.4 million is expected to be collected in November 2017.

# 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 and contingent consideration related to the acquisition of Serendex for which any change is reflected in general and administrative expense, as well as certain warrants classified as liabilities and embedded put options separated from the convertible promissory notes which were converted to common equity or derecognized during the period ended June 30, 2017 as a result of the Merger (Notes 6, 8, and 9). These remaining financial instruments are carried at fair value on a recurring basis.

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.

# Net Loss per Share

Basic net loss attributable to common stockholders per share is calculated by dividing the net loss by the weighted average number of shares of common stock 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.

# Redeemable Convertible Preferred Stock and Series B and Series C Warrants

The Series A, Series B, and Series C redeemable convertible preferred stock, previously classified in temporary equity as it was redeemable at the written request of the holders of at least two-thirds of the then outstanding shares of preferred stock, at any time after October 31, 2022, was converted to common stock on the effective date of the Merger subject to the Exchange Ratio. Additionally, certain outstanding warrants to purchase the Series B convertible preferred stock ("Series B Warrants") previously classified as liabilities were exercised on the effective date of the Merger with any residual Series B warrants expiring in May 2017. Certain outstanding warrants to purchase the Series C redeemable convertible preferred stock ("Series C Warrants") were reclassified from a liability to common equity as the Series C Warrants have been converted to warrants to purchase common stock subject to the Exchange Ratio following the Merger.

# Stock-Based Compensation

The Company recognizes the cost of stock-based awards granted to employees based on the estimated grant-date fair value of the awards. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The Company recognizes the compensation costs for awards that vest over several years on a straight-line basis over the vesting period (see Note 12). Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise. The Company recognizes the cost of stock-based awards granted to nonemployees at their then-current fair values as services are performed, and such awards are remeasured through the counterparty performance date.

# Manufacturing Commitments and Contingencies

The Company is subject to various manufacturing royalties and payments related to its product candidate, Molgradex. Upon the successful development, registration and attainment of approval by the proper health authorities, such as the FDA, in any territory except Latin America, Central America and Mexico, the Company must pay a royalty of three percent (3%) on annual net sales to the manufacturer of its Active Pharmaceutical Ingredients ("API"). Under this agreement with the API manufacturer, no signing fee or milestones are included in the royalty payments, and there is no minimum royalty. Additionally, Savara has a commitment to acquire a working cell bank and a master cell bank for approximately \$2.0 million from this API manufacturer in the third quarter of 2017.

The Company is also subject to certain contingent milestone payments up to approximately 7.0 million euros based upon various development activities and regulatory approvals payable to the Company's manufacturer of its nebulizer used to administer Molgradex. In addition to these milestones, the Company will owe a royalty to the manufacturer of its nebulizer based on net sales. The royalty rate ranges from three and a half percent (3.5%) to five percent (5%) depending on the device technology used by the Company to administer the product.

# Income Taxes

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

#### **Recent Accounting Pronouncements**

In February 2016, the FASB issued Accounting Standards Update 2016-02, "Leases" ("ASU 2016-02"). The update aims at making leasing activities more transparent and comparable, and requires substantially all leases to be recognized by lessees on their balance sheet as a right-of-use asset and a corresponding lease liability, including leases currently accounted for as operating leases. The update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-02 on its financial statements.

In August 2016, the FASB issued Accounting Standards Update 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments" ("ASU 2016-15"), which intended to add or clarify guidance on the classification of certain cash receipts and payments on the statement of cash flows. The new guidance addresses cash flows related to the following: debt prepayment or extinguishment costs, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies and bank-owned life insurance policies, distributions received from equity method investees, beneficial interest in securitization transactions, and the application of predominance principle to separately identifiable cash flows. ASU 2016-15 is effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the effect of this new guidance on its financial statements.

In January 2017, the FASB issued Accounting Standards Update 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business" ("ASU 2017-01"), which intended to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-01 is effective for the Company for annual periods beginning after December 15, 2017. The Company's early adoption of this standard did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued Accounting Standards Update 2017-09, "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"), which intended to provide clarity when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. ASU 2017-09 is effective for the Company for annual periods beginning on or after December 15, 2017 with early adoption permitted. The Company's early adoption of this standard did not have a material impact on the Company's financial statements.

# 3. Prepaid expenses and other current assets

Prepaid expenses, consisted of (in thousands):

	June 30, 2017	ember 31, 2016
R&D tax credit receivable	\$ 1,103	\$ 357
Prepaid clinical trial costs	650	243
VAT receivable	91	111
Prepaid insurance	368	35
Deposits and other	329	94
Total prepaid expenses and other current assets	\$ 2,541	\$ 840

#### 4. Accrued expenses and other liabilities

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

	June 30, 2017	Dee	cember 31, 2016
Accrued contracted research and development costs	\$ 4,100	\$	1,855
Accrued general and administrative costs	849		458
Accrued compensation	527		117
Other	11		47
Total accrued expenses and other liabilities	\$ 5,487	\$	2,477

#### 5. Acquisitions

#### (a) Mast

On April 27, 2017, the Company completed the Merger with Mast as discussed in Note 1. The Merger was accounted for as a reverse merger under the acquisition method of accounting whereby Savara was considered to have acquired Mast for financial reporting purposes because, immediately upon completion of the Merger, Savara stockholders held a majority of the voting interest of the combined company.

Pursuant to business combination accounting, the Company applied the acquisition method, which requires the assets acquired and liabilities assumed be recorded at fair value with limited exceptions. The Company used the Multi-Period Excess Earnings Model (MPEEM), a form of the income approach to value the in-process research and development intangible asset. Under the valuation method, the present value of future cash flows expected to be generated from the in-process research and development of the acquired product candidate, Aironite, was determined using a reasonable discount rate, and identified projected cash flows from Aironite were risk adjusted to take into consideration the probabilities of moving through the various clinical stages. The excess of the purchase price over the assets acquired and liabilities assumed represents goodwill. The goodwill is primarily attributable to the synergies expected to arise after the acquisition and is not expected to be deductible for tax purposes. Transaction costs associated with the Merger of approximately \$2.1 million are included in general and administrative expense. The total purchase price for Mast was \$35.8 million based on the fair value of the outstanding Mast equity on the date of the Merger which was allocated as follows:

Purchase Consideration	(in t	housands)
Fair value of Mast shares outstanding	\$	33,117
Fair value of Mast equity		2,729
Fair value of total consideration	\$	35,846
Assets acquired and liabilities assumed		
Cash and cash equivalents	\$	3,442
Tangible assets		283
In-process research and development intangible assets		21,692
Liabilities		(2,396)
Debt		(3,407)
Deferred tax liability		(8,677)
Total assets acquired and liabilities assumed		10,937
Goodwill		24,909
	\$	35.846

The final allocation of the purchase price is dependent on the finalization of the valuation of the fair value of assets acquired and liabilities assumed and may differ from the amounts included in these financial statements. The Company expects to complete the final allocation as soon as practical but no later than one year from the acquisition date. Management does not expect adjustments, if any, resulting from changes to the purchase price allocation, to have a material effect on the Company's financial position or results of operations.

#### (b) Serendex

On May 13, 2016, the Company entered into a Business Transfer Agreement with Serendex under which Serendex agreed to sell, transfer and assign to the Company all of its assets and subsidiaries, certain of its contracts, and certain of its employees and liabilities. On July 15, 2016, the Company completed the acquisition of Serendex through its wholly-owned subsidiary, Savara ApS, a limited liability company established under the laws in Denmark. Through this acquisition, the Company gained access to the late-stage asset, Molgradex, for the treatment of PAP, with a Phase 3 clinical study ongoing in the EU and Japan which has since been expanded to the United States. In addition to Molgradex, Savara gained access to an experienced development team familiar with all aspects of the Molgradex program. Pursuant to the Business Transfer Agreement, the Company issued 1,965,400 shares of the Company's common stock to the seller, after giving effect of the Exchange Ratio and agreed to pay up to \$21.5 million of contingent cash consideration upon the attainment of certain contingent development milestones of Molgradex.

#### (c) Pro Forma

The following summary pro forma condensed consolidated financial information reflects the Merger with Mast as if it had occurred on January 1, 2016 for purposes of the statements of operations. This summary pro forma information is not necessarily representative of what the Company's results of operations would have been had the Merger in fact occurred on January 1, 2016, and is not intended to project the Company's results of operations for any future period. Included in the Savara condensed consolidated statement of operations for the six months ended June 30, 2017 is \$0 of revenue and \$.6 million of net loss before income tax generated by Mast since April 27, 2017, the acquisition date.

Pro forma condensed consolidated financial information for the six months ended June 30, 2017 and the year ended December 31, 2016 (unaudited) is as follows:

	Ionths Ended ne 30, 2017	Year Ended December 31, 2016		
Net revenues	\$ 94	\$	528	
Net loss	\$ (14,245)	\$	(42,560)	

Pro forma combined net loss includes adjustments to remove transaction costs of \$8.4 million and \$.6 million for the six months ended June 30, 2017 and the year ended December 31, 2016, respectively, because they will not have a continuing impact on operations, and a reduction in historical interest expense of \$1.4 million for the year ended December 31, 2016 due to the new debt to finance the merger and extinguishment of Mast pre-merger debt.

#### 6. Convertible Promissory Notes

#### A. 2016 Convertible Promissory Note

During 2016, the Company borrowed approximately \$4.4 million from several investors under convertible subordinate promissory notes (the "2016 Notes"). Under the amended terms, the 2016 Notes converted into equity in connection with the Merger. See further discussion under Accounting for the 2016 Notes below.

The 2016 Notes accrued interest at 8.0% per annum computed on the basis of the actual number of days elapsed and a 365-day year. All unpaid principal, together with any then accrued but unpaid interest was due and payable on the earliest of (i) June 30, 2018 (the "Maturity Date"), (ii) the closing of a change of control as defined, or (iii) the occurrence of an event of default, as defined (such earliest date is hereinafter referred to as Maturity). The 2016 Notes were prepayable only with the written consent of the holders of a majority of the principal amount of the then-outstanding 2016 Notes. The following paragraphs describe the original and amended conversion features of the 2016 Notes.

#### Automatic Conversion

The principal and any accrued interest automatically convert into shares of Qualified Private Placement Financing Securities at the 2016 Note Conversion Price, upon the closing of a Qualified Private Placement Financing ("Private Placement Automatic Conversion"). In the event of a Private Placement Automatic Conversion, the 2016 Notes are converted into a number of Qualified Private Placement Financing Securities determined by dividing (i) the aggregate outstanding principal amount and accrued but unpaid interest by (ii) the 2016 Note Conversion Price. A Qualified Private Placement Financing is defined as the next Private Placement transaction (or series of related transactions) after the date of the 2016 Notes and before Maturity in which the Company issues and sells shares of its preferred stock in exchange for aggregate gross proceeds of at least \$5 million (excluding amounts received upon conversion of indebtedness). Private Placement means any equity financing transaction (or series of related transactions) pursuant to a private placement exempt from the registration requirements of the Securities Act, other than pursuant to the exemption provided by Regulation A under the Securities Act (i.e., not a Regulation A Offering or an Initial Public Offering).

The Note Conversion Price is the lesser of (A) (i) the price per share of the Next Round Securities, Qualified Financing Shares or Regulation A Offering Shares, as the case may be, times (ii) 0.8 (i.e. a 20% discount), or (B) the quotient obtained by dividing \$125 million (the "Valuation Cap") by the Company's fully diluted capitalization immediately prior to the initial closing of the Qualified Financing, Non-Qualified Financing, Qualified Regulation A Offering or Non-Qualified Regulation A Offering in which the Notes are converted. Non-Qualified Private Placement Financing means any transaction (or series of related transactions) after the date of the 2016 Notes and before Maturity in which the Company issues and sells shares of its capital stock in any Private Placement transaction that is not deemed to be a Qualified Private Placement Financing. Next Round Securities means the equity shares sold in a Non-Qualified Private Placement Financing.

The entire outstanding principal amount of the 2016 Notes and any accrued but unpaid interest will be converted automatically into shares of Regulation A securities at the Note Conversion Price upon the closing of a Qualified Regulation A Offering. In the event of an automatic conversion under a Qualified Regulation A Offering, the 2016 Notes will be converted into that number of Regulation A securities determined by dividing (i) the aggregate outstanding principal amount of the 2016 Notes and any accrued but unpaid interest by (ii) the Note Conversion Price. A Qualified Regulation A Offering means a Regulation A Offering with gross proceeds to the Company of at least \$5 million in one or more closings during a twelve-month period, excluding amounts received on conversion of the 2016 Notes.

# Voluntary Conversion

In the event that the Company consummates a Non-Qualified Private Placement Financing, at the option of each holder or holders of a majority of the outstanding aggregate principal amount, all or part of the outstanding principal and any accrued interest may be converted into Next Round Securities. A Non-Qualified Private Placement Financing is any transaction (or series of related transactions) after the date of the 2016 Notes and before Maturity in which the Company issues and sells shares of its capital stock in any Private Placement transaction that is not deemed to be a Qualified Private Placement Financing at the applicable 2016 Note Conversion Price as defined above.

In the event that the Company consummates a Non-Qualified Regulation A Offering (i) at the option of the holder, but subject to the consent of the board of directors, all or part of the outstanding principal amount of the 2016 Notes and any accrued but unpaid interest may be converted into Regulation A Securities, and (ii) at the option of the holders of a majority of the outstanding principal amount of the 2016 Notes, all or part of the outstanding principal amount of the 2016 Notes and any accrued but unpaid interest will be converted into shares of Regulation A Securities. In the event of such conversion, the 2016 Notes and any accrued but unpaid interest of Regulation A Securities determined by dividing (x) the aggregate outstanding principal amount of the 2016 Notes and any accrued but unpaid interest by (y) the Note Conversion Price. A Non-Qualified Regulation A Offering means the closing of a Regulation A Offering with gross proceeds to the Company of less than \$5 million excluding amounts received on conversion of the 2016 Notes.

# **Change in Control Conversion**

In the event of a Change of Control after the date of the 2016 Notes but prior to Maturity, at the option of each holder or holders of a majority of the outstanding aggregate principal amount, all or part of the outstanding principal amount and any accrued interest, (i) may be converted into the number of shares of Series C Redeemable Convertible Preferred Stock ("Series C Preferred Stock") determined by dividing (x) the aggregate outstanding principal amount and any accrued interest by (y) the quotient obtained by dividing (1) the Valuation Cap by (2) the Company's capital stock outstanding immediately prior to such Change of Control.

A Change of Control means any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, and shall be deemed to be occasioned by, or to include, (i) a merger or consolidation of the Company into or with another entity after which the stockholders of the Company immediately prior to such transaction do not own, immediately following the consummation of the transaction by virtue of their shares in the Company or securities received in exchange for such shares in connection with the transaction, a majority of the voting power of the surviving entity in proportions substantially identical to those that existed immediately prior to such transaction and with substantially the same rights, preferences, privileges and restrictions as the shares they held immediately prior to the transaction, (ii) the sale, transfer or other disposition (but not including a transfer or disposition by pledge or mortgage to a bona fide lender) of all or substantially all of the assets of the Company (other than to a wholly-owned subsidiary), or (iii) the sale or transfer by the Company or its stockholders of more than 50% of the voting power of the Company in a transaction or series of related transactions other than in a transaction or series of transactions effected by the Company primarily for financing purposes.

# **IPO** Conversion

Upon an initial public offering of the Company's common stock, the entire outstanding principal amount plus any accrued interest under the 2016 Notes automatically converts into shares of Company common stock at the IPO Conversion Price. The IPO Conversion Price means the lesser of the (x) quotient obtained by dividing (1) the Valuation Cap by (2) the Company's fully diluted capitalization immediately prior to the consummation of the initial public offering or (y) quotient obtained by dividing (1) the pre-money valuation of the Company approved by the board of directors in connection with the Initial Public Offering, by (2) the Company's fully diluted capitalization immediately prior to the consummation of the Initial Public Offering.

#### Maturity Date Conversion

The entire outstanding principal amount and any accrued interest under the 2016 Notes automatically converts into shares of Series C Preferred Stock at the Series C Price upon the close of business of the Maturity Date. In the event of such automatic conversion, the 2016 Notes convert into that number of Series C Preferred Stock determined by dividing (i) the aggregate outstanding principal amount of the 2016 Notes plus any accrued interest by (ii) the Series C Price. The Series C Price is \$5.2605 as adjusted for stock dividends, stock splits, recapitalizations and other similar events.



# **Public Listing Conversion**

The 2016 Notes and the Series C Warrants, issued with the note subscriptions, were amended to include a conversion clause in the case of the Merger. The amendment provides the warrant holder the right to voluntarily exercise the Series C Warrants; however, the 2016 Notes would be automatically converted in the case of the Merger. Upon the consummation of the Merger or a similar transaction that results in the listing of capital stock of the Company or shares issued in exchange for the capital stock of the Company, the entire principal amount plus any accrued interest under the 2016 Notes automatically converts into shares of Common Stock at \$4.22 per share, which was 80% of the estimated Merger per share value, for notes issued on or prior to August 15, 2016 and 80% of the amount equal to the average trading price of Mast's common stock for the twenty day period ending two days prior to the closing of the Merger, as adjusted by the Exchange Ratio described in the Merger Agreement.

#### Accounting for the 2016 Notes

Management determined that the automatic conversion upon a Qualified Private Placement Financing, a Qualified Regulation A Offering, a Non-Qualified Private Placement Financing, or a Non-Qualified Regulation A Offering as defined above represented, in substance, a put option (redemption feature) designed to provide the investor with a fixed monetary amount, settleable in shares. Management determined that this put option should be separated and accounted for as a derivative primarily because the put option met the net settlement criterion and the settlement provisions were not consistent with a fixed-for-fixed equity instrument. With respect to the Series C Warrants issued to investors who purchased 2016 Notes prior to August 15, 2016, management determined that the Series C Warrants should also be separated and accounted for as a derivative and classified as a liability.

Both the put option, with a fair value of approximately \$1.0 million and warrant liability, with a fair value of approximately \$.3 million at inception, were initially recorded as derivative liabilities on the accompanying balance sheet and a corresponding discount to the 2016 Notes. The Company accreted the discount to interest expense on the statement of operations and comprehensive loss over the term of the 2016 Notes using the effective interest rate method. The Company recorded interest expense of \$.2 million during the six months ended June 30, 2017 related to the accretion of the total discount through the date of conversion.

Upon the Merger, the date of the automatic conversion under the Public Listing Conversion provisions, the 2016 Notes were surrendered in exchange for shares of the Company's common stock after giving effect to the Exchange Ratio. The debt host contract and separated derivative liability were both subject to extinguishment accounting, and a loss in the amount of \$.9 million was recorded in the Statement of Operations and Comprehensive Loss. The loss was calculated as the difference between the net book value of the 2016 Notes plus the fair value of the put option immediately prior to the Automatic Conversion, and the fair value of the common stock into which the 2016 Notes were converted.

#### B. 2017 Convertible Promissory Note

During 2017, the Company borrowed approximately \$3.6 million from several investors under convertible subordinate promissory notes (the "2017 Notes") which converted into equity in connection with the Merger. The 2017 Notes accrued interest at 8.0% per annum computed on the basis of the actual number of days elapsed and a 365-day year. All unpaid principal, together with any then accrued but unpaid interest was due and payable on the earliest of (i) June 30, 2018, (ii) the closing of a change of control as defined, or (iii) the occurrence of an event of default, as defined (such earliest date is hereinafter referred to as Maturity). The 2017 Notes were prepayable only with the written consent of the holders of a majority of the principal amount of the then-outstanding 2017 Notes. The terms and conditions of the 2017 Notes were substantially consistent with the 2016 Notes as described above, other than the Public Listing Conversion feature which is described below.

#### **Public Listing Conversion**

Immediately prior to, but in any event conditioned upon the consummation of a merger or similar transaction that results in the listing of capital stock the Company or shares issued in exchange for the capital stock of the Company on any tier of any U.S. national securities exchange, including the transactions described in the Merger Agreement, the entire outstanding principal amount of the 2017 Notes, any accrued but unpaid interest and any other amounts payable under the 2017 Notes shall be converted automatically into shares of the Company's common stock, as adjusted for the Exchange Ratio, at the Reverse Merger Conversion Price. Upon such occurrence, the 2017 Notes shall be converted into that number of shares of common stock determined by dividing (i) the aggregate outstanding principal amount of the 2017 Notes, any accrued but unpaid interest, and any other amounts payable under the 2017 Notes by (ii) the Reverse Merger Conversion Price. The Reverse Merger Conversion Price means eighty percent of the amount equal to the average trading price of Mast's common stock for the twenty-day period prior to the Merger date.

# Accounting for the 2017 Notes

Management determined that the automatic conversion upon a Qualified Private Placement Financing, a Qualified Regulation A Offering, a Non-Qualified Private Placement Financing, or a Non-Qualified Regulation A Offering as defined above represented, in substance, a put option (redemption feature) designed to provide the investor with a fixed monetary amount, settleable in shares. Management determined that this put option should be separated and accounted for as a derivative primarily because the put option met the net settlement criterion and the settlement provisions were not consistent with a fixed-for-fixed equity instrument.

The put option, with a fair value of approximately \$.8 million at inception, was initially recorded as a derivative liability on the accompanying balance sheet and a corresponding discount to the 2017 Notes. The Company accreted the discount to interest expense on the statement of operations and comprehensive loss over the term of the 2017 Notes using the effective interest rate method. The Company recorded interest expense of approximately five thousand dollars during the six months ended June 30, 2017 related to the accretion of the discount through the date of conversion.

Upon the Merger, the date of the automatic conversion under the Public Listing Conversion provisions, the 2017 Notes were surrendered in exchange for the Company's common stock after giving effect to the Exchange Ratio. The debt host contract and separated derivative liability were both subject to extinguishment accounting, and a loss in the amount of approximately \$.9 million was recorded in the Statement of Operations and Comprehensive Loss. The loss was calculated as the difference between the net book value of the 2017 Notes plus the fair value of the put option immediately prior to the Automatic Conversion, and the fair value of the common stock into which the 2017 Notes were converted.

# 7. Debt Facility

On April 28, 2017, the Company entered into a loan and security agreement with Silicon Valley Bank (the "Loan Agreement"). The Loan Agreement provides for a \$15 million debt facility, of which the first tranche, or \$7.5 million, was immediately available to the Company upon completion of the Merger with a minimum market cap of \$100 million. The Company executed the first tranche in early May 2017. The primary use of the capital was for the repayment of \$3.7 million of principal debt and fees of Mast assumed in the Merger. The residual capital will be utilized to fund ongoing development programs of the Company and for general corporate purposes. Under the terms of the Loan Agreement, the Company may, but is not obligated to draw a second tranche of \$7.5 million available through June 30, 2017, subject to the achievement of certain corporate milestones specifically a minimum new capital raise with combined proceeds of at least \$40 million through a secondary offering, private investment in public entity (PIPE), ATM, partnerships or grant to be received within twelve months of signing the agreement.

On June 15, 2017, following an underwritten public offering of 9,034,210 shares of the Company's common stock and the sale of 23,550 shares of the Company's common stock under the At The Market Sales Agreement (Note 9), the Company executed the second tranche of the Loan Agreement for \$7.5 million as the financing conditions under the Loan Agreement had been met.

The Loan Agreement contains customary affirmative and negative covenants, including among others, covenants limiting our ability and our subsidiaries 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.

The Loan Agreement bears interest at the prime rate reported in The Wall Street Journal, plus a spread of 4.25%. Interest only payments are due through September 2018 followed by monthly payments of principal plus interest over the following thirty (30) months. Since the second tranche was fully extended, the interest only period was extended for an additional six (6) months, through March 2019 followed by monthly payments of principal plus interest over the following twenty-four (24) months through the maturity date of March 1, 2021 under the Loan Agreement provisions. We were obligated to pay customary closing fees and are obligated to pay a final payment of 6.0% of the aggregate principal amount of term loans advanced under the facility. The end of term charge of \$.9 million 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.

In connection with the Loan Agreement, we paid \$.1 million in legal costs directly attributable to issuing 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.

Upon funding the first tranche of the Loan Agreement, the Company was obligated to issue warrants to purchase shares of the Company's common stock equal to 3.0% of the funded amount divided by the exercise price to be set based on the average price per share over the preceding 10 trading days prior to closing. The number of shares callable under the warrant agreement for the first tranche and exercise price were 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 was obligated to issue warrants to purchase shares of the Company's common stock equal to 3.0% of the funded amount divided by an exercise price to be set based on the average price per share over the preceding 10 trading days prior to funding or the price per share prior to the day of funding. As such, the Company issued a second warrant for 41,736 shares at an exercise price of \$5.39 with a ten year life, expiring June 15, 2027 ("June 2017 Warrants").

The April 2017 Warrants and June 2017 Warrants issued were valued using the Black-Scholes option pricing model with the following assumptions: volatility of 71.42% and 71.57%, respectively, expected term of ten years, risk-free interest rate of 2.33% and 2.16%, respectively, and a zero dividend yield. The collective warrant fair value of \$.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.

# Summary of Carrying Value

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

		As of June 30, 2017				
	Shor	t-term	Lo	ong-term		
Principal payments to lender and end of term charge	\$	_	\$	15,025		
Debt Issuance costs		—		(99)		
Debt discount related to warrants		_		(347)		
Carrying Value	\$	_	\$	14,579		

#### 8. Fair Value Measurements

The Company measures and reports certain financial instruments at fair value on a recurring basis and evaluates its financial instruments subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them in each reporting period. The Company determined that the warrant liability for the Series B and Series C Warrants, the put options on the 2016 Notes and 2017 Notes, described further in Note 6, and the contingent consideration, described further below, were Level 3 financial instruments. The fair value of these instruments as of June 30, 2017 and December 31, 2016 was as follows (in thousands):

	Pri A Mar Ide A	Quoted Prices in Active Markets for Identical Assets (Level 1)		Prices in Active Markets for Identical		ignificant Other bservable Inputs (Level 2)	Significant nobservable Inputs (Level 3)
As of June 30, 2017:							
Contingent consideration	\$	_	\$	—	\$ 11,685		
As of December 31, 2016:							
Put option	\$		\$		\$ 979		
Warrant liability	\$		\$	—	\$ 303		
Contingent consideration	\$		\$		\$ 9,708		

The estimated fair value of the put option on the 2016 Notes was determined using a multi-scenario probability weighted average method analysis in which the future probability of the equity financing event or Merger was weighted for its respective probability. The Company used the following assumptions to value the put option on the 2016 Notes and 2017 Notes as of June 30, 2017 and December 31, 2016. Upon the Merger date, April 27, 2017, the 2016 Notes and 2017 Notes were automatically converted into shares of common stock of the Company.

Assumption	June 30, 2017	December 31, 2016
Discount rate	—	0.43%
Probability of event	—	85.0%

Changes in the unobservable inputs noted above would impact the fair value of the put options and have a corresponding impact on the Company's net loss. The probability of the automatic conversion feature was determined by management based on its consideration of the expected timeline for the next round of Financing, Merger, and historical experience. Increases (decreases) in discount rate would decrease (increase) the value of the put options, and an increase (decrease) in the probability of the equity financing event or Merger event occurring would increase (decrease) the value of the put options.

The estimated fair value of the warrant liability (Series B Warrants and Series C Warrants) was determined using a Noreen Wolfson option pricing model. The assumptions used in valuing these warrants are presented in the table below. The warrant liability was reclassified as common equity upon the Merger date.

Assumption	June 30, 2017	December 31, 2016
Expected term	_	0.42 - 4.50
Expected dividend yield	—	_
Expected volatility	_	44.65% - 60.66%
Risk-free interest rate		0.58% - 1.82%

Changes in the unobservable inputs noted above would impact the fair value of the liabilities and have a corresponding impact on the Company's net loss. Increases (decreases) in the expected term and expected volatility would increase (decrease) net loss and the value of the warrant liability and an increase(decrease) in the risk-free interest rate would decrease (increase) net loss and the value of the warrant liability. Pursuant to the acquisition of certain assets, liabilities, and subsidiaries of Serendex (see Note 1), Savara agreed to pay the seller, in addition to a stipulated amount of shares of Savara's common stock, (i) \$5 million upon receipt of marketing approval of Molgradex (the Product) by the European Medicines Agency, (ii) \$15 million upon receipt of marketing approval of the Product by the FDA, and (iii) \$1.5 million upon receipt of marketing approval of the Product by the FDA, and (iii) \$1.5 million upon receipt of marketing approval of the Product by the FDA, and (iii) \$1.5 million upon receipt of marketing approval of the Product by the FDA, and (iii) \$1.5 million upon receipt of marketing approval of the Product by the FDA, and (iii) \$1.5 million upon receipt of marketing approval of the Product by the FDA, and (iii) \$1.5 million upon receipt of marketing 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 are similar to a business expense of the Company and would be senior to any Company debt obligations. The resulting weighted average present value factor is then applied to discount the probability adjusted Contingent Milestone Payments for each region to derive the fair value of the Contingent Milestone Payments.

The following tables sets forth a summary of the changes in the fair value of the Company's Level 3 financial instrument (in thousands) for the six months ended June 30, 2017 and year ended December 31, 2016:

	Warrant Liability	Put Option on 2016 Note and 2017 Note		Contingent Consideration
As of December 31, 2015	\$ 274	\$ -	- 5	s —
Put option at issuance of 2016 Notes	—	97	7	—
Contingent consideration	—	-	_	9,524
Issuance of Series C Warrants	259	-	_	
Change in fair value	(230)		2	184
Balance at December 31, 2016	\$ 303	\$ 97	9 5	\$ 9,708
Change in fair value	67	16	<u>69</u>	1,977
Put option at issuance of 2017 Notes	—	82	28	—
Reclassification of warrant liability to common equity	(370)	-	_	
Conversion of 2016 and 2017 Notes		(1,97	76)	
Balance at June 30, 2017	\$ 	\$ -	_ \$	\$ 11,685

The Company records changes in fair value of the contingent consideration in general and administrative expense.

As of June 30, 2017, the Company determined that there would be a change to the Molgradex program due to the FDA's guidance on the clinical program requirements for a New Drug Application submission in the U.S. related to the Molgradex product, which was issued in May 2017. Based on the FDA's guidance, the Company will modify certain criteria of its Molgradex development program which the Company believes will accelerate the development timeline in the U.S. The Company accordingly accounted for this change in its valuation of the contingent consideration as of June 30, 2017. The Company also accounted for the time value of money related to the Contingent Milestone Payments from December 31, 2016 to June 30, 2017 in its assessment. Accordingly, the related contingent consideration liability was remeasured to \$11.7 million as of June 30, 2017.

The Company did not transfer any assets measured at fair value on a recurring basis to or from Level 1 and Level 2 during the six months ended June 30, 2017 and 2016.

#### 9. Shareholders' Equity

#### **Public Offering**

On June 7, 2017, the Company completed an underwritten public offering consisting of 9,034,210 shares of its common which included 613,157 shares upon the partial exercise of the underwriters' option to purchase additional shares of Savara common stock at the public offering price, less the underwriting discounts and commissions. The underwriters' option to purchase the remaining balance of additional shares expired as of June 30, 2017. The net proceeds from the offering, after deducting the underwriting discounts and commissions and offering expenses, were approximately \$39.5 million. The Company intends to use the net proceeds from this offering 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 its product candidates, and general and administrative expenses. The public offering was executed under an existing shelf registration statement as previously filed with the Securities and Exchange Commission on August 12, 2015 and declared effective on August 19, 2015.

#### Common Stock Sales Agreement/At The Market (ATM)

On April 28, 2017, the Company entered into a Common Stock Sales Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), 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 \$18.0 million. The Shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3. 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.

On April 27, 2017, the Company delivered written notice to Cowen and Company, LLC that it was terminating its prior Sales Agreement, dated August 21, 2015.

During the six months ended June 30, 2017, the Company sold 23,550 shares of common stock under the sales agreement, for net proceeds, of approximately \$.1 million.

#### **Common Stock**

The Company's amended and restated certificate of incorporation, effective upon the completion of the Merger, authorizes the Company to issue 501 million shares of common and preferred stock, consisting of 500 million shares of common stock with \$0.001 par value and 1 million shares of preferred stock with \$0.001 par value. The following is a summary of the Company's common stock at June 30, 2017 and December 31, 2016, which reflects Savara as a private company prior to the Merger, as restated for the Exchange Ratio upon closing of the Merger.

	June 30, 2017	December 31, 2016
Common stock authorized	500,000,000	27,000,000
Common stock outstanding	24,203,464	3,162,573

The Company's shares of common stock reserved for issuance as of June 30, 2017 and December 31, 2016 were as follows:

	June 30, 2017	December 31, 2016
Series A Preferred Stock		1,799,906
Series B Preferred Stock	—	5,675,387
Series C Preferred Stock	—	4,452,582
Series B Warrants	—	289,966
Series C Warrants	—	125,885
Warrants from Mast acquired in Merger	1,152,231	_
Warrants Converted Pursuant to Merger	74,992	_
April 2017 SVB Warrants	24,725	_
June 2017 SVB Warrants	41,736	_
Stock options outstanding	1,746,500	1,814,645
Total shares reserved	3,040,184	14,158,371

# **Redeemable Convertible Preferred Stock**

Prior to the Merger and the effect of the Exchange Ratio, the Company had 11,927,875 issued and outstanding shares of preferred stock, of which 1,799,906 shares were designated as Series A redeemable convertible preferred stock ("Series A"), 5,675,387 shares were designated as Series B redeemable convertible preferred stock ("Series B"), and 4,452,582 shares were designated as Series C convertible preferred stock ("Series C").

In the Merger, the previously outstanding shares of Series A and Series B preferred stock were converted on a one-to-one basis into shares of common stock and then subject to the Exchange Ratio. Due to the conversion of the 2016 Notes and 2017 Notes upon the Merger, the holders of Series C preferred stock received broad-based weighted average anti-dilution protection such that the previously outstanding shares of Series C preferred stock were converted on a 1:1.01706 basis (the "Anti-Dilution Conversion Ratio") into shares of common stock and then adjusted for the Exchange Ratio. Following the merger, there were no shares of preferred stock outstanding.

# Warrants

Immediately prior to the Merger, Series B preferred stock warrants were exercised (either on a net exercise basis or for cash) and exchanged for 111,799 shares of the Company's common stock after giving effect to the Exchange Ratio. Proceeds from the cash exercises were \$.4 million.

Pursuant to the Merger, the warrants for Series C preferred stock ("Series C Warrants") were converted to warrants to purchase 74,992 shares of the Company's common stock after giving effect to both the Anti-Dilution Conversion Ratio and Exchange Ratio.

The following table summarizes the outstanding warrants for the Company's common stock as of June 30, 2017:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
401,391	\$ 45.50	June 2018
314,446	\$ 52.50	November 2019
32,467	\$ 7.00	August 2020
403,927	\$ 29.40	February 2021
74,992	\$ 8.98	June 2021
24,725	\$ 9.10	April 2027
41,736	\$ 5.39	June 2027
1,293,684		

#### **Beneficial Conversion Feature**

Due to the conversion of the 2016 Notes and 2017 Notes upon the Merger resulting in an Anti-Dilution Conversion Ratio to the holders of Series C preferred stock and Series C Warrants, a Contingent Beneficial Conversion Feature ("BCF") was triggered resulting in an intrinsic BCF value attributable to the securities of approximately \$.4 million , collectively. Since the conversion of the Series C preferred stock and Series C Warrants occurred contemporaneously on the BCF commitment date, the Company measured the value on that date and recorded the BCF as a "deemed dividend."

#### Financial Advisor Fees

The Company executed an agreement with Canaccord Genuity in February 2016 as modified in March 2017 (collectively the "Advisory Agreement") where the Company was obligated to pay Canaccord a success fee upon the closing of the Merger. As of June 30, 2017, following the Merger and public offering on June 7, 2017, the Company paid Canaccord Genuity \$.5 million related to the success fee for the Merger and recorded a liability of \$.5 million for the remaining fee due under the Advisory Agreement following the public offering and which was paid in July 2017.

#### 10. Commitments

# **Operating Leases**

On March 23, 2017, we entered into a sub-sublease agreement for approximately 13,707 square feet of rentable office space located in San Diego, California. The subleased space served as Mast's corporate headquarters. However, as a result of the Merger, the Company no longer had an ongoing need for these facilities. 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. Monthly base rent under the sub-sublease is approximately forty-four thousand dollars, subject to increases of 3.0% annually on the anniversary of the commencement date of the sub-sublease term. However, monthly base rent for calendar month two of the sub-sublease term was abated.

#### Settlement with Clinical Vendor

On June 29, 2017, the Company executed a Memorandum of Understanding ("MOU") with TFS Trial Form Support International AB ("TFS") and DOT World Co., Ltd. ("DOT") in order to resolve the issue of outstanding payment for services owed to DOT by Serendex in connection with the Molgradex clinical trial conducted prior to our acquisition of Serendex in July 2016. As part of this MOU, the Company agreed to pay TFS approximately 53 million Japanese Yen (approximately \$.5 million) based on an installment payment schedule through December 31, 2017, if Serendex failed to pay the parties in full by June 30, 2017. As of June 30, 2017, Serendex failed to pay TFS in full. Therefore, the Company has accrued the settlement amount in full at June 30, 2017 and is pursuing collection from Serendex.

#### **Risk Management**

The Company maintains various forms of insurance that the Company's management believes are adequate to reduce the exposure to these risks to an acceptable level.

#### **Employment Agreements**

Certain executive officers are entitled to payments if they are terminated without cause or as a result of a change in control. Upon termination without cause, and not as a result of death or disability, each of such officers is entitled to receive a payment of base salary for three to twelve months following termination of employment and such officer will be entitled to continue to receive coverage under medical and dental benefit plans for three to twelve months or until such officer is covered under a separate plan from another employer. Upon a termination other than for cause or for good reason within twelve months following a change in control, each of such officers will be entitled to the same benefits as upon termination without cause and will also be entitled to certain acceleration of such officer's outstanding unvested options at the time of such termination.

#### **11. Related Party Transactions**

Pursuant to the public offering on June 7, 2017 (Note 9), Zambon SpA purchased 4,693,540 shares of the Company's common stock and holds approximately 19.4% of the Company's outstanding shares and voting interests of the Company as of June 30, 2017.



#### 12. Stock-Based Compensation

# A. 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 1) the option grant program providing for both incentive and non-qualified stock options, as defined by the Internal Revenue Code, and 2) 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 unvested shares issued in conjunction with the stock issuance program at the fair market value per share as of the date of termination.

Prior to the closing of the Merger, the Company had 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, are 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. As of June 30, 2017, 562,596 shares of restricted stock had been issued excluding forfeited shares of restricted stock and after giving effect to the Exchange Ratio.

#### **Restricted Stock**

The Company values stock-based compensation related to grants of its restricted stock, which have been issued up to the Merger date, based on the fair value of the Company's common stock as of the grant date and recognizes the expense over the requisite service period, usually four years, adjusted for estimated forfeitures. To determine the value of its common stock, the Company utilized the Option Pricing Method. The valuation methodology includes estimates and assumptions that require the Company's judgment. Inputs used to determine the estimated fair value of the Company's common stock include the equity value of the Company, expected timing to a liquidity event, a risk-free interest rate and the expected volatility. Generally, increases or decreases in these unobservable inputs would result in a directionally similar impact on the fair value measurement of the Company's common stock.

During the six months ended June 30, 2017 and 2016, the Company did not issue any shares of restricted stock to employees for compensation.

#### **Stock Options**

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, which is consistent with the Company's history of not paying dividends. The valuation of stock options is also impacted by the valuation of common stock. Refer to the section above for further information on the valuation methodology utilized by the Company to determine the value of its common stock.

#### Changes in 2008 Plan

Subsequent to the Merger, the Company will no longer issue any stock based awards under the 2008 Plan.

#### B. 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 2015. The 2015 Plan provides for the grant of incentive and non-statutory stock options, as well as share appreciation rights, restricted shares, restricted share units ("RSUs"), performance units, shares and other share-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, 2017, the number of shares of our common stock available for grant under the 2015 Plan was 523,321 shares.



# C. Stock-Based Award Activity

The following table provides a summary of stock-based awards for the 2008 Plan and 2015 Plan (the "Plans") for the six months ended June 30, 2016, after giving effect of the Reverse Stock Split and Exchange Ratio:

	Six mont	ths ended June 30, 201	7	Six r	nonths ended June 30	, 2016
	Stock Options	RSUs	Total	Stock Options	RSUs	Total
Outstanding as of December 31	2,129,856	_	2,129,856	1,079,674		1,079,674
Granted	7,500	72,588	80,088	137,838	—	137,838
Exercised	(4,822)	(72,361)	(77,183)	(823)	—	(823)
Forfeited	(386,034)	(227)	(386,261)	(642)	—	(642)
Outstanding as of June 30	1,746,500		1,746,500	1,216,047		1,216,047

# **D.** Stock-Based Compensation

Stock-based compensation expense is included in the following line items in the accompanying statements of operations and comprehensive loss for the three months ended June 30, 2017 and 2016 and six months ended June 30, 2017 and 2016 (in thousands):

	Three Months EndedJune 30,June 30,20172016			lune 30,	J	Six Mont June 30, 2017	nded June 30, 2016
Research and development	\$	38	\$	22	\$	74	\$ 45
General and administrative		117		29		162	67
Total stock-based compensation	\$	155	\$	51	\$	236	\$ 112

In May 2017, the Company accelerated the vesting of 67,755 stock options and 18,246 shares of restricted stock, after giving effect to the Exchange Ratio. The acceleration was a preexisting condition of the incentive stock awards at the issuance date and did not trigger a modification of the respective incentive stock awards. The Company recognized additional expense of \$0.1 million during the six months ended June 30, 2017 as a result of the acceleration.

# 13. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding. Diluted net loss per share is computed similarly to basic net loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. Diluted net loss per share is the same as basic net loss per common share, since the effects of potentially dilutive securities are antidilutive.

As of June 30, 2017 and 2016, potentially dilutive securities include:

	Six Months Ended				
	June 30, 2017	June 30, 2016			
Awards under equity incentive plan	1,746,500	1,216,047			
Unvested restricted shares	40,604	144,612			
Series A Contingent Redeemable Preferred Stock		1,054,744			
Series B Contingent Redeemable Preferred Stock	_	3,325,776			
Series C Contingent Redeemable Preferred Stock	_	2,653,726			
Warrants to purchase Series B Contingent					
Redeemable Preferred Stock	—	169,816			
Warrants to purchase common stock	1,293,684				
Total	3,080,788	8,564,721			

The following table reconciles basic earnings per share of common stock to diluted earnings per share of common stock for the three months ended June 30, 2017 and 2016 and six months ended June 30, 2017 and 2016.

	Three Months Ended				Six Months Ended			
		June 30, 2017		June 30, 2016		June 30, 2017		June 30, 2016
Net loss	\$	(11,504)	\$	(2,051)	\$	(16,477)	\$	(3,728)
Accretion of convertible redeemable preferred stock		(554)		(2)		(578)		(26)
Deemed dividend on beneficial conversion feature		(404)				(404)		
Net loss attributable to common stockholders		(12,462)		(2,053)	_	(17,459)		(3,754)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted		(12,462)		(2,053)		(17,459)		(3,754)
Weighted average common shares outstanding, basic and diluted		13,807,861		1,043,984		8,465,053		1,034,553
Basic and diluted EPS	\$	(0.90)	\$	(1.97)	\$	(2.06)	\$	(3.63)

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

The following discussion contains forward-looking statements that involve risks and uncertainties, such as Savara's plans, objectives, expectations, intentions and beliefs. 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 34 through 55.

#### Overview

Savara is a clinical stage specialty pharmaceutical company focused on the development and commercialization of product candidates for patients with rare respiratory diseases, including cystic fibrosis (CF), and pulmonary alveolar proteinosis (PAP). Savara's first lead clinical stage product candidate, Molgradex, is an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF), intended for the treatment of PAP. Savara's second lead clinical stage product candidate, AeroVanc, is an inhaled formulation of vancomycin, intended for the treatment of persistent methicillin-resistant *Staphylococcuaureus* (MRSA) lung infection in CF patients. Savara operates in one segment and has its principal offices in Austin, Texas. Since inception, Savara has devoted substantially all of its efforts and resources to identifying and developing its product revenue from inception to date. Savara has not yet commenced commercial operations. From inception of Savara, as a private company prior to the Merger, to June 30, 2017, Savara has raised net cash proceeds of approximately \$101.4 million, from a public offering and private placements of convertible preferred stock, note financings and debt financings.

Savara has never been profitable and has incurred operating losses in each year since inception. Savara's net losses were \$16.5 million for the six months ended June 30, 2017 and \$10.9 million for the year ended December 31, 2016. As of June 30, 2017, Savara had an accumulated deficit of \$54.9 million. Substantially all of Savara's operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations.

Savara has chosen to operate by outsourcing its manufacturing and most of its clinical operations. Savara expects to incur significant additional expenses and increasing operating losses for at least the next several years as it initiates and continues the clinical development of, and seeks regulatory approval for, its product candidates and adds personnel necessary to operate as a public company, following the Merger, with an advanced clinical candidate pipeline of products. In addition, Savara operating as a publicly traded company, following the Merger, will involve the hiring of additional financial and other personnel, upgrading financial information systems and incurring costs associated with operating as a public company. Savara expects that its 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, 2017, Savara had cash of \$61.1 million. Savara will continue to require substantial additional capital to continue its clinical development and potential commercialization activities. Accordingly, Savara will need to raise substantial additional capital to continue to fund its operations. The amount and timing of its future funding requirements will depend on many factors, including the pace and results of its clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on its financial condition and its ability to develop its product candidates.

#### **Recent Events**

On April 27, 2017, Savara completed its business combination with Mast in accordance with the terms of the Merger Agreement, dated January 6, 2017. In connection with and immediately prior to the effective time of the Merger, Mast implemented a reverse stock split at a ratio of one new share for every 70 shares of its common stock outstanding. Under the terms of the Merger Agreement, each outstanding share of Savara common stock was then converted into Mast common stock at the Exchange Ratio. No fractional shares were issued and instead, shareholders received cash for the value of their fractional shares. As a result of the Merger, the Mast equity holders own approximately 23% of the combined company, and Savara's pre-existing equity holders own approximately 77%.

Prior to the closing of the Merger, the Company completed a 2017 Convertible Promissory Note (the "2017 Notes") financing. The 2017 Notes carry an annual simple interest rate of 8.0% and were convertible into shares of the Company's equity dependent upon the earlier of the maturity date of June 30, 2018, a subsequent qualified financing, change of control event, Regulation A offering, a public offering, including an initial public offering or a public listing conversion such as a reverse merger, or at the consent of a majority of the noteholders. Upon the occurrence of the Merger on April 27, 2017, the 2017 Notes, principal only, automatically converted at a conversion price of 80% percent of the amount equal to the average trading price of Mast common stock for the twenty-day period ending two days prior to the closing of the Merger, or \$0.13, as adjusted by an exchange ratio described in the Merger Agreement. Subsequent to March 31, 2017, the Company raised approximately \$3.5 million under the 2017 Notes.



On April 28, 2017, Savara entered into a Common Stock Sales Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), pursuant to which Savara may offer and sell, from time to time, through Wainwright, shares of its common stock (the "Shares"), having an aggregate offering price of not more than \$18.0 million. The shares will be offered and sold pursuant to Savara's shelf registration statement on Form S-3. 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 Savara's instructions. Savara 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" ('ATM') as defined in Rule 415 under the Securities Act of 1933, as amended. Savara 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.

On April 28, 2017, Savara and its subsidiary, Aravas, entered into a Loan and Security Agreement with Silicon Valley Bank . The agreement provides for a \$15 million debt facility, \$7.5 million of which was immediately available to Savara upon completion of the Merger with a minimum market cap of \$100 million. The primary use of the capital was for the repayment of pre-merger debt of \$3.7 million owed to Hercules Technology Growth Capital. In addition, the capital will be utilized to fund ongoing development programs of Savara and for general corporate purposes. Under the terms of the agreement, Savara may draw an additional amount of \$7.5 million through June 30, 2017, subject to the achievement of certain corporate milestones specifically a minimum new capital raise with combined proceeds of at least \$40 million through a secondary offering, private investment in public entity (PIPE), ATM, partnerships or grants to be received within twelve months of signing the agreement. This achievement was met during Q2 2017 and Savara subsequently drew the additional \$7.5 million on June 15, 2017.

Initially, interest only payments were due through September 2018 followed by monthly payments of principal plus interest over the following thirty (30) months. With the second tranche fully utilized, the interest only period has been extended for an additional six (6) months, through March 2019 followed by monthly payments of principal plus interest over the following twenty-four (24) months. Interest of prime plus 4.25% will be charged per the agreement and the maturity date is March 1, 2021. Upon funding the first tranche, Savara issued warrants to purchase shares of Savara's common stock equal to 3.0% of the funded amount divided by the exercise price to be set based on the average price per share over the preceding 10 trading days prior to closing or the price per share prior to the day of closing. Upon funding of the second tranche, Savara issued warrants to purchase shares of Savara common stock equal to 3.0% of the funded amount divided by an exercise price to be set based on the average price per share over the preceding 10 trading days prior to funding or the price per share prior to the day of funding.

# **Financial Operations Overview**

#### **Research and Development Expenses**

Research and development expenses represent costs incurred to conduct research and development, such as the development of Savara's product candidates. Savara recognizes 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 Savara's 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 Savara's 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 Savara's operating expenses has historically been its investment in research and development activities. The following table shows Savara's research and development expenses for the three months ended June 30, 2017 and 2016 and six months ended June 30, 2017 and 2016:

	Three Months Ended June 30,				nded						
	 2017 2016		2016		2016		2016		2017		2016
	(in thou	sands	)	(in thousan			nds)				
Product candidates:											
AeroVanc	\$ 1,886	\$	1,290	\$	2,875	\$	2,552				
Molgradex	2,151		—		4,109		_				
Aironite	127				127		—				
Total research and development expenses	\$ 4,164	\$	1,290	\$	7,111	\$	2,552				

Savara expects research and development expenses will increase in the future as Savara advances its product candidates into and through clinical trials and pursues regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing and inventory build-up related costs. In addition, Savara continues 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. Savara may never succeed in timely developing and achieving regulatory approval for its product candidates. The probability of success of Savara's product candidates may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, Savara is unable to accurately determine the duration and completion costs of Savara's development projects or when and to what extent Savara will generate revenue from the commercialization and sale of any of its product candidates.

#### General and Administrative Expenses

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services, and changes in the fair value of certain contingent consideration. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related costs. General and administrative costs also include depreciation expense and other supplies. Savara expects to incur additional expenses as a result of becoming a public company as a result of the Merger, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance, investor relations, and other administrative expenses and professional services.

# **Critical Accounting Policies and Estimates**

Savara's management's discussion and analysis of financial condition and results of operations is based on its condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires Savara to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, Savara evaluates these estimates and judgments. Savara bases its estimates on historical experience and on various assumptions that Savara believes 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. Savara believes that the accounting policies discussed below are critical to understanding its historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

#### Accrued Research and Development Expenses

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

Savara estimates 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. Savara makes significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, Savara adjusts its accrued estimates.



#### Stock-based Compensation

Savara recognizes stock-based awards to employees and directors, including stock options, based on the fair value on the grant date using the Black-Scholes option pricing model. The related stock-based compensation is recognized as expense on a straight line-basis over the employee's or director's requisite service period (generally the vesting period). Noncash stock compensation expense is based on awards ultimately expected to vest and is reduced by forfeitures, if necessary.

Savara accounts for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of options granted to nonemployees is measured using the Black-Scholes option pricing model reflecting similar assumptions for employees except that the expected term is based on the options' remaining contractual term instead of the simplified method in each of the reported periods. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

In determining the fair value of the stock-based awards, Savara uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

*Fair Value of Common Stock.* Prior to the Merger, the fair value of the shares of common stock underlying stock options had been determined by Savara's board of directors. In order to determine the fair value of the common stock at the time of grant of the option, the Savara board of directors considered, among other things, valuations performed by an independent third-party. Because there had been no public market for Savara's common stock, the Savara board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of Savara's common stock, including important developments in Savara's operations, sales of convertible preferred stock, actual operating results and financial performance, the conditions in the life sciences industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of its common stock, among other factors. As of April 28, 2017, the fair value of the Company's common stock is determined by the closing price of our common stock listed on the Nasdaq exchange as of the date of the grant.

*Expected Term.* Savara's expected term represents the period that their stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) for employee options and the contractual term for non-employee options.

*Expected Volatility.* Prior to April 27, 2017, Savara was privately held and did not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, or stage in the life cycle. Until Savara has enough history of its own publicly listed common stock, it will continue using the same methodology.

*Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

*Expected Dividend.* Savara has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, Savara used an expected dividend yield of zero. For the six months ended June 30, 2017 and 2016, stock-based compensation expense was approximately \$0.2 million and \$0.1 million, respectively.

#### Results of Operations — Comparison of Three Months Ended June 30, 2017 and 2016

	Three Months Ended June 30,					Dollar
		2017	2016			Change
				(in thou	isand	s)
Grant revenue	\$	—	\$		\$	—
Operating expenses:						
Research and development	\$	4,164	\$	1,290	\$	2,874
General and administrative		5,088		608	\$	4,480
Depreciation		91		85	\$	6
Total operating expenses		9,343		1,983		7,360
Loss from operations		(9,343)		(1,983)		(7,360)
Other expense		(2,631)		(68)	\$	(2,563)
Net loss before income taxes		(11,974)		(2,051)		(9,923)
Income tax benefit		470		_	\$	470
Net loss	\$	(11,504)	\$	(2,051)	\$	(9,453)

#### Research and development

Research and development expenses increased by \$2.9 million, or 223%, to \$4.2 million for the three months ended June 30, 2017 from \$1.3 million for the three months ended June 30, 2016. The increase was primarily due to \$2.2 million in increased development costs associated with the development of Molgradex, and a \$0.7 million increase in costs related to AeroVanc mainly related to Chemistry, Manufacturing, and Controls ("CMC") activities.

#### General and administrative

General and administrative expenses increased by \$4.5 million, or 737%, to \$5.1 million for the three months ended June 30, 2017 from \$0.6 million for the three months ended June 30, 2016. The increase was due to \$1.9 million of expense in connection with the changes in fair value of the contingent consideration associated with the Serendex acquisition and \$1.7 million of expense in connection with the Merger and financing activities and related costs including legal and accounting expenditures. Savara personnel costs increased \$0.7 million due to increased administrative personnel including bonuses. Additionally, administrative costs of Savara ApS (Denmark) totaled \$0.2 million which was not a part of Savara as of June 30, 2016.

#### Other expense

Other expense increased by \$2.6 million for the three months ended June 30, 2017. The increase was primarily due to \$1.8 million of expense associated with the extinguishment of the 2016 Notes and 2017 Notes and approximately \$0.5 million in interest expense.

#### Income tax benefit

Income tax benefit in 2017 represents a tax benefit provided by the Danish government in the form of a refundable research credit associated with research and development expenditures of Savara's subsidiary, Savara ApS. There was no tax benefit in the first or second quarter of 2016, as the subsidiary was not acquired until July 2016.

#### Results of Operations — Comparison of Six Months Ended June 30, 2017 and 2016

	Six Months Ended June 30,				Dollar	
	 2017 2016		Change			
			(in the	ousands)		
Grant revenue	\$ —	\$	_	\$	—	
Operating expenses:						
Research and development	\$ 7,111	\$	2,552	\$	4,559	
General and administrative	6,924		953	\$	5,971	
Depreciation	181		170	\$	11	
Total operating expenses	14,216		3,675		10,541	
Loss from operations	 (14,216)		(3,675)		(10,541)	
Other expense	(2,968)		(53)	\$	(2,915)	
Net loss before income taxes	 (17,184)		(3,728)		(13,456)	
Income tax benefit	707		—	\$	707	
Net loss	\$ (16,477)	\$	(3,728)	\$	(12,749)	

#### **Research and development**

Research and development expenses increased by \$4.6 million, or 179%, to \$7.1 million for the six months ended June 30, 2017 from \$2.6 million for the six months ended June 30, 2016. The increase was primarily due to \$4.1 million in increased development costs associated with the development of Molgradex.

#### General and administrative

General and administrative expenses increased by \$6.0 million, or 627%, to \$6.9 million for the six months ended June 30, 2017 from \$1.0 million for the six months ended June 30, 2016. The increase was due to \$2.0 million of expense in connection with the changes in fair value of the contingent consideration associated with the Serendex acquisition and approximately \$2.6 million of expense in connection with the Merger and financing activities and related costs including legal and accounting expenditures. Savara personnel costs increased \$0.7 million due to increased administrative personnel including bonuses. Additionally, administrative costs of Savara ApS (Denmark) totaled \$0.4 million which was not a part of Savara as of June 30, 2016.



#### Other expense

Other expense increased by \$2.9 million for the six months ended June 30, 2017. The increase was primarily due \$1.8 million of expense associated with the extinguishment of the 2016 Notes and 2017 Notes and \$0.8 million in interest expense.

#### Income tax benefit

Income tax benefit in 2017 represents a tax benefit provided by the Danish government in the form of a refundable research credit associated with research and development expenditures of Savara's subsidiary, Savara ApS. There was no tax benefit in the first half of 2016, as the subsidiary was not acquired until July 2016.

#### Liquidity and Capital Resources

As of June 30, 2017, Savara had \$61.1 million in cash and an accumulated deficit of \$54.9 million. Savara expects that its research and development and general and administrative expenses will increase, and, as a result, Savara anticipates that it will continue to incur increasing losses in the foreseeable future. Therefore, Savara will need to raise additional capital to fund its operations, which may be through the issuance of additional equity, and potentially through borrowings.

#### Loan Agreement

On April 28, 2017, the Company entered into a loan and security agreement with Silicon Valley Bank (the "Loan Agreement"). The Loan Agreement provides for a \$15 million debt facility, of which the first tranche, or \$7.5 million, was immediately available to the Company upon completion of the Merger with a minimum market cap of \$100 million. The Company executed the first tranche in early May 2017. The primary use of the capital was for the repayment of \$3.7 million of principal debt and fees of Mast assumed in the Merger. The residual capital will be utilized to fund ongoing development programs of the Company and for general corporate purposes. Under the terms of the Loan Agreement, the Company may, but is not obligated to draw a second tranche of \$7.5 million available through June 30, 2017, subject to the achievement of certain corporate milestones specifically a minimum new capital raise with combined proceeds of at least \$40 million through a secondary offering, private investment in public entity (PIPE), ATM, partnerships or grant to be received within twelve months of signing the agreement.

On June 15, 2017, the Company executed the second tranche of the Loan Agreement for \$7.5 million as the financing conditions under the Loan Agreement had been met.

The Loan Agreement contains customary affirmative and negative covenants, including among others, covenants limiting our ability and our subsidiaries 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.

The Loan Agreement bears interest at the prime rate reported in The Wall Street Journal, plus a spread of 4.25%. Interest only payments are due through September 2018 followed by monthly payments of principal plus interest over the following thirty (30) months. Since the second tranche was fully extended, the interest only period was extended for an additional six (6) months, through March 2019 followed by monthly payments of principal plus interest over the following twenty-four (24) months through the maturity date of March 1, 2021 under the Loan Agreement provisions. We were obligated to pay customary closing fees and are obligated to pay a final payment of 6.0% of the aggregate principal amount of term loans advanced under the facility. The end of term charge of \$.9 million will be due on the scheduled maturity date and is being recognized as increases to the principal with a corresponding charge to interest expense over the term of the facility using the effective interest method.

In connection with the Loan Agreement, we paid \$.1 million in legal costs directly attributable to issuing 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.

Upon funding the first tranche of the Loan Agreement, the Company was obligated to issue warrants to purchase shares of the Company's common stock equal to 3.0% of the funded amount divided by the exercise price to be set based on the average price per share over the preceding 10 trading days prior to closing. The number of shares callable under the warrant agreement for the first tranche and exercise price were 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.

Upon funding the second tranche of the Loan Agreement, the Company was obligated to issue warrants to purchase shares of the Company's common stock equal to 3.0% of the funded amount divided by an exercise price to be set based on the average price per share over the preceding 10 trading days prior to funding or the price per share prior to the day of funding. As such, the Company issued a second warrant for 41,736 shares at an exercise price of \$5.39 with a ten year life, expiring June 15, 2027.

# Cash Flows

The following table summarizes Savara's cash flows for the periods indicated:

	 Six Months Ended June 31,			
	2017	2016		
	(in thousands)			
Cash used in operating activities	\$ (10,515)	\$ (3,315)		
Cash provided by / (used in) investing activities	3,382	(5)		
Cash provided by financing activities	54,898	696		
Effect of exchange rate changes	(5)	_		
Net increase / (decrease) in cash	\$ 47,760	\$ (2,624)		

# Cash flows from operating activities

Cash used in operating activities for the six months ended June 30, 2017 was \$10.5 million, consisting of a net loss of \$16.5 million, which was partially offset by noncash charges of \$5.2 million, mainly comprised of depreciation, noncash interest, fair value changes, loss on debt extinguishment, accretion of discount to convertible promissory notes, and stock-based compensation, and by a net increase in assets and liabilities of \$0.8 million. The change in Savara's net operating assets and liabilities was primarily due to an increase accrued liabilities mostly related to research and development costs for both AeroVanc and Molgradex.

Cash used in operating activities for the six months ended June 30, 2016 was \$3.3 million, consisting mainly of a net loss of \$3.7 million.

#### Cash flows from investing activities

Cash provided by investing activities for the six months ended June 30, 2017 was the result of the cash acquired related to the Merger.

#### Cash flows from financing activities

Cash provided by financing activities for the six months ended June 30, 2017 was primarily related to proceeds from the issuance of \$39.5 million (net) of common stock, as well as \$14.9 million in net proceeds from our new debt facility with Silicon Valley Bank.

Cash provided by financing activities for the six months ended June 30, 2016 was related to proceeds from the issuance of Series C preferred stock.

#### Future Funding Requirements

Savara has not generated any revenue from product sales. Savara does not know when, or if, it will generate any revenue from product sales. Savara does not expect to generate any revenue from product sales unless and until it obtains regulatory approval for and commercializes any of its product candidates. At the same time, Savara expects its expenses to increase in connection with its ongoing development and manufacturing activities, particularly as Savara continues the research, development, manufacture and clinical trials of, and seeks regulatory approval for, its product candidates. Savara expects to increase to increase in connection, subject to obtaining regulatory approval of any of its product candidates, Savara anticipates that it will need additional funding in connection with its continuing operations.

As of June 30, 2017, Savara had cash of \$61.1 million. Savara will continue to require additional capital to continue its clinical development and potential commercialization activities. Accordingly, Savara will need to raise additional capital to continue to fund its operations. The amount and timing of its future funding requirements will depend on many factors, including the pace and results of its clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on its financial condition.

Until Savara can generate a sufficient amount of product revenue to finance its cash requirements, Savara expects to finance 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 Savara raises additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of Savara's stockholders will be diluted.



# **Contractual Obligations**

The following provides information supplemental to the tabular summary of contractual obligations as of December 31, 2016 presented in our annual report on Form 10-K filed with the SEC on March 6, 2017, as updated by our quarterly report on Form 10-Q filed on May 9, 2017 and our current report on Form 8-K filed on May 10, 2017:

Under the Loan Agreement, we received a second advance of \$7.5 million on June 15, 2017. For a description of the terms of the Loan Agreement, see Note 7 of Notes to Condensed Consolidated Financial Statements.

#### License and Royalty Agreements

Savara is also subject to certain contingent payments to the Cystic Fibrosis Foundation Therapeutics (CFFT) in connection with a \$1.7 million award from the CFFT that was provided to Savara in support of AeroVanc research (CFF Award). A payment is due to the CFFT equal to three (3) times the amount of the CFFT Award upon approval of AeroVanc for commercial use. The payment is owed in equal installments of 33% due 60 days after first commercial sale; 33% due 90 days of the first anniversary of the first commercial sale; and 34% due within 90 days of 2nd anniversary of first commercial sale. As Savara's product has not yet been approved for commercial use, Savara has not recorded a liability for the commercial approval payment.

In addition, if net sales exceed \$50.0 million for any calendar year occurring during the first five years after the first commercial sale, Savara must remit payment to the CFFT equal to one (1) times the CFF Award. Furthermore, if net sales exceed \$100.0 million for any calendar year occurring during the first five years after first commercial sale, Savara must remit an additional payment to the CFFT equal to one (1) times the CFF Award. Given Savara has not recognized any sales from AeroVanc, Savara has not recorded a liability for any amounts due as additional royalties.

Savara is subject to various manufacturing royalties and payments related to Molgradex. Upon the successful development, registration and attainment of approval by the proper health authorities, such as the FDA, in any territory except Latin America, Central America and Mexico, Savara must pay a royalty of three percent (3%) on annual net sales to the manufacturer of its Active Pharmaceutical Ingredients ("API"). Under this agreement with the API manufacturer, no signing fee or milestones are included in the royalty payments, and there is no minimum royalty. Additionally, Savara has a commitment to acquire a working cell bank and a master cell bank for \$2.0 million from this API manufacturer in the third quarter of 2017.

Savara is also subject to certain contingent milestone payments up to approximately seven million euros (approximately \$8.0 USD) based upon various development activities and regulatory approvals payable to Savara's manufacturer of its nebulizer used to administer Molgradex. In addition to these milestones, Savara will owe a royalty to the manufacturer of its nebulizer based on net sales. The royalty rate ranges from three and a half percent (3.5%) to five percent (5%) depending on the device technology used by Savara to administer to product.

#### Acquisition of Serendex Pharmaceuticals

On July 15, 2016, Savara closed on a Business Transaction Agreement ("BTA") under which Savara acquired certain assets, liabilities, employees, and subsidiaries of Serendex Pharmaceuticals A/S ("Seller"), a limited liability company incorporated under the laws of Denmark which delisted from the Oslo Axxes ("Oslo Stock Exchange") on or about May 4, 2016. The Seller's wholly owned subsidiaries include Pharmaorigin ApS and Drugrecure ApS (the "Subsidiaries") which are limited liability companies incorporated under the laws of Denmark. The Seller was a biopharmaceutical development company which, directly and through its Subsidiaries, advanced a pipeline and portfolio of novel inhalation therapies and related technologies for the treatment of severe pulmonary conditions. Its primary focus was on the medicinal product Molgradex (an inhalation formulation of recombinant human GM-CSF for the treatment of pulmonary alveolar proteinosis). The purchase price consists of 1,965,400 shares, after giving effect to the Exchange Ratio, of Savara's common stock in the name of the Seller as security for the Seller's obligations under the BTA until the lapse of the deadline for submission of claims, and \$21.5 million of contingent cash consideration based upon the achievement of certain milestones.

# **Other Contracts**

Savara enters into contracts in the normal course of business with various third parties for research studies, clinical trials, testing and other services. These contracts generally provide for termination upon notice, and therefore Savara believes that its non-cancelable obligations under these agreements are not material except for certain obligations under its agreement for its capitalized lease asset.

#### **Off-Balance Sheet Arrangements**

Savara has not entered into any off-balance sheet arrangements and does not have any holdings in variable interest entities.



#### **Recent Accounting Pronouncements**

In February 2016, the FASB issued Accounting Standards Update 2016-02, "Leases" ("ASU 2016-02"). The update aims at making leasing activities more transparent and comparable, and requires substantially all leases to be recognized by lessees on their balance sheet as a right-of-use asset and a corresponding lease liability, including leases currently accounted for as operating leases. The update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 with early adoption permitted. Savara is currently evaluating the impact of the adoption of ASU 2016-02 on its financial statements.

In August 2016, the FASB issued Accounting Standards Update 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments" ("ASU 2016-15"), which intended to add or clarify guidance on the classification of certain cash receipts and payments on the statement of cash flows. The new guidance addresses cash flows related to the following: debt prepayment or extinguishment costs, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies and bank-owned life insurance policies, distributions received from equity method investees, beneficial interest in securitization transactions, and the application of predominance principle to separately identifiable cash flows. ASU 2016-15 is effective for Savara for annual periods beginning after December 15, 2017, and interim periods within those fiscal years with early adoption permitted. Savara is currently evaluating the effect of this new guidance on its financial statements.

In January 2017, the FASB issued Accounting Standards Update 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business" ("ASU 2017-01"), which intended to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-01 is effective for Savara for annual periods beginning after December 15, 2017. Savara's early adoption of this standard did not have a material impact on Savara's financial statements.

In May 2017, the FASB issued Accounting Standards Update 2017-09, "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"), which intended to provide clarity when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. ASU 2017-09 is effective for the Savara for annual periods beginning on or after December 15, 2017 with early adoption permitted. Savara's early adoption of this standard did not have a material impact on Savara's financial statements.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of June 30, 2017, Savara had cash of \$61.1 million, which consisted of bank deposits. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. Savara has not been exposed nor does it 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 Savara's condensed consolidated financial statements.

Savara has ongoing operations in Denmark as a result of its acquisition of Serendex and pays those vendors in local currency (Danish Krone) or Euros. Savara does not participate in any foreign currency hedging activities and it does not have any other derivative financial instruments. Savara did not recognize any significant exchange rate losses during the six-month period ended June 30, 2017. A 10% change in the krone-to-dollar or euro-to-dollar exchange rate on June 30, 2017 would not have had a material effect on Savara's 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, 2017. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2017 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, 2017, we incurred a net loss of \$16.5 million, and net cash used in operating activities was \$10.5 million. At June 30, 2017, our cash, cash equivalents and investment securities were \$61.1 million, and working capital was \$55.5 million. At June 30, 2017, we had an accumulated deficit of \$54.9 million. We expect to continue to incur substantial operating losses for the next several years as we seek to advance our product candidates through clinical development, global regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, one of our product candidates is approved by the FDA or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve.

# We will require additional financing to obtain regulatory approval for AeroVanc, Molgradex and Aironite, 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, most of our resources have been dedicated to the development and acquisition of our product candidates, AeroVanc and Molgradex. As part of the Merger, we acquired the Aironite program, which we plan to continue developing. We believe that our existing capital resources will be sufficient to fund our operations into 2019. We may raise additional capital from new investors, including through our "at the market" (ATM) offering program. We will require additional capital to continue operations and execute on our current business strategy to develop AeroVanc, Molgradex and Aironite through to regulatory approval. 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 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, conduct preclinical or clinical studies, or other development activities.

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. 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 between us and Aravas, as co-borrowers, and Silicon Valley Bank, which we refer to as the Loan Agreement. The 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 Loan Agreement includes covenants requiring, among other things, that we provide financial statements, comply with all laws, pay all taxes and maintain insurance. If we are not able to comply with these covenants, the loans under the Loan Agreement could become immediately due and payable and would have a material adverse effect on our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

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

As of June 30, 2017, we had goodwill and IPR&D of approximately \$61.3 million. These intangible assets are subject to an impairment analysis whenever an event or change in circumstances indicates the carrying amount of such an asset may not be recoverable. We test our goodwill and IPR&D for impairment annually, or more frequently if an event or change in circumstances indicates that the asset may be impaired. If an impairment is identified, we would be required to record an impairment charge with respect to the impaired asset to consolidated statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations.

We will continue to evaluate our intangible assets for potential impairment in accordance with its accounting policies. If additional impairments are identified, we would be required to record an impairment charge with respect to the impaired asset to its consolidated statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations.

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, AeroVanc, Molgradex and Aironite. 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 AeroVanc for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) infections in the lungs of cystic fibrosis patients, and Molgradex for the treatment of patients with pulmonary alveolar proteinosis (PAP) and Aironite for the treatment of heart failure with preserved ejection fraction, or HFpEF, also known as diastolic heart failure or heart failure with preserved systolic function. The AeroVanc Phase 3 study is scheduled to start in the United States and Canada in Q3 2017, the Molgradex Phase 3 clinical study (IMPALA) is ongoing in Europe and Japan, and Aironite is in Phase 2 clinical development. We expect to announce top-line results from the Phase 3 study of Molgradex in the fourth quarter of 2018.

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

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

- slow implementation, enrollment and completion of the clinical trials;
- inability to enroll enough patients in the clinical trials;
- low patient compliance and adherence to dosing and reporting requirements, for example incomplete reporting of patient reported outcomes in the clinical trials or missed doses;
- lack of safety and efficacy in the clinical trials;
- delays in manufacture of supplies for both drug and device components due to delays in formulation, process development, or manufacturing activities;



- requirements for additional nonclinical or clinical studies based on changes to formulation and/or changes to regulatory requirements; and
- requirements for additional clinical studies based on inconclusive clinical results or changes in market, standard of care, and/or regulatory requirements.

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

- FDA rejection of our NDA submissions for our product candidates;
- regulatory rejection in the EU, Japan, and other markets;
- delays during regulatory review and/or requirements for additional CMC, nonclinical, or clinical studies, resulting in increased costs and/or delays in marketing approval and subsequent commercialization of the product candidates in the United States 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:

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- the ability 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;
- poor prescription coverage and inadequate reimbursement for our product candidates;
- our inability to enforce our intellectual property rights in and to 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 in part 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 of our product candidates. 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 in our office 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 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, including the Aironite program that we acquired as a result of the Merger, and do not plan to establish our own manufacturing facilities. To manufacture our product candidates, we have made numerous custom modifications at 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 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 ultimately 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 United States may require that we have an alternate manufacturer of a drug product before approving it for marketing and sale in the United States or abroad and securing such alternate manufacturer before approval of an NDA could result in considerable additional time and cost prior to NDA 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 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 drug product of its performance. The manufacturing of the drug substance of Molgradex, molgramostim, a biological drug substance, as well as the drug product, Molgradex, is currently being transferred to a new manufacturing site. Producing a pharmaceutically and biologically similar product may prove to be challenging, and may take more time and resources than currently anticipated. The transfer of the manufacturing to the new site may also cause regulatory agencies, including the FDA, to require additional nonclinical studies, which may cause delay or failure to obtain regulatory approval, and incur substantial additional cost.

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, AeroVanc and Molgradex are currently manufactured entirely or partially outside the United States 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

#### 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, 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 GCP, GLP and GMP 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 the Savara project 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 United States 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 United States through a focused, specialized sales force, which will be costly and time consuming. 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 United States, 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.

### We are in the process of integrating the systems, products and contracts from the recent merger with Mast and the complete scope and impact of the integration is unknown.

Our merger with Mast on April 27, 2017 has inherent risks, including risks associated with the integration of systems, products and contracts. We have devoted resources towards the successful integration of the companies, but there is potential exposure to unknown or contingent liabilities, liability associated with the assumption of legacy agreements, and many other such risks typical for such mergers.

#### 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 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 stock acquisition would dilute our stockholders' ownership.

### 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 June 30, 2017, we had 14 full-time employees, including 8 employees engaged in research and development. As we advance our product candidates through the development process and to commercialization, we will need to continue to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. As our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers and other organizations.

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

### 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 to the patient population observed in later stage studies, where larger groups of patients are required. For example, patients in earlier stage 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 planned for 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 its 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 discussed in other risk factors above, 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 that relate to the data required to be included in NDAs 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 ethics and conduct, it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against them, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. For example, if one of our manufacturing partners was placed under a consent decree, we may be hampered in our ability to manufacture clinical or commercial supplies.

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

We rely on information technology systems, including third-party "cloud based" service providers, to keep financial records, maintain laboratory, clinical data and corporate records, communicate with staff and external parties and operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories, and archives. If any of these



third-party information technology (IT) providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber-attacks or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and 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 a loss of 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.

#### 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 and terrorist attacks or severe weather conditions, could significantly disrupt our operations and result in additional, unplanned expense. As a small company with limited resources, we have not prepared or implemented a formal business continuity or disaster recovery plan and any natural disaster or catastrophic event could disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that are not covered by or exceed the coverage available under these insurance policies.

#### **Risks Related to Drug Development and Commercialization**

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

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

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

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

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

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

AeroVanc has been granted Orphan Drug Designation in the United States by the FDA for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in patients with cystic fibrosis and Molgradex has received Orphan Drug Designation in the United States by the FDA and in Europe by the European Medicines Agency for the treatment of pulmonary alveolar proteinosis (PAP). Orphan Designation will not shorten the regulatory review or reduce the clinical data requirements needed to obtain approval. If approval is received to market either AeroVanc or Molgradex for the respective indications, FDA will not approve a similar product, with the same active ingredient, to AeroVanc or Molgradex for seven years and the European Medicines Agency 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 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 could 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 contract research organizations, or CROs, and 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 ethic committee approval to conduct a clinical study at a prospective site;
- delays in reaching agreements on acceptable terms with prospective contract manufacturing organizations, or 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 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 planned AeroVanc Phase 3 study, or otherwise;
- delays in having patients complete participation in a clinical study, including returning for post-treatment follow-up;
- delays resulting from study sites dropping out of a trial, providing inadequate staff support for the study, problems with shipment of study supplies to clinical sites or focusing its staff's efforts on enrolling studies that compete for the same patient population;
- suspension of enrollment at a study site or the imposition of a clinical hold by the FDA or other regulatory authority following an inspection of clinical study operations at study sites or finding of a drug-related serious adverse event; and
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

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

Clinical studies may not begin on time or be completed in the time frames we anticipate and may be costlier than we anticipate for a variety of reasons, including one or more of those described above. The length of time necessary to successfully complete clinical studies varies significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and/or availability of results from our clinical studies, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons, including patient enrollment rates, length of time needed to prepare raw study data for analysis and then to review and analyze it, and other factors described above. If we experience delays in the completion of a clinical study, if a clinical study is terminated, or if failure to conduct a study in accordance with regulatory requirements or the study's protocol leads to deficient safety and/or efficacy data, the regulatory approval and/or commercial prospects for our product candidates may be harmed and our ability to generate product revenue will be delayed. In addition, any delays in completion of 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 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.

We are preparing AeroVanc for a Phase 3 trial, the success of which will be needed for FDA approval to market AeroVanc in the United States to treat persistent MRSA lung infection in cystic fibrosis patients. 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 is required by the FDA to conduct a two-year nonclinical carcinogenicity study on the AeroVanc powder. The results of this study will not be known until a short time prior to potential submission of an NDA for AeroVanc. If the carcinogenicity study cannot be completed for technical or other reasons, or provides results that the FDA determine to be concerning, this may cause a delay or failure in obtaining approval for AeroVanc.

Molgradex is currently undergoing a Phase 3 clinical study in Europe and Japan. Concurrently, we plan to explore formulation changes to Molgradex that could simplify the composition of the drug product by eliminating one or more potentially unnecessary or harmful excipients. While we expect this change 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 formulation changes. We currently plan not to make any formulation changes prior to submitting applications to regulatory authorities for regulatory approvals of Molgradex, but instead, to qualify the excipients in its nonclinical and clinical studies. However, regulatory agencies may request that we attempt to make the aforementioned formulation changes prior to approval of the product, and therefore, even if current clinical studies are deemed successful, such formulation changes could require us to expend substantial additional resources, including conducting an additional Phase 3 clinical study that would significantly extend the timeline for clinical development of Molgradex in PAP.

We have has recently received guidance from the FDA on the requirements to initiate clinical studies in the United States and on the clinical study requirements to achieve BLA approval for Molgradex. Based on the guidance, we plan to amend our ongoing Phase 3 clinical study to include more patients, and to amend our endpoint hierarchy and statistical analyses to be used for U.S. approval purposes prior to submission of a U.S. IND. However, no agreement has yet been reached on the specific details of the statistical analysis plan, which we plan to submit for FDA review prior to the data analysis. Furthermore, even if the clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results to provide persuasive evidence of efficacy across multiple clinical endpoints. Instead, they may require additional clinical studies and/or other costly studies, including an additional Phase 3 study, which would require us to expend substantial additional resources and would significantly extend the timeline for clinical development prior to market approval, or in failure to complete the clinical development of Molgradex.

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including AeroVanc, Molgradex, and Aironite. Regardless of any guidance the FDA or foreign regulatory agencies may provide a drug's sponsor during its development, the FDA or foreign regulatory agencies retain complete discretion in deciding whether to accept an NDA or BLA or the equivalent foreign regulatory approval submission for filing or, if accepted, approve an NDA or BLA. There are many components to an NDA or BLA or marketing authorization application submission in addition to clinical study data. For example, the FDA or foreign regulatory agencies will review the sponsor's internal systems and processes, as well as those of its CROs, CMOs and other vendors, related to development of its product candidates, including those pertaining to its clinical studies and manufacturing processes. Before accepting an NDA for review or before approving the NDA or BLA, the FDA or foreign regulatory agencies may request that we provide additional information that may require significant resources and time to generate and there is no guarantee that its product candidates will be approved for any indication for which we may apply. The FDA or foreign regulatory agencies may choose not to



approve an NDA or BLA for any of a variety of reasons, including a decision related to the safety or efficacy data, manufacturing controls or systems, or for any other issues that the agency may identify related to the development of its product candidates. Even if one or more Phase 3 clinical studies are successful in providing statistically significant evidence of the efficacy and safety of the investigational drug, the FDA or foreign regulatory agencies may not consider efficacy and safety data from the submitted studies adequate scientific support for a conclusion of effectiveness and/or safety and may require one or more additional Phase 3 or other studies prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and its 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-down or budget sequestration, such as one that occurred during 2013, 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.

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 AeroVanc, Molgradex, or Aironite 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 current good manufacturing processes, or cGMP, good clinical practices, international conference on harmonization regulations and good laboratory practices, which are regulations and guidelines that are enforced by the FDA or foreign regulatory agencies for all of its clinical development and for any clinical studies that we conduct post-approval. The FDA or foreign regulatory agencies may decide to withdraw approval, add warnings or narrow the approved indications in the product label, or establish risk management programs that could restrict distribution of our products. These actions could result from, among other things, safety concerns, including unexpected side effects or drug interaction problems, or concerns over misuse of a product. If any of these actions were to occur following approval, we may have to discontinue commercialization of the product, limit our sales and marketing efforts, implement risk minimization procedures, and/or conduct post-approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

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

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

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

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical studies;

- refuse to approve pending applications or supplements to approved applications;
- exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare;
- impose restrictions or affirmative obligations on our or our CMO's operations, including costly new manufacturing requirements;
- close the facilities of a CMO; or
- seize or detain products or require a product recall.

### If any of our product candidates for which we receive regulatory approval fails to achieve significant market acceptance among the medical community, patients or third-party payers, the revenue we generate from its sales will be limited and our business may not be profitable.

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

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

We cannot predict with reasonable accuracy whether physicians, patients, healthcare insurers or health maintenance organizations, or the medical community in general, will accept or utilize any of our products, if approved. If our product candidates are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or remain profitable. In addition, our efforts to educate the medical community and thirdparty 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 expenditure 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 United States, we may never receive approval or commercialize our products outside of the United States, which would limit our ability to realize the full commercial potential of our product candidates.

In order to market products outside of the United States, 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 United States, 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 United States. 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 United States in the future, we may not meet the FDA requirements in the United States 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 in part 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 United States, AeroVanc's primary market. AeroVanc has either been issued patents or is prosecuting patent applications in numerous countries outside the United States. We have no patent protection for Molgradex for the treatment of PAP, and primarily rely on the Orphan Drug exclusivity as our primary barrier to competition. Both AeroVanc and Molgradex utilize proprietary delivery devices with exclusive supply agreements. Molgradex is eligible for protection via a proprietary cell bank used in the production of the drug substance. For Aironite, which is administered via nebulization, we have no patent protection and may rely on regulatory exclusivity for the combination of Aironite and its delivery system. Other medications that alter pulmonary pressures include the delivery device in their U.S. and European market labels, and are approved for use only with the specified proprietary delivery device. However, there is no assurance that our Aironite product and its delivery system, if approved, will benefit from this type of market protection.

Our success will depend in part on our ability to:

- obtain and maintain patent and other exclusivity with respect to our products and its 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 United States 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 United States 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 United States and, after March 15, 2013, in the United States. In addition, changes in or different interpretations of patent laws in the United States and foreign countries may affect our patent rights and limit the number of patents we

can obtain, which could permit others to use our discoveries or to develop and commercialize our technology and products without any compensation to us.

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

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

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

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

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

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

We have filed for patent protection in the U.S. and other countries to cover various methods of therapeutic use of our product candidates, including the use of inhaled inorganic nitrite for treating HFpEF. The potential use and therapeutic benefits of inorganic nitrite, such as sodium nitrite (the API in Aironite) have been known for decades. There is substantial prior art describing the uses of inorganic nitrite in a wide range of diseases and conditions. As a result, our ability to find novel and non-obvious uses of Aironite is uncertain. Further, a patent examiner may combine numerous, disparate references in order to reject a claimed composition, formulation and/or use for obviousness. If the prior art suggests, even implicitly, the desirability of combining previously known elements, such as the use of Aironite in a particular indication, the subsequent use of Aironite in that indication may 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 the best interests of us. 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 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 United States. 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 those of us once Orphan Drug and Qualified Infectious Disease Product exclusivities have expired. See the section entitled "Risks Related to Our Industry" for further description of Orphan Drug and Qualified Infectious Disease Product exclusivities.

Enforcement of intellectual property rights in certain countries outside the United States, including China in particular, 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, or USPTO, and various governmental patent agencies outside of the United States 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 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 its 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 third parties 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 its 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 we 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.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain 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. 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.

AeroVanc and Molgradex have received Orphan Drug Designation from the FDA and Molgradex has received Orphan Drug Designation from the European Medicines Agency. Orphan Drug Designation will provide market exclusivity in the U.S. for 7 years and 10 years in Europe, but only if (1) AeroVanc and Molgradex receive market approval before a competitor using the same active compound for the same indication, (2) we are able produce sufficient supply to meet demand in the marketplace, and (3) another product with the same active ingredient is not deemed clinically superior. AeroVanc has also received Qualified Infectious Disease Product (QIDP) status extending market exclusivity by an additional five years in addition to any other exclusivity obtained in the United States.

In terms of Aironite, we are not aware of any pharmacologic therapy of proven benefit for patients with HFpEF. Therapies that have demonstrated efficacy in heart failure with reduced ejection fraction (HFrEF) have thus far failed to demonstrate improved outcomes in patients with HFpEF. A couple Phase 3 studies of Novartis' LCZ696 in patients with HFpEF are underway. We are aware of other therapies under investigation in earlier stage clinical studies for the treatment of HFpEF. We also are aware of a non-surgical medical device being studied for treatment of HFpEF patients in the U.S., which device has received CE Mark approval in the European Union. Should any therapy that receives approval prior to our product candidates become entrenched in the standard of care, the need for our product candidates may be diminished and/or such competing products may be difficult to displace. However, we believe that, as with HFrEF, there will be a need for a multimodal therapy approach to treating patients with HFpEF.

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 theirs, 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 in part 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 United States, 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 in part 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 the new U.S. President has stated that reducing drug pricing is a priority for his administration. We expect that federal, state and local governments in the United States, 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 reforms 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, including the possible repeal and replacement of the Affordable Care Act, which the Trump administration has stated is a priority, 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 product. Any reduction in reimbursement from Medicare or other governmentfunded 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 us 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 decrease our cash and adversely affect our business.

#### **Risks Related to our Common Stock**

#### Our stock price is expected to be volatile.

The market price of our common stock will 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 the common stock to fluctuate include:

- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- 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;

- 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;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an 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 cystic fibrosis market generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of the combined organization;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

In the past, following periods of volatility in the market price of our 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.

#### Future sales of shares by existing stockholders could cause our stock price to decline.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the existing lock-up agreements lapse, the trading price of our common stock could decline. As of August 8, 2017, we had approximately 24.2 million shares of common stock outstanding. Substantially all of such shares of common stock may be sold in the public market; however, approximately 10.5 million of such shares are subject to lock-up restrictions, which restrictions expire beginning on October 27, 2017. If substantial additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

We will incur significant legal, accounting and other expenses that we did not incur as a private company prior to the Merger, including costs associated with public company reporting requirements. We will also 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 will consist of certain officers of us prior to the Merger, some of whom 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.

## Because the Merger likely has resulted in an ownership change under Section 382 of the Code, our pre-merger net operating loss carryforwards and certain other tax attributes will be subject to limitation. The net operating loss carryforwards and certain other tax attributes may also be subject to limitations as a result of ownership changes.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the 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. The merger likely has resulted in an ownership change for us and, accordingly, our net operating loss carryforwards and certain other tax attributes with respect to the pre-closing period will be subject to limitations on use after the Merger. The Merger may also have resulted in an ownership change for us, in which case, our net operating loss carryforwards and certain other tax attributes would also be subject to limitations. 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 its 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.

#### 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 9, 2017	By: /s/ Dave Lowrance Dave Lowrance Chief Financial Officer (Principal Financial and Accounting Officer)
Date: August 9, 2017	By: /s/Robert Neville Robert Neville Chief Executive Officer (Principal Executive Officer)
	56

#### Exhibit Index

Exhibit Number	Description
4.1	Amendment to Warrant to Purchase Shares of Common Stock of the registrant issued to Life Science Loans II, LLC on June 26, 2017.
4.2	Amendment to Warrant to Purchase Shares of Common Stock of the registrant issued to SVB Financial Group on June 26, 2017.
4.3	Warrant to Purchase Shares of Common Stock of the registrant issued to Life Science Loans II, LLC on June 26, 2017.
4.4	Warrant to Purchase Shares of Common Stock of the registrant issued to Silicon Valley Bank on June 26, 2017.
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

#### AMENDMENT TO WARRANT TO PURCHASE COMMON STOCK

This Amendment to Warrant to Purchase Common Stock (this "Amendment") is entered into as of June 26, 2017, by and between LIFE SCIENCE LOANS II, LLC ("Holder") and SAVARA INC. a Delaware corporation ("Company").

#### RECITALS

Company has issued for the benefit of Holder that certain Warrant to Purchase Common Stock dated April 28, 2017 (as amended from time to time, the "Warrant"). Holder and Company now desire to amend the Warrant in accordance with the terms of this Amendment.

NOW, THEREFORE, Holder and Company agree as follows:

1. The Number of Shares of Common Stock for which the Warrant is exercisable is amended and restated in its entirety to read as follows:

"Number of Shares of Common Stock: 12,362"

2. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Warrant. The Warrant, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects.

3. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

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

#### SAVARA INC.

By:	/s/ David L. Lowrance	
Name:	David L. Lowrance	
Title:	CFO	

#### LIFE SCIENCE LOANS II, LLC

By:	/s/ Trent Dawson	
Name:	Trent Dawson	

Title: Chief Financial Officer

[Signature Page to Amendment to Warrant to Purchase Common Stock]

#### AMENDMENT TO WARRANT TO PURCHASE COMMON STOCK

This Amendment to Warrant to Purchase Common Stock (this "Amendment") is entered into as of June 26, 2017, by and between SVB FINANCIAL GROUP ("Holder") and SAVARA INC. a Delaware corporation ("Company").

#### RECITALS

Company has issued for the benefit of Silicon Valley Bank ("Bank") that certain Warrant to Purchase Common Stock dated April 28, 2017 (as amended from time to time, the "Warrant"). Bank has assigned the Warrant to Holder. Holder and Company now desire to amend the Warrant in accordance with the terms of this Amendment.

NOW, THEREFORE, Holder and Company agree as follows:

follows:

1.

"Number of Shares of Common Stock: 12,362"

2. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Warrant. The Warrant, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects.

3. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

#### [Balance of Page Intentionally Left Blank]

The Number of Shares of Common Stock for which the Warrant is exercisable is amended and restated in its entirety to read as

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

#### SAVARA INC.

By:	/s/ David L. Lowrance	
Name:	David L. Lowrance	
Title:	CFO	
SVB FIN	'B FINANCIAL GROUP	
By:	/s/ Igor DaCruz	

[Signature Page to Amendment to Warrant to Purchase Common Stock]

Name:

Title:

Igor DaCruz

Vice President

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

#### WARRANT TO PURCHASE COMMON STOCK

Company: SAVARA INC. Number of Shares of Common Stock: 20,868 Warrant Price: \$5.39 Issue Date: June 26, 2017 Expiration Date: June 26, 2027 Credit Facility:

#### See also Section 5.1(b).

This Warrant to Purchase Common Stock ("<u>Warrant</u>") is issued in connection with that certain Loan and Security Agreement of even date herewith between Silicon Valley Bank and the Company (the "<u>Loan Agreement</u>").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, LIFE SCIENCE LOANS II, LLC (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "<u>Holder</u>") is entitled to purchase the number of fully paid and non-assessable shares (the "<u>Shares</u>") of the above-stated common stock (the "<u>Common</u> <u>Stock</u>") of the above-named company (the "<u>Company</u>") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant.

#### SECTION 1. EXERCISE.

1.1 <u>Method of Exercise</u>. Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 <u>Cashless Exercise</u>. On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

$$X = Y(A-B)/A$$

where:

- X = the number of Shares to be issued to the Holder;
- Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);
- A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and
- B = the Warrant Price.

1.3 <u>Fair Market Value</u>. If the Company's Common Stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "<u>Trading Market</u>"), the fair market value of a Share shall be the closing price or last sale price of a share of Common Stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company's Common Stock is not traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

1.4 <u>Delivery of Certificate and New Warrant</u>. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

1.5 <u>Replacement of Warrant</u>. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

#### 1.6 <u>Treatment of Warrant Upon Acquisition of Company</u>.

(a) <u>Acquisition</u>. For the purpose of this Warrant, "<u>Acquisition</u>" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power.

(b) Treatment of Warrant at Acquisition. In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a "Cash/Public Acquisition"), and the fair market value of one Share as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date immediately prior to such Cash/Public Acquisition, and Holder has not exercised this Warrant pursuant to Section 1.1 above as to all Shares, then this Warrant shall automatically be deemed to be Cashless Exercised pursuant to Section 1.2 above as to all Shares Exercise, Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon exercise. In the event of a Cash/Public Acquisition where the fair market value of one Share as determined in accordance with Section 1.3 above would be promptly notify the Green of the fair market value of one Share as the date thereof and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon exercise. In the event of a Cash/Public Acquisition where the fair market value of one Share as determined in accordance with Section 1.3 above would be less than the Warrant Price in effect immediately prior to such Cash/Public Acquisition, then this Warrant will expire immediately prior to the consummation of such Cash/Public Acquisition.

(c) Upon the closing of any Acquisition other than a Cash/Public Acquisition defined above, the acquiring, surviving or successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

(d) As used in this Warrant, "<u>Marketable Securities</u>" means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "<u>Exchange Act</u>"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from

publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise or convert this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

#### SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

2.1 <u>Stock Dividends, Splits, Etc.</u> If the Company declares or pays a dividend or distribution on the outstanding shares of the Common Stock payable in securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Common Stock by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares of the Common Stock are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Warrant Price shall be proportionately increased and the number of Shares shall be proportionately increased.

2.2 <u>Reclassification, Exchange, Combinations or Substitution</u>. Upon any event whereby all of the outstanding shares of the Common Stock are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, this Warrant will be exercisable for the number, class and series of Company securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, and subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, combinations substitutions, replacements or other similar events.

#### 2.3 <u>Intentionally Omitted</u>.

#### 2.4 <u>Intentionally Omitted</u>.

2.5 <u>No Fractional Share</u>. No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

2.6 <u>Notice/Certificate as to Adjustments</u>. Upon each adjustment of the Warrant Price, Common Stock and/or number of Shares, the Company, at the Company's expense, shall notify Holder in writing within a reasonable time setting forth the adjustments to the Warrant Price, class and/or number of Shares and facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer, including computations of such adjustment and the Warrant Price, class and number of Shares in effect upon the date of such adjustment.

#### SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 <u>Representations and Warranties</u>. The Company represents and warrants to, and agrees with, the Holder as follows: All Shares which may be issued upon the exercise of this Warrant, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of securities as will be sufficient to permit the exercise in full of this Warrant.

3.2 <u>Notice of Certain Events</u>. If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Company's stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to the holders of the outstanding shares any additional shares of any class or series of the Company's stock (other than pursuant to contractual pre-emptive rights);

(c) effect any reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Common Stock; or

(d) effect an Acquisition or to liquidate, dissolve or wind up;

then, in connection with each such event, the Company shall give Holder:

(1) in the case of the matters referred to in (a) and (b) above, at least seven (7) Business Days prior written notice of the earlier to occur of the effective date thereof or the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Common Stock will be entitled thereto) or for determining rights to vote, if any; and

(2) in the case of the matters referred to in (c) and (d) above at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice).

Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

#### SECTION 4. <u>REPRESENTATIONS, WARRANTIES OF THE HOLDER.</u>

The Holder represents and warrants to the Company as follows:

4.1 <u>Purchase for Own Account</u>. This Warrant and the Shares to be acquired upon exercise of this Warrant by Holder are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

4.2 <u>Disclosure of Information</u>. Holder is aware of the Company's business affairs and financial condition and 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 acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

4.3 <u>Investment Experience</u>. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

4.4 <u>Accredited Investor Status</u>. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

4.5 <u>The Act</u>. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that this Warrant and the Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

4.6 <u>No Voting Rights</u>. Holder, as a Holder of this Warrant, will not have any voting rights until the

#### SECTION 5. MISCELLANEOUS.

#### 5.1 <u>Term and Automatic Conversion Upon Expiration</u>.

(a) Term. Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

5.2 <u>Legends</u>. The Shares (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) shall be imprinted with a legend in substantially the following form:

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "<u>ACT</u>"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE COMMON STOCK ISSUED BY THE ISSUER TO LIFE SCIENCE LOANS II, LLC DATED JUNE 26, 2017, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

5.3 <u>Compliance with Securities Laws on Transfer</u>. This Warrant and the Shares issuable upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transferee is an "accredited investor" as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.

5.4 <u>Notices</u>. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by facsimile or electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 5.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

Life Science Loans II, LLC c/o Chief Financial Officer 3720 Carillon Point Kirkland, Washington 98033-7455 Attention: Trent Dawson Telephone: (425) 952-3951 Email: tdawson@westrivermgmt.com]

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address:

SAVARA INC. 900 S. Capital of Texas Hwy; Suite 150 Austin, TX 78746 Attn: David Lowrance, CFO Fax: \_\_\_\_\_\_ Email: dave.lowrance@savarapharma.com

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

WILSON SONSINI GOODRICH & ROSATI, P.C. Attn: J. Robert Suffoletta 900 S. Capital of Texas Highway Las Cimas IV, Fifth Floor Austin, TX 78746 Telephone: (512) 338-5400 Facsimile: (512) 338-5499 Email: <u>rsuffoletta@wsgr.com</u>

5.5 <u>Waiver</u>. This Warrant and any term hereof may be changed, waived, discharged or terminated (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.6 <u>Attorney's Fees</u>. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.

5.7 <u>Counterparts; Facsimile/Electronic Signatures</u>. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement. Any signature page delivered electronically or by facsimile shall be binding to the same extent as an original signature page with regards to any agreement subject to the terms hereof or any amendment thereto.

5.8 <u>Governing Law</u>. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

5.9 <u>Headings</u>. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

5.10 <u>Business Days</u>. "<u>Business Day</u>" is any day that is not a Saturday, Sunday or a day on which Silicon Valley Bank is closed.

[Remainder of page left blank intentionally] [Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Common Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

# "COMPANY"

### SAVARA INC.

By:	/s/ David L. Lowrance			
Name:	David L. Lowrance			
Title:	(Print) CFO			
"HOLDER"				
LIFE SCIENCE LOANS II, LLC				
By:	/s/ Trent Dawson			
Name:	Trent Dawson			
Title:	Chief Financial Officer			

### APPENDIX 1

#### NOTICE OF EXERCISE

1. The undersigned Holder hereby exercises its right purchase \_\_\_\_\_\_ shares of the Common Stock of SAVARA INC. (the "<u>Company</u>") in accordance with the attached Warrant To Purchase Common Stock, and tenders payment of the aggregate Warrant Price for such shares as follows:

[ ] check in the amount of \$\_\_\_\_\_ payable to order of the Company enclosed herewith

[ ] Wire transfer of immediately available funds to the Company's account

[ ] Cashless Exercise pursuant to Section 1.2 of the Warrant

[ ] Other [Describe]

2. Please issue a certificate or certificates representing the Shares in the name specified below:

Holder's Name

(Address)

3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Section 4 of the Warrant to Purchase Common Stock as of the date hereof.

# HOLDER:

By:	
Name:	
Title:	
(Date):	

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

# WARRANT TO PURCHASE COMMON STOCK

Company: SAVARA INC. Number of Shares of Common Stock: 20,868 Warrant Price: \$5.39 Issue Date: June 26, 2017 Expiration Date: June 26, 2027 Credit Facility:

#### See also Section 5.1(b).

This Warrant to Purchase Common Stock ("<u>Warrant</u>") is issued in connection with that certain Loan and Security Agreement of even date herewith between Silicon Valley Bank and the Company (the "<u>Loan Agreement</u>").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, SILICON VALLEY BANK (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "Holder") is entitled to purchase the number of fully paid and non-assessable shares (the "Shares") of the above-stated common stock (the "Common Stock") of the above-named company (the "Company") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. Reference is made to Section 5.4 of this Warrant whereby Silicon Valley Bank shall transfer this Warrant to its parent company, SVB Financial Group.

### SECTION 1. EXERCISE.

1.1 <u>Method of Exercise</u>. Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 <u>Cashless Exercise</u>. On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

$$X = Y(A-B)/A$$

where:

- X = the number of Shares to be issued to the Holder;
- Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);
- A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and
- B = the Warrant Price.

1.3 <u>Fair Market Value</u>. If the Company's Common Stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "<u>Trading Market</u>"), the fair market value of a Share shall be the closing price or last sale price of a share of Common Stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company's Common Stock is not traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

1.4 <u>Delivery of Certificate and New Warrant</u>. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

1.5 <u>Replacement of Warrant</u>. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

#### 1.6 <u>Treatment of Warrant Upon Acquisition of Company</u>.

(a) <u>Acquisition</u>. For the purpose of this Warrant, "<u>Acquisition</u>" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power.

(b) Treatment of Warrant at Acquisition. In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a "Cash/Public Acquisition"), and the fair market value of one Share as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date immediately prior to such Cash/Public Acquisition, and Holder has not exercised this Warrant pursuant to Section 1.1 above as to all Shares, then this Warrant shall automatically be deemed to be Cashless Exercised pursuant to Section 1.2 above as to all Shares Exercise, Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon exercise. In the event of a Cash/Public Acquisition where the fair market value of one Share as determined in accordance with Section 1.3 above would be less than the Warrant Price in effect immediately prior to such Cash/Public Acquisition. In connection with such Cashless Exercise. In the event of a Cash/Public Acquisition where the fair market value of one Share as determined in accordance with Section 1.3 above would be less than the Warrant Price in effect immediately prior to such Cash/Public Acquisition, then this Warrant will expire immediately prior to the consummation of such Cash/Public Acquisition.

(c) Upon the closing of any Acquisition other than a Cash/Public Acquisition defined above, the acquiring, surviving or successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

(d) As used in this Warrant, "<u>Marketable Securities</u>" means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "<u>Exchange Act</u>"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from

publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise or convert this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

# SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

2.1 <u>Stock Dividends, Splits, Etc</u>. If the Company declares or pays a dividend or distribution on the outstanding shares of the Common Stock payable in securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Common Stock by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares of the Common Stock are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Warrant Price shall be proportionately increased and the number of Shares shall be proportionately increased.

2.2 <u>Reclassification, Exchange, Combinations or Substitution</u>. Upon any event whereby all of the outstanding shares of the Common Stock are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, this Warrant will be exercisable for the number, class and series of Company securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, and subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, combinations substitutions, replacements or other similar events.

# 2.3 <u>Intentionally Omitted</u>.

# 2.4 <u>Intentionally Omitted</u>.

2.5 <u>No Fractional Share</u>. No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

2.6 <u>Notice/Certificate as to Adjustments</u>. Upon each adjustment of the Warrant Price, Common Stock and/or number of Shares, the Company, at the Company's expense, shall notify Holder in writing within a reasonable time setting forth the adjustments to the Warrant Price, class and/or number of Shares and facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer, including computations of such adjustment and the Warrant Price, class and number of Shares in effect upon the date of such adjustment.

### SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 <u>Representations and Warranties</u>. The Company represents and warrants to, and agrees with, the Holder as follows: All Shares which may be issued upon the exercise of this Warrant, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of securities as will be sufficient to permit the exercise in full of this Warrant.

3.2 <u>Notice of Certain Events</u>. If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Company's stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to the holders of the outstanding shares any additional shares of any class or series of the Company's stock (other than pursuant to contractual pre-emptive rights);

(c) effect any reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Common Stock; or

(d) effect an Acquisition or to liquidate, dissolve or wind up;

then, in connection with each such event, the Company shall give Holder:

(1) in the case of the matters referred to in (a) and (b) above, at least seven (7) Business Days prior written notice of the earlier to occur of the effective date thereof or the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Common Stock will be entitled thereto) or for determining rights to vote, if any; and

(2) in the case of the matters referred to in (c) and (d) above at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice).

Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

# SECTION 4. <u>REPRESENTATIONS, WARRANTIES OF THE HOLDER.</u>

The Holder represents and warrants to the Company as follows:

4.1 <u>Purchase for Own Account</u>. This Warrant and the Shares to be acquired upon exercise of this Warrant by Holder are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

4.2 <u>Disclosure of Information</u>. Holder is aware of the Company's business affairs and financial condition and 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 acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

4.3 <u>Investment Experience</u>. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

4.4 <u>Accredited Investor Status</u>. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

4.5 <u>The Act</u>. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that this Warrant and the Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

4.6 <u>No Voting Rights</u>. Holder, as a Holder of this Warrant, will not have any voting rights until the

### SECTION 5. MISCELLANEOUS.

#### 5.1 <u>Term and Automatic Conversion Upon Expiration</u>.

(a) Term. Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

5.2 <u>Legends</u>. The Shares (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) shall be imprinted with a legend in substantially the following form:

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "<u>ACT</u>"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE COMMON STOCK ISSUED BY THE ISSUER TO SILICON VALLEY BANK DATED JUNE 26, 2017, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

5.3 <u>Compliance with Securities Laws on Transfer</u>. This Warrant and the Shares issuable upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transferee is an "accredited investor" as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.

5.4 <u>Transfer Procedure</u>. After receipt by Silicon Valley Bank of the executed Warrant, Silicon Valley Bank will transfer all of this Warrant to its parent company, SVB Financial Group. By its acceptance of this Warrant, SVB Financial Group hereby makes to the Company each of the representations and warranties set forth in Section 4 hereof and agrees to be bound by all of the terms and conditions of this Warrant as if the original Holder hereof. Subject to the provisions of Section 5.3 and upon providing the Company with written notice, SVB Financial Group and any subsequent Holder may transfer all or part of this Warrant or the Shares issuable upon exercise of this Warrant (or the securities issuable directly or indirectly, upon conversion of the Shares, if any) to any transferee, provided, however, in connection with any such transfer, SVB Financial Group or any subsequent Holder will give the Company notice of the portion of the Warrant to the Company for reissuance to the transferee(s) (and Holder if applicable); and provided further, that any subsequent transferee other than SVB Financial Group shall agree in writing with the Company to be bound by all of the terms and conditions of this Warrant.

5.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by facsimile or electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 5.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

SVB Financial Group Attn: Treasury Department 3003 Tasman Drive, HC 215 Santa Clara, CA 95054 Telephone: (408) 654-7400 Facsimile: (408) 988-8317 Email address: <u>derivatives@svb.com</u>

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address:

SAVARA INC. 900 S. Capital of Texas Hwy; Suite 150 Austin, TX 78746 Attn: David Lowrance, CFO Fax: Email: dave.lowrance@savarapharma.com

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

WILSON SONSINI GOODRICH & ROSATI, P.C. Attn: J. Robert Suffoletta 900 S. Capital of Texas Highway Las Cimas IV, Fifth Floor Austin, TX 78746 Telephone: (512) 338-5400 Facsimile: (512) 338-5499 Email: <u>rsuffoletta@wsgr.com</u>

5.6 <u>Waiver</u>. This Warrant and any term hereof may be changed, waived, discharged or terminated (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.7 <u>Attorney's Fees</u>. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.

5.8 <u>Counterparts; Facsimile/Electronic Signatures</u>. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement. Any signature page delivered electronically or by facsimile shall be binding to the same extent as an original signature page with regards to any agreement subject to the terms hereof or any amendment thereto.

5.9 <u>Governing Law</u>. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

5.10 <u>Headings</u>. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

5.11 <u>Business Days</u>. "<u>Business Day</u>" is any day that is not a Saturday, Sunday or a day on which Silicon Valley Bank is closed.

[Remainder of page left blank intentionally] [Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Common Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

# "COMPANY"

SAVARA INC.

By:	/s/ David L. Lowrance			
Name:	David L. Lowrance (Print)			
Title:	CFO			
"HOLDER"				
SILICON VALLEY BANK				
By:	/s/ Igor DaCruz			
Name:	Igor DaCruz			
Title:	(Print) Vice President			

### APPENDIX 1

#### NOTICE OF EXERCISE

1. The undersigned Holder hereby exercises its right purchase \_\_\_\_\_\_ shares of the Common Stock of SAVARA INC. (the "<u>Company</u>") in accordance with the attached Warrant To Purchase Common Stock, and tenders payment of the aggregate Warrant Price for such shares as follows:

[ ] check in the amount of \$\_\_\_\_\_ payable to order of the Company enclosed herewith

[ ] Wire transfer of immediately available funds to the Company's account

[ ] Cashless Exercise pursuant to Section 1.2 of the Warrant

[ ] Other [Describe]

2. Please issue a certificate or certificates representing the Shares in the name specified below:

Holder's Name

(Address)

3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Section 4 of the Warrant to Purchase Common Stock as of the date hereof.

# HOLDER:

By:		
Name:		
Title:		
(Date):		

#### 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;
- 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 9, 2017

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

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

I, David Lowrance, certify that:

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

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

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

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

- a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- 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 9, 2017

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

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

In connection with the Quarterly Report of Savara Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2017, 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 his 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 9, 2017

/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, 2017, 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 his 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 9, 2017

/s/ David Lowrance

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