Savara Inc
Form 10-Q
August 09, 2018

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, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-32157

Savara Inc.

(Exact name of registrant as specified in its charter)

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

(512) 961-1891

(Registrant's telephone number, including area code)

N/A

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

Indicate by check mark whether the registrant has submitted electronically 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 No

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
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

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

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

As of August 9, 2018, the registrant had 35,094,274 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$23,604	$22,121
Short-term investments	51,151	72,192
Prepaid expenses and other current assets	2,680	3,551
Total current assets	77,435	97,864
Property and equipment, net	720	925
In-process R&D	11,608	33,626
Goodwill	26,987	27,082
Other non-current assets	1,191	131
Total assets	$117,941	$159,628
Liabilities and stockholders’ equity (deficit)		
Current liabilities:		
Accounts payable	$2,523	$2,784
Accrued expenses	2,804	2,966
Debt facility	1,875	—
Current portion of capital lease obligation	318	265
Total current liabilities	7,520	6,015
Long-term liabilities:		
Debt facility, net of current portion	13,123	14,775
Contingent consideration	11,945	11,948
Deferred tax liability	2,554	7,181
Capital lease obligation, net of current portion	—	297
Other long-term liabilities	90	103
Total liabilities	35,232	40,319
Stockholders’ equity:		
Common stock, $0.001 par value, 200,000,000 and 500,000,000 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 30,836,774 and 30,509,522 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	32	32
Additional paid-in capital	188,866	186,522
Accumulated other comprehensive income (loss)	456	958
Accumulated deficit	(106,645)	(68,203)
Total stockholders’ equity	82,709	119,309
Total liabilities and stockholders' equity	$117,941	$159,628

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

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Savara Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2018	2017	June 30, 2018	2017
Operating expenses:				
Research and development	$9,268	$4,164	17,807	7,111
General and administrative	2,486	5,088	4,254	6,924
Impairment of acquired IPR&D	—	—	21,692	—
Depreciation	153	91	260	181
Total operating expenses	11,907	9,343	44,013	14,216
Loss from operations	(11,907)	(9,343)	(44,013)	(14,216)
Other income (expense):				
Interest expense, net	(113)	(516)	(217)	(761)
Foreign currency exchange gain (loss)	155	(122)	94	(154)
Loss on extinguishment of debt	—	(1,816)	—	(1,816)
Change in fair value of financial instruments	(6)	(177)	(62)	(237)
Total other income (expense)	36	(2,631)	(185)	(2,968)
Loss before income taxes	(11,871)	(11,974)	(44,198)	(17,184)
Income tax benefit	277	470	5,756	707
Net loss	$(11,594)	$(11,504)	$(38,442)	$(16,477)
Accretion of redeemable convertible preferred stock	—	(554)	—	(578)
Deemed dividend on beneficial conversion feature	—	(404)	—	(404)
Net loss attributable to common stockholders	$(11,594)	$(12,462)	$(38,442)	$(17,459)
Other comprehensive income:				
Gain (loss) on foreign currency translation	(856)	851	(515)	995
Unrealized gain (loss) on short-term investments	37	—	13	—
Total Comprehensive Loss	$(12,413)	$(10,653)	$(38,944)	$(15,482)
Net loss per share:				
Basic and diluted	$(0.38)	$(0.90)	$(1.26)	$(2.06)
Weighted average common shares outstanding				
Basic and diluted	30,658,494	13,807,861	30,601,425	8,465,053

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

Savara Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

Period Ended June 30, 2018

(In thousands, except share amounts)

(Unaudited)

	Stockholders' Equity (Deficit)					
	Common Stock		Additional		Accumulated Other	
	Number of Shares	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Income	Total
Balance on December 31, 2017	30,509,522	$ 32	186,522	$ (68,203)	$ 958	$ 119,309
Issuance of common stock upon At The Market sales, net	46,900	—	493	—	—	493
Issuance of common stock for settlement of RSUs	24,375	—	—	—	—	—
Net issuance of common stock upon cashless exercise of stock options	115,754	—	—	—	—	—
Issuance of common stock upon exercise of stock options	30,521	—	33	—	—	33
Issuance of common stock upon exercise of warrants	2,123	—	19	—	—	19
Common stock issued for purchase of assets	107,579	—	995	—	—	995
Stock-based compensation	—	—	804	—	—	804
Foreign exchange translation adjustment	—	—	—	—	(515)	(515)
Unrealized gain (loss) on short-term investments	—	—	—	—	13	13
Net loss incurred	—	—	—	(38,442)	—	(38,442)
Balance on June 30, 2018	30,836,774	$ 32	$ 188,866	$ (106,645)	$ 456	$ 82,709

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

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Savara Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(38,442)	$(16,477)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	260	181
Impairment of acquired IPR&D	21,692	—
Changes in fair value of financial instruments	62	237
Change in fair value of contingent consideration	(3)	1,977
Noncash interest	54	400
Loss on extinguishment of debt	—	1,816
Acquired IPR&D	995	—
Foreign currency gain/(loss)	(94)	154
Amortization of debt issuance costs	223	204
Accretion on discount to short-term investments and convertible promissory notes	(278)	—
Stock-based compensation	804	236
Provision (benefit) for deferred taxes	(4,555)	—
Changes in operating assets and liabilities:		
Grant and award receivable	—	400
Tax refund receivable	(1,237)	(666)
Prepaid expenses and other current assets	956	(817)
Deferred rent	(13)	(7)
Accounts payable and accrued expenses	(444)	1,847
Net cash used in operating activities	$(20,020)	$(10,515)
Cash flows from investing activities:		
Cash acquired through Merger	$—	$3,442
Purchase of property and equipment	(65)	(60)
Sales of available-for-sale securities	6,513	—
Maturities of available-for-sale securities	39,500	—
Purchase of available-for-sale securities, net	(24,724)	—
Net cash provided by / (used in) investing activities	$21,224	$3,382
Cash flows from financing activity:		
Proceeds from debt facility	$—	$14,894
Proceeds from convertible promissory notes	—	3,569
Issuance of common stock upon exercise of warrants	19	385
Issuance of common stock upon public offering	—	39,522
Issuance of common stock upon at the market offerings, net	493	100
Repayment of long-term debt	—	(3,567)
Proceeds from exercise of stock options	33	—
Capital lease obligation principal payments	(258)	(5)

Net cash provided by financing activities	$287	$54,898
Effect of exchange rate changes on cash and cash equivalents	(8)	(5)
Increase / (Decrease) in cash and cash equivalents	$1,483	$47,760
Cash and cash equivalents beginning of period	22,121	13,373
Cash and cash equivalents end of period	$23,604	$61,133
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 redeemable convertible preferred stock	$—	$578
Beneficial conversion feature	$—	$404
Common stock issued for IPR&D, net	$995	$—
Supplemental disclosure of cash flow information:		
Cash paid for interest	$685	$102

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 an orphan lung disease company. The Company’s pipeline comprises Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for autoimmune pulmonary alveolar proteinosis (“aPAP”), in Phase 2a development for nontuberculous mycobacterial (“NTM”) lung infection, and in preparation of Phase 2a development in cystic fibrosis (“CF”) affected individuals with chronic NTM lung infection, and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of persistent methicillin-resistant Staphylococcus aureus (“MRSA”) lung infection in individuals living with CF. The Company and its wholly owned subsidiaries operate in one segment with its principal offices in Austin, Texas.

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

Basis of Presentation

The interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) as defined by the Financial Accounting Standards Board (“FASB”). These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2017.

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, 2018, and its results of operations for the three and six months ended June 30, 2018 and 2017, and cash flows for the six months ended June 30, 2018 and 2017. The results of operations for interim periods shown in this report are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The December 31, 2017 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, 2017.

2. Summary of Significant Accounting Policies

Liquidity

As of June 30, 2018, the Company had an accumulated deficit of approximately $106.6 million. The Company also had negative cash flow from operations of approximately $20.0 million during the six months ended June 30, 2018. The cost to further develop and obtain regulatory approval for any drug is substantial and, as noted below, the

Company may have to take certain steps to maintain a positive cash position. Accordingly, the Company will need additional capital to further fund the development of, and seek regulatory approvals for, its product candidates and begin to commercialize any approved products.

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

While the Company had cash and cash equivalents of $23.6 million and short-term investments of $51.2 million as of June 30, 2018, we intend to continue to raise additional capital as needed through the issuance of additional equity and potentially through borrowings, and strategic alliances with partner companies. However, if such financings are not available timely and at adequate levels, the Company will need to reevaluate its operating plans. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Principles of Consolidation

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

Use of Estimates

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

Risks and Uncertainties

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

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

Cash and Cash Equivalents

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

Short-term Investments

The Company has classified its investments in debt securities with readily determinable fair value as available-for-sale securities. These securities are carried at estimated fair value with the aggregate unrealized gains and losses related to

these investments reflected as a part of “Accumulated other comprehensive income (loss)” within stockholders' equity.

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

Concentration of Credit Risk

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

Accrued Research and Development Costs

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

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

Business Combinations

Assets acquired and liabilities assumed as part of a business acquisition are recorded at their estimated fair value at the date of acquisition. The excess of purchase price over the fair value of assets acquired and liabilities assumed is recorded as goodwill. Determining fair value of identifiable assets, particularly intangibles, and liabilities acquired also requires management to make estimates, which are based on 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, Acquired In-Process Research and Development (IPR&D) and Deferred Tax Liability

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 in-process research and development ("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. During the six months ended June 30, 2018, the Company experienced a $0.1 million and $0.3 million decrease in the carrying value of goodwill and IPR&D, respectively, related to its acquisition of Savara ApS on July 15, 2016, which was due to foreign currency translation. In addition, during the six months ended June 30, 2018, the Company recorded $21.7 million of impairment charges and a corresponding decrease to the carrying value of IPR&D related to the Aironite drug candidate assumed in the Merger as further described in Note 6 due to the unfavorable results from a Phase 2 study that demonstrated a failure of Aironite to meet the endpoints of the study and limited effectiveness of the compound in patients. As a result of the

IPR&D impairment charges recorded in the first quarter of 2018, the Company reduced the associated deferred tax liability related to the acquired IPR&D from the Merger by $4.6 million and recorded a tax benefit.

Tax Refund Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS, for the six months ended June 30, 2018. 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, 2018, credits totaling $1.7 million had been generated but not yet received. Of this Danish tax credit of approximately $1.7 million, $0.8 million is related to research and development activities incurred during the year ended December 31, 2017 and recorded as a receivable in prepaid expenses and other current assets, as receipt is expected to occur in the fourth quarter of 2018. The remaining portion of the Danish tax credit of $0.9 million which was generated during the six months ended June 30, 2018 is recorded in other non-current assets and is expected to be received in the fourth quarter of 2019.

The Company also recognized a tax benefit for the six months ended June 30, 2018 as provided by the Australian Taxation Office for qualified research and development expenditures incurred on the NTM program incurred through our subsidiary, Savara Australia Pty. Limited. Under Australian tax law, Australia remits a research and development tax credit equal to 43.5% of qualified research and development expenditures, not to exceed established thresholds. As of June 30, 2018, credits totaling $0.3 million had been generated but not yet received. This Australian tax credit of approximately $0.3 million includes approximately $0.1 million in tax credits generated during the year ended December 31, 2017 and is recorded as a receivable in prepaid expenses and other current assets as receipt is expected to occur in the fourth quarter of 2018. The remaining portion of the Australian tax credit of $0.2 million which was generated during the six months ended June 30, 2018 and is recorded in other non-current assets and is expected to be received in the fourth quarter of 2019.

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 (Note 8) for which any change is reflected in general and administrative expense, foreign exchange derivatives, certain warrants previously classified as liabilities, and embedded put options separated from the convertible promissory notes which were converted to equity or derecognized in connection with the Merger.

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 attributable to common stockholders by the weighted average number of shares of common stock, restricted stock and restricted stock units outstanding during the period without consideration of common stock equivalents. Since the Company was

in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods presented as the inclusion of all potential dilutive securities would have been antidilutive.

Stock-Based Compensation

The Company recognizes the cost of stock-based awards granted to employees based on the estimated grant-date fair value of the awards. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The Company recognizes the compensation costs for awards that vest over several years on a straight-line basis over the vesting period (see Note 12). Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise. 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. Under an agreement, as amended, with the Active Pharmaceutical Ingredients (“API”) manufacturer, no signing fee or milestones are included in the royalty payments, and there is no minimum royalty. Upon the successful development, registration and attainment of approval by the proper health authorities, such as the FDA, in any territory except Latin America, Central America and Mexico, the Company must pay a royalty of three percent (3%) on annual net sales to the manufacturer of its API. Additionally, Savara must make certain payments to the API manufacturer upon the achievement of the milestones outlined in the following table.

The Company is also subject to certain contingent milestone payments, disclosed in the following table, 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.

Manufacturing Contingent Milestone Payments (in thousands):

	June 30, 2018
Molgradex API manufacturer:	
Delivery of working and master cell banks	$600
Achievement of certain milestones related to regulatory approval of Molgradex	2,000
Molgradex nebulizer manufacturer:	
Achievement of various development activities and regulatory approval of nebulizer utilized to administer Molgradex	8,132
Total manufacturing commitments	$10,732

As of June 30, 2018 and December 31, 2017, none of the above milestones had been met.

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 May 2014, the FASB issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers” and has subsequently issued several supplemental and/or clarifying ASUs, which comprise the new comprehensive revenue recognition standard that will replace all current U.S. GAAP guidance on this topic and eliminate all industry-specific guidance. The standard’s core principle is that a reporting entity will recognize revenue when it transfers control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We have performed an assessment of our contracts with third parties and determined that there would not be a material impact on our financial statements.

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 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.

3. Prepaid expenses and other current assets

Prepaid expenses consisted of (in thousands):

	June 30, 2018	December 31, 2017
R&D tax credit receivable	$899	$ 834
Prepaid clinical trial costs	966	2,129
VAT receivable	236	196
Prepaid insurance	430	158
Forward currency exchange derivative	—	40
Deposits and other	149	194
Total prepaid expenses and other current assets	$2,680	