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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-38155

Sienna Biopharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-3364627**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
30699 Russell Ranch Road, Suite 140 Westlake Village, California	**91362**
(Address of Principal Executive Offices)	**(Zip Code)**

(818) 629-2256
(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	**SNNA**	**The Nasdaq Global Select Market**

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

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

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

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

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

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

As of August 6, 2019, there were 30,907,542 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

Sienna Biopharmaceuticals, Inc.
Form 10-Q For The Quarter Ended June 30, 2019
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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

Sienna Biopharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except per share amounts)

	June 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 49,207	$ 48,526
Restricted cash	181	181
Prepaid expenses and other current assets	1,229	1,705
Total current assets	50,617	50,412
Property and equipment, net	237	311
Operating lease right-of-use asset	712	—
In-process research and development	45,172	45,594
Goodwill	10,887	10,989
Total assets	$ 107,625	$ 107,306
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,522	$ 2,792
Accrued personnel costs	1,945	3,057
Other accrued expenses	3,246	5,000
Contingent consideration, current portion	14,100	13,500
Total current liabilities	20,813	24,349
Contingent consideration—net of current portion	19,400	15,700
Operating lease liability—net of current portion	544	—
Long-term debt, net	29,474	30,125
Deferred tax liability	10,406	10,503
Other long-term liabilities	5	48
Total liabilities	80,642	80,725
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000 shares authorized, no shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.0001 par value, 300,000 shares authorized, 30,732 and 21,177 shares issued and 30,534 and 20,870 outstanding at June 30, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	208,261	182,750
Accumulated other comprehensive income	2,772	3,199
Accumulated deficit	(184,050)	(159,368)
Total stockholders' equity	26,983	26,581
Total liabilities and stockholders' equity	$ 107,625	$ 107,306

See accompanying notes.

Sienna Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 5,084	$ 15,692	$ 12,177	$ 28,672
General and administrative	2,643	5,976	11,389	11,473
Total operating expenses	7,727	21,668	23,566	40,145
Loss from operations	(7,727)	(21,668)	(23,566)	(40,145)
Other income (expense), net	(537)	1,429	(1,080)	2,803
Net loss	$ (8,264)	$ (20,239)	$ (24,646)	$ (37,342)
Other comprehensive income (loss):				
Cumulative translation adjustment	586	(2,494)	(427)	(1,120)
Comprehensive loss	$ (7,678)	$ (22,733)	$ (25,073)	$ (38,462)
Per share information:				
Net loss, basic and diluted	$ (0.27)	$ (1.00)	$ (0.90)	$ (1.84)
Basic and diluted weighted average shares outstanding	30,354	20,289	27,496	20,258

See accompanying notes.

Sienna Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands)
(unaudited)

	Six Months Ended June 30, 2019					
	Common Stock					
	Shares	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2018	20,870	$ —	$182,750	$ 3,199	$ (159,368)	$ 26,581
Cumulative effect of adoption of ASU 2016-02	—	—	—	—	(36)	(36)
Vesting of early exercised shares	55	—	56	—	—	56
Stock-based compensation expense	—	—	1,533	—	—	1,533
Issuance of shares of common stock, net of issuance cost of $1,555 pursuant to the follow on offering	9,200	—	21,445	—	—	21,445
Issuance of warrants to purchase common stock	—	—	1,105	—	—	1,105
Repurchase of early exercised shares	(1)	—	(3)	—	—	(3)
Foreign currency translation adjustments	—	—	—	(1,013)	—	(1,013)
Net loss	—	—	—	—	(16,382)	(16,382)
Balance at March 31, 2019	30,124	$ —	$206,886	$ 2,186	$ (175,786)	$ 33,286
Vesting of early exercised shares	54	—	52	—	—	52
Stock-based compensation expense	—	—	871	—	—	871
Issuance of shares of common stock, net of issuance cost of $159 pursuant to the ATM Offering Program	329	—	425	—	—	425
Shares issued pursuant to the employee stock purchase plan	27	—	27	—	—	27
Foreign currency translation adjustments	—	—	—	586	—	586
Net loss	—	—	—	—	(8,264)	(8,264)
Balance at June 30, 2019	30,534	$ —	$208,261	$ 2,772	$ (184,050)	$ 26,983

	Six Months Ended June 30, 2018					
	Common Stock					
	Shares	Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2017	20,194	$ —	$171,726	$ 5,370	$ (85,897)	$ 91,199
Vesting of early exercised shares	60	—	70	—	—	70
Stock-based compensation expense	—	—	901	—	—	901
Repurchase of early exercised shares	(8)	—	(18)	—	—	(18)
Foreign currency translation adjustments	—	—	—	1,374	—	1,374
Net loss	—	—	—	—	(17,103)	(17,103)
Balance at March 31, 2018	20,246	$ —	$172,679	$ 6,744	$ (103,000)	$ 76,423
Vesting of early exercised shares	52	—	54	—	—	54
Stock-based compensation expense	—	—	995	—	—	995
Issuance of common stock in connection with exercise of stock options	37	—	407	—	—	407
Shares issued pursuant to the employee stock purchase plan	30	—	388	—	—	388
Foreign currency translation adjustments	—	—	—	(2,494)	—	(2,494)
Net loss	—	—	—	—	(20,239)	(20,239)
Balance at June 30, 2018	20,365	$ —	$174,523	$ 4,250	$ (123,239)	$ 55,534

See accompanying notes

Sienna Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2019	**2018**
Operating activities		
Net loss	$(24,646)	$(37,342)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	76	78
Amortization of debt discount and issuance costs	470	—
Stock-based compensation	2,404	1,896
Fair value adjustment of success payment liability	—	(2,404)
Fair value adjustment of contingent consideration	4,300	2,300
Non-cash interest expense	428	—
Loss on disposal of property and equipment	2	—
Impairment of operating lease – right-of-use asset	13	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	475	122
Accounts payable and other accrued liabilities	(4,708)	5,145
Net cash used in operating activities	(21,186)	(30,205)
Investing activities		
Investment in property and equipment	(4)	(17)
Net cash used in investing activities	(4)	(17)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs, early exercise liability and repurchase of unvested early exercise stock options	21,867	389
Net proceeds from issuance of long-term debt (payment of debt issuance costs)	(16)	29,897
Proceeds from issuance of common stock upon ESPP purchase	27	388
Net cash provided by financing activities	21,878	30,674
Effect of exchange rate changes on cash	(7)	(32)
Net increase in cash, cash equivalents and restricted cash	681	420
Cash, cash equivalents and restricted cash at beginning of period	48,707	74,648
Cash, cash equivalents and restricted cash at end of period	$ 49,388	$ 75,068
Supplemental Disclosure of Cash Flow Information:		
Right-of-use asset obtained in exchange for lease liability	$ 844	$ —
Warrants issued	$ 1,105	$ —

See accompanying notes.

1. Organization and Description of Business

In these notes to the unaudited condensed consolidated financial statements, the "Company," "Sienna," "we," "us,"" and "our" refers to Sienna Biopharmaceuticals, Inc. (formerly Sienna Labs, Inc.) and its subsidiaries on a consolidated basis.

Sienna Biopharmaceuticals, Inc., was incorporated on July 27, 2010, under the laws of the State of Delaware and is headquartered in Westlake Village, California. The Company is a clinical-stage biopharmaceutical company focused on bringing unconventional scientific innovations to patients whose lives remain burdened by their disease.

On August 5, 2019, the Company announced that it has retained Cowen and Company, LLC ("Cowen") as an independent financial advisor to assist in exploring financial and strategic alternatives designed to maximize shareholder value. With Cowen's assistance, the Company will continue to explore capital raising to enable the initiation of its planned Phase 3 pivotal clinical trials for its lead product candidate, SNA-120 (pegcantratinib), for psoriasis and the associated pruritus (itch), in addition to exploring a wide range of financial and strategic alternatives. The Company may be unable to identify or execute such financial or strategic alternatives, and even if executed, such financial or strategic alternatives may not enhance stockholder value or the Company's financial position. The Company does not intend to initiate its planned Phase 3 clinical trials of SNA-120 until the Company secures sufficient additional capital.

On June 29, 2018, the Company entered into a new loan and security agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"), pursuant to which SVB agreed to make available to the Company term loans with an aggregate principal amount of up to $40.0 million, $30.0 million of which was funded on June 29, 2018. On January 28, 2019, the Company entered into an amendment to the loan and security agreement, under which the Company's total access to term loans is now $30.0 million, with additional minimum liquidity requirements. See Note 8, "Long-Term Debt."

On August 3, 2018 the Company entered into a sales agreement (the "Sales Agreement") with Cowen, pursuant to which the Company may sell from time to time, at its option, up to $75.0 million of the Company's common stock through an "at-the-market" equity offering program under which Cowen will act as sales agent (the "ATM Offering Program").

On August 3, 2018, the Company also filed a Registration Statement on Form S-3 (the "Shelf Registration Statement"), covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units. The Shelf Registration Statement included a prospectus covering the offering, issuance and sale of up to $75.0 million of the Company's common stock from time to time through the ATM Offering Program. The Registration Statement became effective on August 14, 2018. The shares to be sold under the Sales Agreement, may be issued and sold pursuant to the Shelf Registration Statement. During the year ended December 31, 2018, the Company issued 340,307 shares of its common stock through the ATM Offering Program and received net proceeds of approximately $5.0 million, after deducting commissions of $0.2 million and other offering expenses of $0.4 million. During the three and six months ended June 30, 2019, the Company issued an additional 329,588 shares of its common stock through the ATM Offering Program and received net proceeds of approximately $0.4 million, after deducting commissions of $18,000 and other offering expenses of $0.1 million. See Note 11, "Stockholders' Equity."

On January 2, 2019, the Company implemented a corporate restructuring to focus resources on its lead product candidate, SNA-120 for psoriasis and the associated pruritus, resulting in a reduction in force to reduce operational costs and preserve capital. The restructuring resulted in an elimination of 20 positions. At March 31, 2019, the Company had completed the activities associated with the restructuring plan and all related payments had been made.

In February 2019, the Company completed an underwritten public offering of 9,200,000 shares of common stock at a price to the public of $2.50 per share, including 1,200,000 shares of common stock pursuant to the underwriters' option to purchase additional shares. The Company received net proceeds from the offering of approximately $21.4 million, after deducting the underwriters' discounts and commissions and offering expenses payable by the Company. See Note 11, "Stockholders' Equity."

2. Liquidity Risks and Going Concern

The Company has incurred operating losses and has an accumulated deficit as a result of ongoing efforts to develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. The Company had an accumulated deficit of $184.1 million and $159.4 million as of June 30, 2019 and December 31, 2018, respectively. The Company had net losses of $8.3 million and $24.6 million for the three and six months ended June 30, 2019 and $20.2 million and $37.3 million for the three and six months ended June 30, 2018, respectively, and net cash used in operating activities of $21.2 million and $30.2 million for the six months ended June 30, 2019 and 2018, respectively. The Company had cash and cash equivalents of $49.2 million and $48.5 million at June 30, 2019 and December 31, 2018, respectively. These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts, or amounts and classification of liabilities that might result from this uncertainty.

To alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, the Company will be required to raise additional capital to fund future operations through the sale of its equity securities, incurring additional debt, entering into licensing or collaboration agreements with partners, grants or other sources of financing. There can be no assurance that sufficient funds will be available to the Company at all or on attractive terms when needed from equity or debt financings, or any strategic transactions that will provide the required capital. If the Company is unable to obtain additional funding from these or other sources when needed, or to the extent needed, there will not be sufficient cash resources and liquidity to fund business operations for at least the next year following the date when the unaudited condensed consolidated financial statements are issued, and it may be necessary to significantly reduce the Company's current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs.

The Company has historically financed its operations primarily through private and public equity issuances and debt offerings, and more recently through term loans under the SVB Loan Agreement and proceeds from the Company's ATM Offering Program. See Note 8, "Long-Term Debt."

3. Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP, and the applicable rules and regulations of the Securities and Exchange Commission, or the SEC, regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted.

Going Concern

The accompanying unaudited condensed consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business.

Unaudited Condensed Consolidated Financial Statements

The accompanying financial information for the three and six months ended June 30, 2019 and 2018 are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position as of June 30, 2019 and its results of operations for the three and six months ended June 30, 2019 and 2018 and cash flows for the six months ended June 30, 2019 and 2018. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other period(s).

Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of Sienna Biopharmaceuticals, Inc. and results of its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated. For the three and six months ended June 30, 2019 and 2018, the subsidiaries' net loss included in the Company's consolidated statement of operations was $0.3 million and $0.7 million, and $1.5 million and $2.4 million, respectively.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. The most significant estimates in the Company's consolidated financial statements relate to equity awards, warrants, clinical trial accruals and the valuation of contingent consideration obligations and the impairment assessment of the in-process research and development and goodwill incurred in connection with the acquisition of Creabilis plc, or Creabilis. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

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 in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment and one reportable segment, primarily in the United States.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. The reclassifications were not material to the unaudited condensed consolidated financial statements.

Cash and Cash Equivalents

The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, money market instruments, and obligations issued by U.S. government and U.S. government agencies, and places restrictions on maturities and concentration by type and issuer. The Company considers all highly liquid securities with original final maturities of three months or less from the date of purchase to be cash equivalents. As of June 30, 2019, cash and cash equivalents are comprised of funds in cash and U.S. Treasury money market funds. From time to time, the Company maintains cash balances in excess of amounts insured by the Federal Deposit Insurance Corporation. The accounts are monitored by management to mitigate the risk.

Restricted Cash

At June 30, 2019 and December 31, 2018, the Company held $0.2 million of restricted cash related to cash collateralized standby letters of credit in connection with obligations under the facility lease.

Fair Value Measurements

The Company's financial instruments, in addition to those presented in Note 7, "Fair Value Measurements", include restricted cash, accounts payable, accrued liabilities and long-term debt. The carrying amount of restricted cash, accounts payable and accrued liabilities approximate fair value because of the short-term nature of these instruments. Further, based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the carrying amount of the long-term debt approximates its fair value.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets which range from three to five years. Maintenance and repairs are expensed as incurred. The Company reviews the carrying values of its property and equipment for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There were no material impairments recognized during the six months ended June 30, 2019 and the year ended December 31, 2018.

In-process Research and Development and Goodwill

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date (which is regarded as their cost). Intangible assets related to acquired in-process research and development are treated as indefinite lived intangible assets and not amortized until they become definite lived assets upon regulatory approval. At that time, the Company will determine the useful life of the asset and begin amortization. Indefinite lived intangible assets are reviewed for impairment at least annually or if indicators of potential impairment exist. There were no impairments of intangible assets for the six months ended June 30, 2019 and the year ended December 31, 2018.

Goodwill represents the excess of the purchase price over the estimated fair value of the identifiable assets acquired and liabilities assumed in a business combination. The Company evaluates goodwill for impairment annually and upon the occurrence of triggering events or substantive changes in circumstances that could indicate a potential impairment. An impairment loss is recognized when the fair value of the reporting unit to which the goodwill relates is below its carrying value. The recent decline in the Company's market capitalization was determined to be a triggering event for potential goodwill impairment and accordingly, the Company performed the goodwill impairment analysis.

In determining the fair value utilized in the goodwill impairment assessment, the Company considered qualitative factors such as changes in strategy, cash flows, the regulatory environment, overall market conditions, as well as the market capitalization of the Company's publicly traded common stock. The Company operates as a single reporting unit and estimates the fair value of its single reporting unit using the Company's market capitalization plus an estimated control premium. Market capitalization is determined by multiplying the shares outstanding on the assessment date by the market price of the Company's common stock. If it is determined through the impairment evaluation process that goodwill has been impaired, an impairment charge would be recorded in the consolidated statement of operations and comprehensive loss. The Company completed the impairment test and determined that there was no impairment.

The Company's share price is highly volatile and subsequent declines in the market share price could pose risks of impairment in the future. It is not possible at this time to determine if an impairment charge would result from these factors, or, if it does, whether such charge would be material. The Company will continue to monitor the recoverability of its goodwill. There was no impairment of goodwill for the six months ended June 30, 2019 and the year ended December 31, 2018.

Research and Development Costs

Research and development costs are expensed as incurred. These costs include direct program expenses, which are payments made to third parties that specifically relate to the Company's research and development, such as payments to clinical research organizations, clinical investigators, manufacturing of clinical material, pre-clinical testing and consultants. In addition, employee costs (salaries, payroll taxes, benefits, stock-based compensation and travel) for employees contributing to research and development activities are classified as research and development costs.

Stock-Based Compensation

The Company measures employee and director stock-based compensation expense for all stock-based awards at the grant date based on the fair value measurement of the award. The expense is recorded on a straight-line basis over the requisite service period, which is generally the vesting period, for the entire award. Expense is adjusted for actual forfeitures of unvested awards as they occur. The Company calculates the fair value measurement of stock options using the Black-Scholes valuation model. Prior to the adoption of a new accounting pronouncement on January 1, 2019 related to share-based payments issued to non-employees for goods or services, stock options issued to non-employees were valued on their grant date and remeasured at the current fair value at the end of each reporting period until they vested. Under the new guidance, the measurement of equity-classified non-employee awards is fixed at the grant date, and no longer remeasured. The Company estimates the fair value of restricted stock unit awards based on the closing price of the Company's common stock on the date of issuance. Proceeds from options exercised by employees prior to vesting pursuant to an early exercise provision, the related shares of which the Company has the option to repurchase prior to the vesting date should employment of the early exercise holder be terminated, are recognized as a liability until the shares vest.

Clinical Trial Accruals

As part of the process of preparing its consolidated financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate trial expenses in its consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its rate of clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date in its consolidated financial statements based on the facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. Through June 30, 2019, there have been no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials. The Company's clinical trial accrual is dependent in part upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Other accrued expenses include accrued clinical trial costs of $1.4 million and $2.3 million as of June 30, 2019 and December 31, 2018, respectively. Prepaid expenses and other current assets include prepaid clinical trial expenses of $0.7 million as of June 30, 2019. There were no prepaid clinical trial expenses as of December 31, 2018.

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, excluding the effects of converting preferred stock, stock options and unvested restricted stock outstanding. Diluted net loss per common share is computed by dividing the net loss by the sum of the weighted average number of shares of common stock outstanding during the period plus the potential dilutive effects of convertible preferred stock, convertible notes, stock options and unvested restricted stock outstanding during the period calculated in accordance with the treasury stock method but are excluded if their impact is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between the weighted average number of shares used to calculate basic and diluted net loss per common share for the three and six months ended June 30, 2019 and 2018. Shares excluded from the calculation were 3.8 million and 2.5 million at June 30, 2019 and 2018, respectively.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred taxes are recognized based on the differences between financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The Company has provided a full valuation allowance on its deferred tax assets. The provision for income taxes represents the current tax payable for the period and the change during the period in deferred tax assets and liabilities. The Company recognizes the effect of an income tax position only if, based on its merits, the position is more likely than not to be sustained on audit by the taxing authorities. Interest and penalties related to uncertain tax positions are recorded as income tax expense.

Other Comprehensive Income (Loss)

Included in other comprehensive income (loss) for the three and six months ended June 30, 2019 and 2018 are an unrealized foreign currency translation gain of $0.6 million and a loss of $0.4 million, and losses of $2.5 million and $1.1 million, respectively. This is the Company's only component of other comprehensive income (loss) for the three and six months ended June 30, 2019 and 2018.

Foreign currency translation

The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. These include the entities acquired as part of the Creabilis acquisition. See Note 4, "Contingent Consideration". As part of this transaction, the Company acquired entities in the United Kingdom, denominated in British pounds, and Italy and Luxembourg, denominated in euros. The U.S. dollar effects that arise from translating net assets of these subsidiaries at changing rates are recognized in other comprehensive income (loss) in the condensed consolidated balance sheet. The earnings or loss of these subsidiaries are translated into U.S. dollars using average exchange rates for the periods.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (ASC 842),* which requires lessees to recognize most leases on the balance sheet. Lessees and lessors are required to apply the new standard at the beginning of the earliest period presented in the financial statements in which they first apply the new guidance, using a modified retrospective approach to adoption. The primary effect of adoption is the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. The requirements of this standard generally include a significant increase in required disclosures.

The FASB subsequently issued the following amendments to ASU 2016-02, which have the same effective date and transition date of January 1, 2019:

- ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, which amends certain narrow aspects of the guidance issued in ASU 2016-02; and
- ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.

On January 1, 2019, the Company adopted ASC 842, which resulted in the recognition of right-of-use assets of approximately $0.8 million and related lease liabilities on the consolidated balance sheets of approximately $1.0 million related to its operating lease commitments, with no material impact to the opening balance of retained earnings. The Company adopted the new leasing standards using the modified retrospective transition approach, applying to leases existing as of, or entered into after, January 1, 2019. Prior periods were not adjusted. The new standard provides a number of optional practical expedients in transition. The Company has elected the package of practical expedients to not reassess prior conclusions about lease identification under the new standard, lease classification, and initial direct costs. The Company also elected the practical expedient allowing the use of hindsight in determining the lease term and assessing impairment of right-of-use assets based on all facts and circumstances through the effective date of the new standard. The new standard also provides practical expedients for ongoing lease accounting, including electing the recognition exemption for short-term leases for all leases that qualify. Under this exemption, the Company did not recognize right-of-use, assets or lease liabilities for those leases that qualify as a short-term lease (leases with lease terms of 12 months or less), which includes not recognizing right-of-use assets or lease liabilities for existing short-term leases in transition. The Company also elected the practical expedient to not separate lease and non-lease components for all leases.

In June 2018 the FASB issued ASU 2018-07, "*Compensation —Stock Compensation (Topic 718) —Improvements to Nonemployee Share-Based Payment Accounting"* ("ASU 2018-07"), which expands the scope of Topic 718, *Compensation—Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees.* The amendments in ASU 2018-07 are effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted this standard on January 1, 2019 with no impact on the consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, "*Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income",* which provides the option to reclassify stranded tax effects within accumulated other comprehensive income to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (or portion thereof) is recorded. The Company adopted this standard on January 1, 2019 with no impact on the consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This new standard modifies certain disclosure requirements on fair value measurements. This new standard will be effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company does not expect the adoption of this new standard to have a significant impact on its disclosures.

4. Contingent Consideration

In December 2016, the Company entered into a Share Purchase Agreement, or the Purchase Agreement, to acquire the entire issued share capital of Creabilis. Pursuant to the acquisition of Creabilis, the Company obtained SNA-120, SNA-125 and the related intellectual property. SNA-120 is a first-in-class inhibitor of Tropomyosin receptor kinase A (TrkA) for the treatment of psoriasis, as well as the associated pruritus. SNA-125 is a topical dual Janus kinase 3 (JAK3)/TrkA inhibitor being developed for the treatment of various inflammatory conditions, including atopic dermatitis, psoriasis and the associated pruritus.

Upon closing, Creabilis became a direct wholly-owned subsidiary. As part of the terms of the acquisition, the Company agreed to make contingent payments up to an aggregate of $58.0 million in a combination of cash and stock upon the achievement of certain development and approval milestones, of which $5.0 million has been previously satisfied. Upon the commencement of the first Phase 3 clinical trial of SNA-120, the Company will become obligated to issue $18.0 million in shares of common stock, less certain offsets if applicable, to the former Creabilis shareholders. In addition, the Company is obligated to make certain contingent payments up to an aggregate of $80.0 million in cash upon the achievement of certain annual net sales thresholds and one-time royalties of less than 1% of the amount by which annual net sales exceeds each threshold in the year such threshold is achieved. Where milestone payments are required to be paid in stock, the number of shares will be determined based on the volume weighted average price of the common stock as reported on the Nasdaq Global Select Market, ("Nasdaq"), for the preceding 20-day trading period.

The agreement to pay the future milestones and potential one-time royalties resulted in the recognition of a contingent consideration liability, which is recognized at the inception of the transaction. Other than these payments, subsequent changes to the estimated amounts of contingent consideration to be paid are recognized in the consolidated statement of operations in general and administrative expense. The fair value of the contingent consideration is determined using preliminary cash flow projections, based on estimated timing and probabilities around the achievement of certain development, approval and sales milestones, expected product sales and other assumptions. The fair value of the contingent consideration was determined to be $33.5 million at June 30, 2019 and $29.2 million at December 31, 2018. The fair value of the contingent consideration was and continues to be determined by a third-party valuation firm applying the income approach, using several significant unobservable inputs as discussed in Note 7, "Fair Value Measurements". These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance.

5. Identifiable Intangible Assets

The Company's only identifiable intangible assets were in-process research and development related to SNA-120 and SNA-125 as of June 30, 2019 and December 31, 2018. The total intangible in-process research and development assets were recorded at an initial value of $42.3 million as a result of the Company's acquisition of Creabilis, are foreign denominated and subject to translation, and had a carrying value of $45.2 million and $45.6 million as of June 30, 2019 and December 31, 2018, respectively. The Company used the income approach to determine the fair value of the in-process research and development assets. This approach calculated fair value by estimating future cash flows attributable to the assets, using several unobservable inputs such as future revenues and expenses, time and resources needed to complete development and probabilities of obtaining market approval, and then discounting these cash flows to a present value using a risk-adjusted discount rate commensurate with the Company's cost of capital and expectation of the revenue growth for products at their life cycle stage. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance. See Note 7, "Fair Value Measurements".

Identifiable intangible assets are initially measured at their respective fair values and will not be amortized until commercialization. If commercialization occurs, intangible assets will be amortized over their estimated useful lives. In-process research and development assets were initially recognized at their fair value as determined on the date of acquisition of December 6, 2016 and are reviewed for impairment at least annually or whenever changes in circumstances indicate a potential impairment or upon regulatory approval resulting in the reclassification to a finite-lived intangible asset. No impairment has been recognized as of June 30, 2019 and December 31, 2018. Changes in value as a result of translation adjustments are included in other comprehensive income in the consolidated balance sheets.

6. Property and Equipment

Property and equipment consisted of the following as of June 30, 2019 and December 31, 2018 (in thousands):

	Estimated Useful Life (in years)	June 30, 2019	December 31, 2018
Lab equipment	5	$ 307	$ 307
Computer hardware	3	119	142
Capital lease equipment	3	46	46
Furniture and fixtures	5	87	87
Software	3	9	9
Leasehold improvements		105	105
Total		673	696
Less accumulated depreciation		(436)	(385)
Property and equipment, net		$ 237	$ 311

Leasehold improvements are depreciated over the shorter of the lease term or the estimated useful life of the related asset. Depreciation expense was $38,000 and $76,000 for the three and six months ended June 30, 2019, and $39,000 and $78,000 for the three and six months ended June 30, 2018, respectively.

7. Fair Value Measurements

The Company determines the fair value of financial and nonfinancial assets and liabilities using the fair value hierarchy, which describes three levels of inputs that may be used to measure fair value, as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities;

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. These inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on the best information available in the circumstances.

In certain cases where there is limited activity or less transparency around inputs to valuation, assets are classified as Level 3 within the valuation hierarchy.

The following tables set forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019		
	Level 1	Level 2	Level 3
Assets:			
Cash equivalents	$49,207	$ —	$ —
Total	$49,207	$ —	$ —
Liabilities:			
Contingent consideration	$ —	$ —	$33,500
Total	$ —	$ —	$33,500

	December 31, 2018		
	Level 1	Level 2	Level 3
Assets:			
Cash equivalents	$48,526	$ —	$ —
Total	$48,526	$ —	$ —
Liabilities:			
Contingent consideration	$ —	$ —	$29,200
Total	$ —	$ —	$29,200

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial liabilities (in thousands):

	Contingent Consideration
Balance at December 31, 2018	$ 29,200
Change in fair value due to remeasurement	4,300
Balance at June 30, 2019	$ 33,500

Cash equivalents

At June 30, 2019, the Company's cash equivalents are comprised of U.S. Treasury money market funds whose value is based upon quoted market prices in active markets for identical assets or liabilities with no adjustments applied. Accordingly, these investments are classified as Level 1 of the fair value measurements and disclosure guidance.

Intangible assets

In connection with the acquisition of Creabilis, the Company acquired intangible in-process research and development assets which were recorded at fair value based on significant unobservable (Level 3) inputs. The fair value of in-process research and development ("IPR&D") assets was determined by an independent third-party valuation firm applying the income approach. This approach calculates fair value by estimating future cash flows attributable to the IPR&D assets using several significant unobservable inputs, including a risk adjusted discount rate commensurate with the perceived risk of the IPR&D assets of 20.5%, projected future revenues and expenses based on the cumulative probabilities of multiple scenarios with individual probabilities ranging from 0.1% to 22.5%, and estimates of the timing of the achievement of the various product development, regulatory approval and sales milestones. These intangible assets are not measured at fair value on a recurring basis but are subject to fair value measurement as part of the related impairment test.

Warrants

In connection with the amendment to the SVB Loan Agreement, the Company issued warrants to purchase shares of the Company's common stock. Based upon the characteristics and provisions of the warrants, they were classified as equity and recorded at their fair value as of the date of issuance. The estimated fair value of the warrants was calculated using the Black-Scholes option-pricing model, using a term of 10 years, an estimated volatility of 78.02%, a risk-free interest rate of 2.75% and an expected dividend yield of 0%. The warrants are not measured at fair value on a recurring basis.

Contingent consideration

In connection with the acquisition of Creabilis, the Company agreed to pay additional amounts based on the achievement of certain development, approval and sales milestones. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Contingent consideration may change significantly as development progresses and additional data is obtained, impacting the Company's assumptions regarding probabilities of successful achievement of related milestones used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value information, judgment is required to interpret the market data used to develop the estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates.

The fair value of the contingent consideration was determined by an independent third-party valuation firm applying the income approach. This approach calculates fair value by estimating future cash flows attributable to the related IPR&D assets using several significant unobservable inputs, including risk adjusted discount rates ranging from 5.3% to 15.9%, projected future revenues and expenses based on the cumulative probabilities of multiple scenarios with individual probabilities ranging from 3.6% to 52.6%, and estimates of the probabilities and timing of the achievement of the various product development, regulatory approval and sales milestones. Significant increases or decreases in any of the probabilities of success and other inputs, such as the timing of achievement of any of the milestones, would result in a significantly higher or lower fair value measurement, respectively. Changes in the fair values of the contingent consideration obligations are recorded in general and administrative expense in the condensed consolidated statement of operations.

The change in value during the three and six months ended June 30, 2019 was a decrease of $0.3 million and an increase of $4.3 million, respectively, and the increase in value during the three and six months ended June 30, 2018 was $0.8 million and $2.3 million, respectively. The increases were primarily related to the passage of time, changes in probabilities of success, and progress toward milestone dates as well as changes in external market factors.

There were no transfers of assets or liabilities between the fair value measurement levels during the six months ended June 30, 2019 or the year ended December 31, 2018.

8. Long-Term Debt

On June 29, 2018 the Company entered into the SVB Loan Agreement with SVB. Under the SVB Loan Agreement, SVB initially provided the Company with access to term loans in an aggregate principal amount of up to $40.0 million. The first credit extension, of a principal amount of $30.0 million, was funded on June 29, 2018, and is repayable in monthly installments until July 1, 2023, including an initial interest-only period through July 31, 2020. On January 28, 2019, the Company entered into an amendment to the loan and security agreement (as amended, the "SVB Agreement"). Under the amended SVB Agreement, the Company's total access to term loans is $30.0 million.

The Company may prepay the outstanding principal balance of the term loans advanced by SVB in whole but not in part, subject to a prepayment fee ranging from 1.0% to 3.0% of any amount prepaid, depending upon when the prepayment occurs. The Company will also pay a final payment fee equal to 6.50% of the total term loans advanced, due upon the earliest of maturity, acceleration, prepayment or termination of the SVB Agreement.

If unrestricted cash at SVB falls below the greater of (i) $30.0 million and (ii) the sum of (x) $15.0 million, plus (y) the Company's six month cash burn, tested monthly as of the last day of each month, then the Company has the option to either (a) prepay the term loans in denominations of $15.0 million (plus accrued and unpaid interest, the final payment fee in respect to the portion of the terms loans being repaid and the prepayment fee in respect to the pro rata portion of the term loans being prepaid in excess of $15.0 million) or (b) immediately cash secure not less than the lesser of the outstanding balance or $15.0 million of the principal balance of all outstanding indebtedness under the term loans. Interest on the term loans accrue at a per annum rate of the greater of (i) the Wall Street Journal prime rate plus 2.50% and (ii) 7.25%. On June 30, 2019, the rate was 8.0%.

In connection with the amendment, the Company issued to SVB and its affiliate, Life Science Loans II, LLC, warrants to purchase an aggregate of 535,714 shares of the Company's common stock at an exercise price of $2.80 per share. The warrants are immediately exercisable and have a term of ten years. The Company classified the warrants as equity and their fair value at the time of issuance was determined using a Black-Scholes valuation model and was recorded in the condensed consolidated balance sheets as a debt discount to the debt obligation and will be accreted to interest expense using the effective interest method through the maturity date of the term loan.

Under the terms of the SVB Loan Agreement, the Company granted first priority liens and security interests in substantially all of the Company's assets (excluding all of its intellectual property, which is subject to a negative pledge) and a pledge of the shares of one of its wholly-owned subsidiaries as collateral for the obligations thereunder. The SVB Loan Agreement also contains representations and warranties by the Company and SVB and indemnification provisions in favor of SVB and customary covenants (including limitations on other indebtedness, liens, acquisitions, and investments and dividends), and events of default (including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of SVB's security interest in the collateral, and events relating to bankruptcy or insolvency).

As of June 30, 2019, the carrying value of the term loan consists of $30.0 million principal outstanding less the debt issuance costs of approximately $0.1 million and the warrants of approximately $1.1 million. The final maturity payment of $2.0 million is recognized over the life of the term loan through interest expense using the effective interest method. The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan. The amended SVB Agreement was accounted for as a debt modification. Accordingly, issuance costs paid to the lender in connection with the amendment were recorded as a reduction of the carrying amount of the debt liability and were not significant. Issuance costs paid to third parties were recorded as expense and were not significant. The previously deferred fees and costs related to the debt will continue to be amortized over the remaining term.

Interest expense relating to the term loan for the three and six months ended June 30, 2019 was $0.8 million and $1.6 million, respectively. Interest expense relating to the term loan for the three months ended June 30, 2018 was $8,000. Interest expense is calculated using the effective interest method, and is inclusive of non-cash amortization of capitalized loan costs. At June 30, 2019, the effective interest rate was 10.9%.

Future principal payments for the long-term debt are as follows (in thousands):

	June 30, 2019
2019	—
2020	4,500
2021	9,586
2022	10,393
2023	5,521
Total principal payments	30,000
Final fee due at maturity in 2023	1,950
Total principal and final fee payments	31,950
Unamortized discount, debt issuance costs and warrants	(2,476)
Long-term debt, net	$29,474

9. Commitments and Contingencies

Operating Lease

In May 2016, the Company entered into a 40-month operating lease obligation for office space in Westlake Village, California ("Suite 140"), which commenced on October 10, 2016, and terminates on February 29, 2020. The lease contains a renewal option for an additional three-year term. At January 1, 2019, it was reasonably certain that the Company would exercise the renewal option on Suite 140. The Company recorded a $36,000 adjustment to the opening balance of accumulated deficit, upon adopting ASU 2016-02, to recognize the cumulative effect of the updated lease term on previously recorded straight-line rent expense.

In June 2017, the Company amended the lease agreement to include an additional 5,973 square feet ("Suite 215") and an allowance for leasehold improvements of up to $0.1 million. In March 2019, the Company subleased Suite 215 and received an upfront payment of $0.1 million for rental income on the sublease. The lease and sublease terminate concurrently on February 29, 2020. The Company does not plan on exercising a renewal option for Suite 215.

On January 1, 2019, the Company adopted ASC 842, which resulted in the recognition of right-of-use ("ROU") assets of approximately $0.8 million and related lease liabilities in the consolidated balance sheets of approximately $1.0 million related to its operating lease commitments. ROU assets represent the Company's right to control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As most of its leases do not provide an implicit rate, the Company used its incremental borrowing rate based on the information available at the commencement date in determining the discount rate used to present value the lease payments. At January 1, 2019, the discount rate used to present value the lease payments was 12.5%. The Company's leases typically do not include any residual value guarantees, bargain purchase options, or asset retirement obligations.

In March 2019, in connection with the sublease of Suite 215, the Company evaluated the ROU asset for impairment. Because the lease payments for Suite 215 exceeded the sublease income over the remaining lease term, the Company recorded an impairment charge of $13,000 to write-down the ROU asset to the fair value of the sublease income over the remaining term.

As of June 30, 2019 the balance of the ROU asset was $0.7 million and the balance of the lease liability was $0.8 million, of which $0.5 million is considered long-term and $0.3 million is considered short-term and is included in other accrued expenses. Also included in other accrued expenses is a prepaid rent liability of $72,000 for the upfront payment received in connection with the sublease of Suite 215.

Total operating lease expense for the three and six months ended June 30, 2019 was $0.1 million and $0.2 million, respectively. Total sublease income for the three and six months ended June 30, 2019 was $27,000 and $36,000, respectively.

Supplemental cash flow information for the six months ended June 30, 2019 related to operating leases is as follows (in thousands):

	Six Months Ended June 30, 2019
Cash paid for amounts included in the measurement of operating lease liabilities	$ 215
Right-of-use assets obtained in exchange for lease liabilities – operating leases	$ 844

As of June 30, 2019, the maturities of the Company's operating lease liabilities are as follows (in thousands):

2019 (remaining six months)	$ 217
2020	272
2021	239
2022	239
2023	40
Total operating lease payments	1,007
Less: imputed interest	(174)
Total operating lease liabilities	$ 833

As of June 30, 2019, the weighted average remaining lease term for the company's operating leases was 3.2 years.

License and Supply Agreement

The Company has an amended and restated exclusive license agreement with nanoComposix, pursuant to which the Company owes minimum annual royalties of $50,000 or low single digit royalties on net sales of licensed products.

Success Payment Liability

In October 2015, the Company entered into a letter agreement with certain stockholders pursuant to which the Company agreed to make success payments to such stockholders. The agreement ends on its fifth anniversary in October 2020. Success payments are payable in cash or common stock at the Company's sole discretion and will be owed in the event that the value of its common stock meets or exceeds certain specified share price thresholds on certain specified dates during the success payment period. Each success payment and the associated share price threshold is ascending from $10.0 million payable at a share price threshold of $53.71 per share to $35.0 million payable at $71.61 per share and with a maximum payment of $60.0 million at a share price threshold of $107.42 per share. Each success payment is inclusive of any preceding payments, if previously made, such that the success payments to stockholders will not exceed $60.0 million in the aggregate.

Upon their issuance, the success payments did not require any future service to be provided by the recipients and as such, the success payments were accounted for under accounting guidance for derivatives and hedging. Accordingly, the Company recorded an initial liability at fair value and remeasured the liability each reporting period, with changes being recognized in the consolidated statement of operations in other income and expense. The fair value of the success payments liability was estimated based on a third-party valuation using a model which simulates the future movement of stock prices based on several key variables. As of June 30, 2019 and December 31, 2018, the success payment liability was immaterial. During the three and six months ended June 30, 2018, the Company recorded other income of $1.2 million and $2.4 million, respectively, due to remeasurement of the liability. There was no change in the liability during the three and six months ended June 30, 2019.

Indemnifications

The Company has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to certain limits, while the directors and executive officers are serving at the Company's request in such capacities. There have been no claims to date and the Company did not accrue any liabilities related to these agreements as of June 30, 2019 and December 31, 2018.

Contingencies

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business, including those set forth in Part II, Item 1 "Legal Proceedings". As of June 30, 2019, there are no matters where there is at least a reasonable possibility that a material loss has been or will be incurred.

10. Related Party Transactions

Venvest Biotech, LLC

Dr. Beddingfield, the Company's President and Chief Executive Officer and a member of the Company's board of directors, is an advisor to Venvest Biotech, LLC, or Venvest, and is considered a non-managing member of Venvest. Dr. Beddingfield has an economic interest in any gain associated with the shares of the Company's capital stock purchased by Venvest in the Company's Series A-3 and Series B Preferred Stock financings. On May 17, 2018, Dr. Beddingfield acquired 47,594 shares pursuant to a mandatory distribution from Venvest, resulting from the economic gain associated with those shares. Dr. Beddingfield has resigned from his advisory role, is no longer a member of Venvest, and has no management or voting rights in respect of Venvest.

Stock Purchase Rights

In January 2016, in connection with his commencement of employment with the Company, the Company's board of directors granted Dr. Beddingfield, the Company's President and Chief Executive Officer, the right to purchase 553,652 shares of the Company's common stock for a purchase price of $2.35 per share, which the board of directors determined was the fair market value on the date of grant. With respect to 454,912 shares subject to the stock purchase right, 25% of the shares vest on the first anniversary of the grant, and 1/48th of the shares vest monthly thereafter, subject to Dr. Beddingfield continuing to provide services to the Company through each such vesting date. With respect to 49,370 shares subject to the stock purchase right, 50% of the shares vest on the first date the volume-weighted average trading price of the Company's common stock equals or exceeds $71.03 per share, and 1/24th of the shares

vest monthly thereafter, subject to Dr. Beddingfield continuing to provide services to the Company through each such vesting date. With respect to the remaining 49,370 shares subject to the stock purchase right, 50% of the shares vest upon achievement of a milestone related to clinical development, and 1/24th of the shares vest monthly thereafter, subject to Dr. Beddingfield continuing to provide services to the Company through each such vesting date. On December 3, 2018, 50% of these shares vested as a result of achieving the clinical development milestone relating to the top-line results from the Phase 2b study of SNA-120 for the treatment of itch and psoriasis. The Company determined that the stock purchase rights effectively represented an option and the fair value of the option was $1.3 million which is being amortized as compensation expense over the performance period of the award with $0.1 million and $0.2 million recognized as compensation expense for the three and six months ended June 30, 2019, respectively and $0.1 million and $0.1 million recognized as compensation expense for the three and six months ended June 30, 2018, respectively.

In May 2016, Dr. Beddingfield exercised his stock purchase rights in full and purchased restricted stock that vests on the same schedule as the stock purchase rights. As of December 31, 2018, 0.4 million shares subject to the award had vested, and an additional 63,036 shares vested during the six months ended June 30, 2019.

Success Payments

Todd Harris, a member of the Company's board of directors, is a beneficiary of the Success Payments Agreement, as described in Note 9 "Commitments and Contingencies—Success Payment Liability" and will receive 25.22% of any related payouts.

11. Stockholders' Equity

As of June 30, 2019, the authorized stock of the Company was 300.0 million shares of common stock, $0.0001 par value per share, and 10.0 million shares of preferred stock, $0.0001 par value per share.

Common Stock

Holders of common stock are entitled to one vote per share and, upon liquidation, dissolution, or winding up of the Company, are entitled to receive all assets available for distribution to stockholders. The holders have no preemptive or other subscription rights and there are no redemption or sinking fund provisions with respect to such shares.

Shares of common stock reserved for future issuance are as follows (in thousands):

	June 30, 2019
Common stock awards outstanding	2,822
Restricted stock units outstanding	745
Common stock awards available for grant under employee benefit plans	1,091
Common stock warrants outstanding	536
Total shares of common stock reserved for future issuance	5,194

Convertible Preferred Stock

As of June 30, 2019 and December 31, 2018, there was no convertible preferred stock outstanding.

ATM Offering Program

In August 2018, the Company entered into a sales agreement with Cowen pursuant to which the Company may sell from time to time, at its option, up to $75.0 million of the Company's common stock through ATM Offering Program, under which Cowen will act as sales agent. The aggregate compensation payable to Cowen shall be 3% of the gross sales price of the common stock sold by Cowen pursuant to the Sales Agreement. During the year ended December 31, 2018, the Company issued 340,307 shares of its common stock through its ATM Offering Program and received net proceeds of approximately $5.0 million, after deducting commissions of $0.2 million and other offering expenses of $0.4 million. During the three and six months ended June 30, 2019, the Company issued an additional 329,588 shares of its common stock and received net proceeds of approximately $0.4 million, after deducting commissions of $18,000 and other offering expenses of $0.1 million.

Stock Awards and Stock-Based Compensation

In July 2017, the Company's board of directors approved the 2017 Incentive Award Plan, or the 2017 Plan, which became effective upon the completion of the Company's initial public offering ("IPO") on August 1, 2017. The 2017 Plan serves as the successor incentive award plan to the Company's 2010 Equity Incentive Plan, or the 2010 Plan, and has 0.6 million shares of common stock available at June 30, 2019 for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock-based awards, plus shares of common stock that were reserved for issuance pursuant to future awards under the 2010 Plan at the time the 2017 Plan became effective, plus shares represented by awards outstanding under the 2010 Plan that are forfeited or lapse unexercised and which following the effective date of the 2017 Plan are not issued under the 2010 Plan. In addition, the 2017 Plan reserve increased on January 1, 2018 and 2019 and will increase further on each subsequent anniversary through 2027, by an amount equal to the lesser of (a) four percent of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (b) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 12.0 million shares of stock may be issued upon the exercise of incentive stock options.

The terms of awards pursuant to the 2017 Plan are determined by the administrator of the 2017 Plan. The 2017 Plan is administered by the compensation committee of the Company's board of directors unless the Company's board of directors assumes authority for administration. In addition, the Company's board of directors has delegated authority to grant awards to employees other than executive officers and certain senior executives of the Company to a committee consisting of the Company's chief executive officer. Stock options granted pursuant to the 2017 Plan must have an exercise price of not less than the fair market value of the Company's common stock on the date of grant, except that incentive stock options granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of the Company's capital stock (a "10% Holder"), must have an exercise price of at least 110% of the fair market value of a share of common stock on the date of grant. Stock options granted under the 2017 Plan generally expire ten years from the date of the grant, except that incentive stock options granted to a 10% Holder must not be exercisable after five years from the date of grant. The Company's stock awards under the 2017 Plan vest based on terms in the stock award agreements and generally vest over four years.

Following the Company's IPO and in connection with the effectiveness of the Company's 2017 Plan, the 2010 Plan terminated and no further awards will be granted under that plan. However, all outstanding awards under the 2010 Plan will continue to be governed by their existing terms.

The fair value of each employee award granted during 2019 and 2018 was estimated on the grant date using the Black-Scholes option-pricing model. Prior to the adoption of a new accounting pronouncement on January 1, 2019 related to share-based payments issued to non-employees for goods or services, the fair value of each non-employee option granted was estimated on the grant date using the Black-Scholes option-pricing model and subsequently remeasured each reporting period. Under the new guidance, the measurement of equity-classified non-employee awards is fixed at the grant date, and no longer remeasured. The Company estimates the fair value of restricted stock unit awards based on the closing price of the Company's common stock on the date of issuance.

In determining the fair value of stock options granted, the following weighted average assumptions were used in the Black-Scholes option-pricing model for awards granted for the six months ended June 30, 2019 and the year ended December 31, 2018.

	Six Months Ended June 30, 2019	Year Ended December 31, 2018
Expected stock price volatility	69.91–75.27%	65.40–74.21%
Expected dividend yield	— %	— %
Expected term (in years)	2.0–5.6	5.0–6.1
Risk-free interest rate	2.03%–2.52%	2.55–3.06%

Due to limited historical data, the Company estimates stock price volatility based on a combined weighted average of the Company's historical average volatility and that of a selected peer group of comparable publicly traded companies over the expected life of the award. The Company has never paid and does not expect to pay dividends in the foreseeable future. The expected term represents the average time that awards that vest are expected to be outstanding. For employee awards that have an early exercise provision, the Company has sufficient information to utilize four years as an expected term. For awards without an early exercise provision, the Company does not have sufficient history of stock option exercises to estimate the expected term and, thus, calculates expected term using the simplified method, based on the midpoint between the average vesting date and the contractual term. For all non-employees, the expected term is equivalent to the contractual term of 10 years. The risk-free interest rate is based on the United States Treasury yield curve for the expected life of the option. For awards issued prior to the listing of the Company's common stock on Nasdaq, the fair value of the common stock utilized in the fair value estimation of award arrangements has been determined by the Company's board of directors, utilizing contemporaneous third-party valuations. Following the listing of the common stock on Nasdaq, the Company uses its closing stock price as reported on Nasdaq on the grant date for the fair value of its stock. The Company has elected to record forfeitures as they occur and does not adjust its expense based on an estimated forfeiture rate.

Stock Options

The table below summarizes the stock option activity for the six months ended June 30, 2019:

	Number of Shares (in thousands)	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	2,263	$ 12.42	$ —
Granted	1,155	2.18	
Exercised	—	—	—
Cancelled	(596)	12.82	
Outstanding at June 30, 2019	2,822	$ 8.21	$ —
Exercisable at June 30, 2019	988	$ 8.38	$ —

Restricted Stock Units (RSUs)

The table below summarizes the RSU activity for the six months ended June 30, 2019:

	Number of RSUs (in thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	—	$ —
Granted	816	2.32
Vested	—	—
Cancelled	(71)	2.32
Unvested balance at June 30, 2019	745	$ 2.32

The Company did not grant any non-employee options to purchase shares of its common stock during the six months ended June 30, 2019 and 2018.

Total compensation cost recorded in the condensed consolidated statements of operations and comprehensive loss, which includes non-cash stock-based compensation expense, restricted shares issued to non-employees subject to vesting and the value of stock options issued to non-employees for services and non-cash stock-based compensation expense relating to the ESPP are allocated as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Research and development	$ 429	$ 287	$ 843	$ 730
General and administrative	442	708	1,561	1,166
	$ 871	$ 995	$2,404	$1,896

As of June 30, 2019, there was $10.0 million of unrecognized compensation expense related to unvested employee stock award agreements, which is expected to be recognized over a weighted-average period of approximately 2.54 years. For stock option awards subject to graded vesting, the Company recognizes compensation cost on a straight-line basis over the service period for the entire award.

The weighted-average grant date fair value of all stock options granted during the six months ended June 30, 2019 was $1.67. The weighted-average remaining contractual life of options outstanding at June 30, 2019 is 8.8 years. The total fair value of the shares vested during the six months ended June 30, 2019 was $3.2 million. Additionally, stock-based compensation expense includes $20,000, $62,000, $0.1 million and $0.3 million related to non-employee option grants during the three and six months ended June 30, 2019 and 2018, respectively.

Prior to its termination in connection with the effectiveness of the 2017 Plan, the 2010 Plan allowed the Company to grant to employees the right to exercise stock options in exchange for cash before the requisite service was provided (e.g., before the award is vested under its original terms); however, such arrangements permit the Company to subsequently repurchase such shares at the exercise price if the employee ceases to be a service provider. Such an exercise is not substantive for accounting purposes. Therefore, the payment received for the exercise price is recognized as an early exercise liability in the consolidated balance sheets and will be transferred to common stock and additional paid-in capital as such shares vest. As of June 30, 2019 and December 31, 2018, 197,971 and 307,504 unvested shares, respectively, were legally issued but are not considered outstanding for accounting purposes and are therefore excluded from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. In connection with these unvested shares, the Company has recorded an early exercise liability as of June 30, 2019 and December 31, 2018, of $0.1 million and $0.3 million, respectively of which $0.1 million and $0.2 million is included in other accrued expenses, and $2,000 and $0.1 million is included in other long-term liabilities in the condensed consolidated balance sheets at June 30, 2019 and December 31, 2018, respectively.

Warrants

In January 2019, in connection with the amendment to the SVB Loan Agreement, the Company issued warrants to purchase an aggregate of 535,714 shares of the Company's common stock at an exercise price of $2.80 per share. Based upon the characteristics and provisions of the warrants, they were classified as equity and recorded at their fair value as of the date of issuance of $1.1 million to additional paid-in capital, with no further adjustments to their valuation. The estimated fair value of the warrants was calculated using the Black-Scholes option-pricing model, using assumptions that are based on the individual characteristics of the warrants on the valuation date, as well as assumptions for expected volatility, expected life, yield and risk-free interest rate.

2017 Employee Stock Purchase Plan

The Company adopted the 2017 Employee Stock Purchase Plan, or the ESPP, which became effective upon the completion of the IPO on August 1, 2017. The ESPP is designed to allow the Company's eligible employees to purchase shares of the Company's common stock, at semi-annual intervals, with their accumulated payroll deductions. Under the ESPP, participants are offered the option to purchase shares of the Company's common stock at a discount during a series of successive offering periods. The option purchase price will be the lower of 85% of the closing trading price per share of the Company's common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period. The Company began the first offering period on December 31, 2017.

The ESPP is intended to qualify under Section 423 of the U.S. Internal Revenue Service Code of 1986, as amended. The maximum number of the Company's common stock which will be authorized for sale under the ESPP is equal to the sum of (a) 198,883 shares of common stock and (b) an annual increase on the first day of each year beginning in 2018 and ending in 2027, equal to the lesser of (i) 1% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors; provided, however, no more than 3.0 million shares of the Company's common stock may be issued under the ESPP. The ESPP has 0.5 million shares of common stock reserved for future issuance pursuant to the plan.

The Company recognized $0.1 million in compensation expense related to the ESPP for the three and six months ended June 30, 2019, and $0.1 million and $0.2 million for the three and six months ended June 30, 2018, respectively. As of December 31, 2018, 67,508 shares of common stock were issued under the ESPP, and an additional 26,886 shares were issued during the six months ended June 30, 2019.

12. Income Taxes

There is no provision for income taxes for the three and six months ended June 30, 2019, as the Company has incurred operating losses since inception.

The Company has evaluated the available evidence supporting the realization of its deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that its net deferred tax assets will not be realized in the United States and certain foreign jurisdictions. Due to uncertainties surrounding the realization of the deferred tax assets, the Company maintains a full valuation allowance against substantially all deferred tax assets. When the Company determines that it will be able to realize some portion or all of its deferred tax assets, an adjustment to its valuation allowance on its deferred tax assets would have the effect of increasing net income in the period such determination is made.

As of June 30, 2019, the Company does not have any accrued interest or penalties related to uncertain tax positions. The Company's policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. The Company is subject to U.S. federal tax authority and U.S. state tax authority examinations for all years with the net operating loss and credit carryforwards.

13. Subsequent Events

On August 5, 2019, the Company announced that it has retained Cowen as an independent financial advisor to assist in exploring financial and strategic alternatives designed to maximize shareholder value. With Cowen's assistance, the Company will continue to explore capital raising to enable the initiation of its planned Phase 3 pivotal clinical trials for its lead product candidate, SNA-120, for psoriasis and the associated pruritus, in addition to exploring a wide range of financial and strategic alternatives. The Company may be unable to identify or execute such financial or strategic alternatives, and even if executed, such financial or strategic alternatives may not enhance stockholder value or the Company's financial position. The Company does not intend to initiate its planned Phase 3 clinical trials of SNA-120 until the Company secures sufficient additional capital.

On August 1, 2019, in order to retain and incentivize current employees, the Company's Board of Directors approved a repricing of 1,854,462 stock options held by current employees granted prior to August 1, 2019. The options had exercise prices between $2.32 and $20.53 per share, which were reduced to $0.71, the closing price of the Company's common stock as of August 6, 2019. There were no modifications to the vesting schedules of the previously issued options. The repricing of the options will be treated as a modification for accounting purposes and any incremental compensation expense for vested stock options calculated using the Black-Scholes option-pricing model will be recorded in the consolidated statement of operations and comprehensive loss for the quarter ending September 30, 2019. The incremental expense together with the unamortized expense remaining on any unvested options will be amortized over the remaining vesting periods.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q, and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2018, which has been filed with the Securities and Exchange Commission, or SEC.

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we or others on our behalf may make forward-looking statements in press releases or written statements or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage biopharmaceutical company focused on bringing unconventional scientific innovations to patients whose lives remain burdened by their disease. We draw upon our deep knowledge and experience in drug development across multiple therapeutic areas as we build a unique, diversified, multi-asset portfolio of therapies in inflammation and immunology that target select pathways in specific tissues, with our initial focus on one of the most important 'immune' tissues, the skin. Utilizing our novel technology platform, we apply a scientific design process to create potent targeted pharmacologically active molecules that are directed toward a specific target tissue and a select disease pathway, and with minimal to no systemic exposure. Our lead candidate from this platform, SNA-120, is a first-in-class inhibitor of Tropomyosin receptor kinase A (TrkA) which we are developing for the treatment of psoriasis, as well as the associated pruritus (itch). Our second product candidate, SNA-125, is a dual Janus kinase 3 (JAK3)/TrkA inhibitor which we are developing for the treatment of atopic dermatitis, psoriasis and the associated pruritus. Additionally, SNA-001, a silver photoparticle technology derived from our Topical Photoparticle Therapy™ platform to be used in conjunction with commonly used commercial lasers, completed in the first quarter of 2019 pivotal clinical trials for the reduction of unwanted light-pigmented hair and for the treatment of acne. We are seeking a strategic partner to maximize the value of SNA-001. We believe our management team is well positioned to execute on our objectives, having served in clinical, commercial and other leadership roles at several marquee biotechnology and pharmaceutical companies, including Kythera, Amgen, Allergan, Medicis and Celgene.

Since our inception in 2010, we have invested a significant portion of our efforts and financial resources in research and development activities. We have not generated any revenue from product sales and, to date, have funded our operations primarily through private and public equity issuances, debt offerings and term loans. At June 30, 2019, we had cash and cash equivalents of $49.2 million. On June 29, 2018, we entered into a loan and security agreement with Silicon Valley Bank, pursuant to which Silicon Valley Bank agreed to make available to us term loans with an aggregate principal amount of up to $40.0 million, pursuant to which we have drawn $30.0 million. Subsequently, in January 2019, we entered into an amendment to the loan and security agreement which limited our total access to term loans to the $30.0 million we have already drawn, imposed additional minimum liquidity requirements, and increased the final payment fee by 1% to 6.5% of the total term loans advanced. In addition, we issued to SVB and its affiliate, Life Science Loans II, LLC, warrants to purchase an aggregate of 535,714 shares of our common stock at an exercise price of $2.80 per share.

In August 2018, we entered into a Sales Agreement with Cowen and Company, LLC ("Cowen"), pursuant to which we may sell from time to time, at our option, up to $75.0 million of our common stock through an "at-the-market" equity offering program under which Cowen will act as sales agent (the "ATM Offering Program"). During the three and six months ended June 30, 2019, the Company issued 329,588 shares of its common stock through the ATM Offering Program and received net proceeds of approximately $0.4 million, after deducting commissions of $18,000 and other offering expenses of $0.1 million.

In February 2019, we completed an underwritten public offering of 9,200,000 shares of our common stock at a price to the public of $2.50 per share, including 1,200,000 shares of common stock pursuant to the underwriters' option to purchase additional shares. Our net proceeds, after deducting underwriting discounts, commissions and offering related transaction costs, were $21.4 million.

We have incurred net losses in each year since inception, including net losses of $8.3 million and $24.6 million for the three and six months ended June 30, 2019, and $20.2 million and $37.3 million and for the three and six months ended June 30, 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $184.1 million. We expect to continue to incur losses for the foreseeable future and expect to incur increased expenses as we advance our product candidates through clinical trials and regulatory submissions. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval or clearance from the U.S. Food and Drug Administration ("FDA") for our product candidates. If we obtain regulatory approval or clearance for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect to continue to incur losses as we progress nonclinical studies and clinical trials for, and research and development of, our product candidates and maintain and protect our intellectual property portfolio. As a result, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, consolidated results of operations and financial condition.

We rely on third parties in the conduct of our nonclinical studies and clinical trials and for manufacturing and supply of our product candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, many of whom are single-source suppliers, for our nonclinical and clinical trial materials. In addition, we do not yet have a sales organization or commercial infrastructure. Accordingly, we will incur significant expenses to develop a sales organization or commercial infrastructure in advance of generating any product sales.

Through our acquisition of Creabilis we obtained our proprietary technology platform and related product candidates, including SNA-120 and SNA-125. As part of the terms of the acquisition we will be required to make contingent payments in cash and stock upon the achievement of certain development, approval and sales milestones. Upon the achievement of certain specified development and approval milestones for SNA-120 and SNA-125, we are obligated to pay the former Creabilis shareholders up to $53.0 million, which consists of an aggregate of $25.0 million in cash and $28.0 million in shares of our common stock. As part of these milestones, upon the commencement of the first Phase 3 clinical trial of SNA-120, we will become obligated to issue $18.0 million in shares of our common stock, less certain offsets if applicable, to the former Creabilis shareholders. In addition, upon the achievement of certain annual net sales milestone thresholds for qualifying products, including SNA-120 and SNA-125, we are required to pay the former Creabilis shareholders up to an aggregate of $80.0 million in cash as well as one-time royalties of less than 1% on net sales of qualified products that exceed these net sales thresholds in the year such threshold is achieved. See "Critical Accounting Policies and Use of Estimates—Contingent Consideration" below.

In January 2019, we implemented a corporate restructuring to focus resources on our lead product candidate, SNA-120 for psoriasis and the associated pruritus, resulting in a reduction in force to reduce operational costs and preserve capital. The restructuring resulted in an elimination of 20 positions. We completed the workforce reduction in the first quarter of 2019. We recorded one-time cash related charges of approximately $0.8 million for employee severance, other related termination benefits and contract termination fees.

On August 5, 2019, we announced that we had retained Cowen as an independent financial advisor to assist in exploring financial and strategic alternatives designed to maximize shareholder value. With Cowen's assistance, we will continue to explore capital raising to enable the initiation of our planned Phase 3 pivotal clinical trials for SNA-120, in addition to exploring a wide range of financial and strategic alternatives. We may be unable to identify or execute such financial or strategic alternatives, and even if executed, such financial or strategic alternatives may not enhance stockholder value or our financial position. We do not intend to initiate our planned Phase 3 clinical trials of SNA-120 until we secure sufficient additional capital.

Components of Our Results of Operations

Revenue

We have not generated any revenue from the sale of our products, and we do not expect to generate any revenue unless and until we obtain regulatory clearance or approval of, and commercialize, our product candidates, or enter into an out-license agreement or collaboration for any of our product candidates.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. Research and development costs are expensed as incurred. These costs include direct program expenses, which are payments made to third parties that specifically relate to our research and development, such as payments to clinical research organizations, clinical investigators, manufacturing of clinical material, pre-clinical testing and consultants. In addition, employee costs (including salaries, payroll taxes, benefits, stock-based compensation and travel) for employees contributing to research and development activities are classified as research and development costs. We allocate direct external costs to our product candidates; internal costs are not allocated to specific product candidates. Based on our revised clinical plans following our January 2019 restructuring, we expect research and development expenses to decrease, compared to 2018, until such time as we secure sufficient additional capital and initiate our Phase 3 clinical trials for SNA-120. In addition to our internal discovery efforts, we may choose, capital permitting, to selectively in-license or acquire complementary, external product candidates.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of SNA-120 and SNA-125 or any future product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See "Item 1A. Risk Factors" for a discussion of the risks and uncertainties associated with our research and development projects.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, stock-based compensation and travel. Other general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, professional services fees for auditing, tax, marketing and general legal services, insurance premiums, and the changes in the fair value of our contingent consideration liability. Based on our revised clinical plans following our January 2019 restructuring, we expect general and administrative expenses to decrease in the near term, compared to 2018. However, subject to the availability of sufficient capital, we would expect our general and administrative expenses to eventually increase in the future as we expand our operating activities and prepare for potential commercialization of our product candidates, and support a public company, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, foreign subsidiary management, directors and officers liability insurance premiums and investor relations activities.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts

of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2018, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements and understanding and evaluating our reported financial results.

Clinical Trial Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Our objective is to reflect the appropriate trial expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, we adjust the rate of clinical expense recognition if actual results differ from our estimates. We make estimates of accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known at that time. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period. Through June 30, 2019, there have been no material adjustments to our prior period estimates of accrued expenses for clinical trials. Our clinical trial accrual is dependent in part upon the timely and accurate reporting of contract research organizations and other third-party vendors.

In-Process Research and Development and Goodwill

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date (which is regarded as their cost). Intangible assets related to in-process research and development, ("IPR&D"), are treated as indefinite lived intangible assets and not amortized until completion of the associated research and development efforts, typically upon regulatory approval. At that time, we will determine the useful life of the asset and begin amortization. Intangible assets are reviewed for impairment at least annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. There were no impairments of intangible assets for the six months ended June 30, 2019 or the year ended December 31, 2018.

Determining fair value for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Goodwill represents the excess of the purchase price over the estimated fair value of the identifiable assets acquired and liabilities assumed in a business combination. We evaluate goodwill for impairment annually and upon the occurrence of triggering events or substantive changes in circumstances that could indicate a potential impairment. An impairment loss is recognized when the fair value of the reporting unit to which the goodwill relates is below its carrying value for the difference between the fair value and its carrying amounts. The recent decline in our market capitalization was determined to be a triggering event for potential goodwill impairment and accordingly, we performed the goodwill impairment analysis.

In determining the fair value utilized in the goodwill impairment assessment, we considered qualitative factors such as changes in strategy, cash flows, the regulatory environment, overall market conditions, as well as the market capitalization of our publicly traded common stock. We operate as a single reporting unit and estimates the fair value of our single reporting unit using our market capitalization plus an estimated control premium. Market capitalization is determined by multiplying the shares outstanding on the assessment date by the market price of our common stock. If it is determined through the impairment evaluation process that goodwill has been impaired, an impairment charge would be recorded in the consolidated statement of operations and comprehensive loss. We completed the impairment test and determined that there was no impairment.

Our share price is highly volatile and subsequent declines in the market share price could pose risks of impairment in the future. It is not possible at this time to determine if an impairment charge would result from these factors, or, if it does, whether such charge would be material. We will continue to monitor the recoverability of our goodwill. There was no impairment of goodwill for the six months ended June 30, 2019 and the year ended December 31, 2018.

Stock-Based Compensation

We measure employee and director stock-based compensation expense for all stock-based awards at the grant date based on the fair value measurement of the award. The expense is recorded on a straight-line basis over the requisite service period, which is generally the vesting period, for the entire award. Expense is adjusted for actual forfeitures of unvested awards as they occur. Prior to the adoption of a new accounting pronouncement on January 1, 2019, related to share-based payments issued to non-employees for goods or services, stock options issued to non-employees were valued on their grant date and remeasured at the current fair value at the end of each reporting period until they vested. Under the new guidance, the measurement of equity-classified non-employee awards is fixed at the grant date, and no longer remeasured. We estimate the fair value of restricted stock unit awards based on the closing price of our common stock on the date of issuance.

We calculate the fair value measurement of stock options using the Black-Scholes valuation model. In determining the fair value of stock options granted, the following weighted average assumptions were used in the Black-Scholes option-pricing model for awards granted for the six months ended June 30, 2019 and the year ended December 31, 2018.

	Six Months Ended June 30, 2019	Year Ended December 31, 2018
Expected stock price volatility	69.91–75.27%	65.40–74.21%
Expected dividend yield	— %	— %
Expected term (in years)	2.0–5.6	5.0–6.1
Risk-free interest rate	2.03–2.52%	2.55–3.06%

Due to limited historical data, we estimate stock price volatility based on a combined weighted average of the Company's historical average volatility and that of a selected peer group of comparable publicly traded companies over the expected life of the award. We have never paid, and do not expect to pay dividends in the foreseeable future. The expected term represents the average time that awards that vest are expected to be outstanding. For employee awards that have an early exercise provision, there is sufficient information to utilize four years as an expected term. For awards without an early exercise provision, there is not sufficient history of stock option exercises to estimate the expected term and, thus, we calculate the expected term using the simplified method, based on the midpoint between the average vesting date and the contractual term. For all non-employees, the expected term is equivalent to the contractual term of 10 years. The risk-free interest rate is based on the United States Treasury yield curve for the expected life of the option. For awards issued prior to the listing of our common stock on the Nasdaq Global Select Market, or Nasdaq, the fair value of the common stock utilized in the fair value estimation of award arrangements has been determined by our board of directors, utilizing contemporaneous third-party valuations. Following the listing of our common stock on Nasdaq, we use the closing stock price as reported on Nasdaq on the grant date for the fair value of its stock.

We recorded noncash stock-based compensation expense for employee and nonemployee stock option grants and the ESPP for the three and six months ended June 30, 2019 and 2018, as follows:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Research and development	$ 429	$ 287	$ 843	$ 730
General and administrative	442	708	1,561	1,166
	$ 871	$ 995	$2,404	$1,896

As of June 30, 2019, there was $10.0 million of unrecognized compensation expense related to unvested employee stock award agreements, which is expected to be recognized over a weighted-average period of approximately 2.54 years. For stock option awards subject to graded vesting, we recognize compensation cost on a straight-line basis over the service period for the entire award.

Prior to its termination in connection with the effectiveness of our 2017 Incentive Award Plan, our 2010 Equity Incentive Plan allowed us to grant to employees the right to exercise stock options in exchange for cash before the requisite services are provided (e.g., before the award is vested under its original terms); however, such arrangements permit us to subsequently repurchase such shares at the exercise price if the employee ceases to be a service provider. Such an exercise is not substantive for accounting purposes. Therefore, the payment received for the exercise price is recognized as an early exercise liability in the consolidated balance sheets and will be transferred to common stock and additional paid-in capital as such shares vest. As of June 30, 2019 and December 31, 2018, 197,971 and 307,504 unvested shares were issued and outstanding, respectively. In connection with these unvested shares, we recorded an early exercise liability as of June 30, 2019 and December 31, 2018 of $0.1 million and $0.3 million, respectively, of which $0.1 million and $0.2 million is included in other accrued expenses and $2,000 and $0.1 million is included in other long-term liabilities in the condensed consolidated balance sheets at June 30, 2019 and December 31, 2018, respectively. These shares are excluded from basic net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature.

Contingent Consideration

In December 2016, we entered into a Share Purchase Agreement, or the Purchase Agreement, to acquire the entire issued share capital of Creabilis. Upon closing of the transaction, we obtained our proprietary technology platform and related product candidates, including SNA-120 and SNA-125. As part of the terms of the agreement, we agreed to make certain contingent payments up to an aggregate of $58.0 million in a combination of cash and stock upon the achievement of certain development and approval milestones, of which $5.0 million has been previously satisfied.

Upon the commencement of the first Phase 3 clinical trial of SNA-120, we will become obligated to issue $18.0 million in shares of our common stock, less certain offsets if applicable, to the former Creabilis shareholders. In addition, we are obligated to make certain contingent payments up to an aggregate of $80.0 million in cash upon the achievement of certain annual net sales thresholds and one-time cash royalties of less than 1% of the amount by which annual net sales exceed each threshold in the year such threshold is achieved. Where milestone payments are required to be paid in stock, the number of shares will be determined based on the volume weighted average price of the common stock as reported on Nasdaq, for the preceding 20-day trading period.

The agreement to pay the future milestones and potential one-time royalties resulted in the recognition of contingent consideration, which was recognized at the inception of the transaction. Other than these payments, subsequent changes to the estimated amounts of contingent consideration to be paid are recognized in the consolidated statement of operations. The fair value of the contingent consideration is determined using preliminary cash flow projections, which are based on estimated timing and probabilities around the achievement of certain development, approval and sales milestones, expected product sales and other assumptions. The fair value of the contingent consideration was determined to be $33.5 million as of June 30, 2019 and $29.2 million as of December 31, 2018. The fair value of the contingent consideration was and continues to be determined by a third-party valuation firm by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate commensurate with our cost of capital and expectation of the revenue growth for products based on their life cycle stage.

Net Operating Loss and Research and Development Carryforwards

As of December 31, 2018, we had deferred tax assets of $45.4 million and deferred tax liabilities of approximately $10.5 million. The deferred tax assets have been offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of amortization related to capitalized R&D and net operating loss (NOL) carryforwards. As of December 31, 2018, we had federal and state NOL carryforwards of $60.0 million and foreign NOL carryforwards of $41.3 million available to potentially offset future taxable income. As of December 31, 2018, we also had federal research and development tax credit carryforwards of approximately $2.9 million available to potentially offset future federal income taxes. The federal and state NOL carryforwards and research and development tax credit carryforwards expire at various dates between 2031 and 2038. In general, if we experience a greater than 50 percentage point aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL or research and development tax credit carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended. Such limitations may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization and may be substantial. We have not

conducted an assessment to determine whether there may have been a Section 382 ownership change. If we have experienced a Section 382 ownership change or if we experience a Section 382 ownership change as a result of future changes in our stock ownership, some of which changes are outside of our control, the tax benefits related to the NOL or research and development tax credit carryforwards may be limited or lost.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

The following table sets forth our results of operations for the periods indicated:

	(unaudited) Three Months Ended June 30,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 5,084	$ 15,692	$(10,608)	(68%)
General and administrative	2,643	5,976	(3,333)	(56)
Total operating expenses	7,727	21,668	(13,941)	(64)
Loss from operations	(7,727)	(21,668)	13,941	(64)
Other income (expense), net	(537)	1,429	(1,966)	(138)
Net loss	$(8,264)	$(20,239)	$ 11,975	(59%)

Research and development expenses

Research and development expenses were $5.1 million for the three months ended June 30, 2019, compared to $15.7 million for the three months ended June 30, 2018. The decrease of $10.6 million was due to lower clinical and non-clinical costs of $7.8 million, primarily related to SNA-120 of $4.2 million, SNA-001 of $2.0 million, and SNA-125 of $1.6 million, decreased spending on early stage research of $1.1 million and decreased spending on manufacturing costs across all products of $0.9 million. Additionally, there was a decrease of $0.5 million for employee salaries and other compensation costs in connection with reductions in personnel and lower expenses for travel, meals and other outside services of $0.2 million as a result of efforts to reduce costs.

General and administrative expenses

General and administrative expenses were $2.6 million for the three months ended June 30, 2019, compared to $6.0 million for the three months ended June 30, 2018. The decrease of $3.3 million was primarily due to a $1.1 million decrease in the expense recorded to adjust the fair value of the contingent consideration liability relating to the acquisition of Creabilis. During the three months ended June 30, 2019, $0.3 million of income was recorded to reflect a reduction in the fair value of the contingent consideration liability, primarily as a result of updated assumptions around the timing of achievement of milestones. During the three months ended June 30, 2018, the Company recorded an expense of $0.8 million to reflect an increase in the fair value of the liability, primarily related to the passage of time and progress toward milestone dates. The remaining decrease in general and administrative expenses related to lower outside spending as a result of efforts to reduce costs, primarily consisting of a decrease in marketing costs of $1.0 million and a decrease in other outside services of $0.7 million. Additionally, there were decreases in personnel related costs of $0.4 million due to the reduction in force.

Other income (expense), net

Other income (expense), net was a net expense of $0.5 million and a net income of $1.4 million for the three months ended June 30, 2019 and 2018, respectively. The change of $2.0 million was primarily due to the income recorded in 2018 of $1.2 million in connection with the change in the fair value of the success payment liability at June 30, 2018 and no change in the fair value of the success payment liability during the three months ended June 30, 2019. There was also an increase in interest expense recorded in connection with the SVB term loan of $0.8 million during the three months ended June 30, 2019.

Comparison of the Six Months Ended June 30, 2019 and 2018

The following table sets forth our results of operations for the periods indicated:

	(unaudited) Six Months Ended June 30,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 12,177	$ 28,672	$(16,495)	(58%)
General and administrative	11,389	11,473	(84)	(1)
Total operating expenses	23,566	40,145	(16,579)	(41)
Loss from operations	(23,566)	(40,145)	16,579	(41)
Other income (expense), net	(1,080)	2,803	(3,883)	(139)
Net loss	$(24,646)	$(37,342)	$ 12,696	(34%)

Research and development expenses

Research and development expenses were $12.2 million for the six months ended June 30, 2019, compared to $28.7 million for the six months ended June 30, 2018. The decrease of $16.5 million in research and development expenses was primarily due to lower clinical and non-clinical costs of $12.3 million, primarily consisting of $6.2 million for SNA-120, $4.0 million for SNA-001 and $2.1 million for SNA-125. Additionally, there was decreased spending on manufacturing costs across all products of $2.0 million, and decreased spending on early stage research of $1.5 million The remaining decrease in expense related to lower outside spending as a result of efforts to reduce costs of approximately $0.5 million, primarily consisting of decreased expenses for employee travel, meals and other outside services and supplies of $0.3 million, and other decreases of $0.2 million for employee salaries and related compensation costs in connection with reductions in personnel.

General and administrative expenses

General and administrative expenses were $11.4 million for the six months ended June 30, 2019, compared to $11.5 million for the six months ended June 30, 2018. The decrease of $0.1 million in general and administrative expenses was primarily due to lower outside spending as a result of efforts to reduce costs, primarily consisting of a decrease in outside services of $1.4 million, a decrease in marketing costs of $1.0 million and a decrease in employee travel and meals of $0.1 million. These decreases were offset by a $2.0 million increase in the expense recorded to adjust the fair value of the contingent consideration liability relating to the acquisition of Creabilis. During the six months ended June 30, 2019, $4.3 million of expense was recorded to reflect an increase in the fair value of the contingent consideration liability compared to an expense of $2.3 million during the six months ended June 30, 2018. The increase in expense primarily related to changes in probabilities of success, continued passage of time and progress toward milestone dates. In addition to the contingent consideration, there was an increase in personnel related stock compensation expense of $0.4 million as a result of increased expense in connection with new annual employee grants.

Other income (expense), net

Other income (expense), net was a net expense of $1.1 million and a net income of $2.8 million for the six months ended June 30, 2019 and 2018, respectively. The net expense of $1.1 million for the six months ended June 30, 2019 was primarily due to $1.6 million of interest expense incurred in connection with the SVB term loan, offset by $0.6 million of interest earned on our cash balances. The other net income of $2.8 million for the six months ended June 30, 2018 was primarily due to the $2.4 million gain recognized on the decrease in the success payment liability and interest earned on our cash balances of $0.4 million.

Liquidity, Capital Resources and Requirements

We have incurred operating losses and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting nonclinical and clinical trials and providing general and administrative support for these operations. We had an accumulated deficit of $184.1 million and $159.4 million as of June 30, 2019 and December 31, 2018, respectively. We had net losses of $8.3 million and $24.6 million for the three and six months ended June 30, 2019, and $20.2 million and $37.3 million for the three and six months ended June 30, 2018, respectively. We had net cash used in operating activities of $21.2 million and $30.2 million for the six months ended June 30, 2019 and 2018, respectively. These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts, or amounts and classification of liabilities that might result from this uncertainty.

We have historically financed our operations primarily through private and public equity issuances and debt securities, term loans and proceeds from our ATM Offering Program, as well as our recent follow on offering that was completed in February 2019 and will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from our operations. With assistance from Cowen, our independent financial advisor, we will continue to explore capital raising to enable the initiation of our planned Phase 3 pivotal clinical trials for SNA-120, in addition to exploring a wide range of financial and strategic alternatives. However, we will not commence our planned Phase 3 clinical trials for SNA-120 until we secure sufficient additional capital.

In June 2018 we entered into the SVB Loan Agreement, pursuant to which SVB initially provided us with access to term loans in an aggregate principal amount of up to $40.0 million. On June 29, 2018, we drew down term loans of an aggregate principal amount of $30.0 million, which is repayable in monthly installments until July 1, 2023, including an initial interest-only period through July 31, 2020. In January 2019, we entered into an amendment to the loan and security agreement (as amended, the "SVB Agreement"). Under the SVB Agreement, our total access to term loans is $30.0 million and, if our unrestricted cash at SVB falls below the greater of (i) $30.0 million and (ii) the sum of (x) $15.0 million, plus (y) the Company's six month cash burn, tested monthly as of the last day of each month, then we have the option to either (a) prepay the term loans in denominations of $15.0 million (plus accrued and unpaid interest, the final payment fee in respect to the portion of the terms loans being repaid and the prepayment fee in respect to the pro rata portion of the term loans being prepaid in excess of $15.0 million) or (b) immediately cash secure not less than the lesser of the outstanding balance or $15.0 million of the principal balance of all outstanding indebtedness under the term loans. The Company may prepay the outstanding principal balance of the term loans advanced by SVB in whole but not in part, subject to a prepayment fee ranging from 1.0% to 3.0% of any amount prepaid, depending upon when the prepayment occurs. The Company will also pay a final payment fee equal to 6.50% of the total term loans advanced, due upon the earliest of maturity, acceleration, prepayment or termination of the SVB Agreement. In connection with the amendment, we issued to SVB and its affiliate, Life Science Loans II, LLC, warrants to purchase an aggregate of 535,714 shares of our common stock at an exercise price of $2.80 per share.

On August 3, 2018, we entered into a Sales Agreement with Cowen, pursuant to which we may sell from time to time, at our option, up to $75.0 million of our common stock through an ATM Offering Program. On August 3, 2018, we also filed a Registration Statement on Form S-3 (the "Shelf Registration Statement"), covering the offering up to $250.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units. The Shelf Registration Statement included a prospectus covering the offering, issuance and sale of up to $75.0 million of our common stock from time to time through the ATM Offering Program. The Registration Statement became effective on August 14, 2018. The shares to be sold under the Sales Agreement, may be issued and sold pursuant to the Shelf Registration Statement. During the year ended December 31, 2018, we issued 340,307 shares of our common stock through the ATM Offering Program and received net proceeds of approximately $5.0 million, after deducting commissions of $0.2 million and other offering expenses of $0.4 million. During the three and six months ended June 30, 2019, we issued an additional 329,588 shares of common stock through the ATM Offering Program and received net proceeds of approximately $0.4 million, after deducting commissions of $18,000 and other offering expenses of $0.1 million.

In February 2019, we completed an underwritten public offering of 9,200,000 shares of our common stock at a price to the public of $2.50 per share, including 1,200,000 shares of common stock pursuant to the underwriters' option to purchase additional shares. Our net proceeds, after deducting underwriting discounts, commissions and offering related transaction costs, were $21.4 million.

Based on our expected cash burn rate and on our available cash resources, excluding $15.0 million that will be collateralized in connection with the SVB Loan Agreement if our cash balance falls below a certain threshold, we do not have sufficient funds to support current planned operations through the twelve months from the issuance date of the unaudited condensed consolidated financial statements. We will need to raise substantial additional capital to fund our operations through the sale of our equity securities, incurring debt, entering into licensing or collaboration agreements with partners, grants or other sources of financing. On August 5, 2019, we announced that we have begun a review of financial and strategic alternatives to maximize shareholder value. We may be unable to identify or execute such financial or strategic alternatives, and even if executed, such financial or strategic alternatives may not enhance stockholder value or our financial position. There can be no assurance that sufficient funds will be available to us at all or on attractive terms when needed from these sources. In particular, our ability to raise capital through the issuance of equity securities is constrained as a result of the trading price of our common stock under applicable Nasdaq rules. Our ability to obtain debt financing may be limited by covenants we have made under our loan agreement with SVB and our pledge to SVB of substantially all of our assets, other than our intellectual property, as collateral. The negative pledge in favor of SVB with respect to our intellectual property under the loan agreement could further limit our ability to obtain additional debt financing. If we are unable to obtain additional funding from these or other sources when needed, it may be necessary to significantly reduce our current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our current product candidates or any future product candidates, and conducting nonclinical studies and clinical trials, in particular our potential Phase 3 pivotal clinical trials of SNA-120;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our lead product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing of any cash milestone payments to the former Creabilis shareholders if we successfully achieve certain predetermined milestones;
- the timing and amount of any success payments we elect to pay in cash to certain of our existing shareholders if the market price of our common stock meets or exceeds certain specified share price thresholds;
- the cost of manufacturing our lead product candidates or any future product candidates and any products we successfully commercialize, including costs associated with building our supply chain;
- the cost of commercialization activities if our lead product candidates or any future product candidates are approved or cleared for sale, including marketing, sales and distribution costs;
- the cost of building a sales force in anticipation of product commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs associated with maintaining subsidiaries in foreign jurisdictions;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including ongoing litigation costs related to SNA-001 and the outcome of this and any other future patent litigation we may be involved in; and
- the timing, receipt and amount of sales of any future approved or cleared products, if any.

Cash Flows Comparison of the Six Months Ended June 30, 2019 and 2018

The following table sets forth our cash flows for periods indicated:

	(unaudited) (in thousands) Six Months Ended June 30,	
	2019	**2018**
Net cash provided by (used in)		
Operating activities	$ (21,186)	$ (30,205)
Investing activities	(4)	(17)
Financing activities	21,878	30,674
Effect of exchange rate changes on cash	(7)	(32)
Net increase in cash, cash equivalents and restricted cash	$ 681	$ 420

Net Cash Used in Operating Activities

During the six months ended June 30, 2019, net cash used in operating activities was $21.2 million and consisted primarily of a net loss of $24.6 million and a decrease in accounts payable and other accrued liabilities of $4.7 million. The decrease in accounts payable and other accrued liabilities was primarily related to the wind down of SNA-001 and SNA-120 clinical trials and the general decrease in expenses as result of the January 2019 restructuring and related efforts to reduce spending. The net loss was offset by non-cash items, including an increase in fair value of the contingent consideration of $4.3 million, stock-based compensation expense of $2.4 million, amortization of the debt discount and issuance costs relating to the SVB term loans of $0.5 million, interest expense of $0.4 million, and a decrease in prepaid expenses and other current assets of $0.5 million.

During the six months ended June 30, 2018, net cash used in operating activities was $30.2 million and consisted primarily of a net loss of $37.3 million and a decrease in the fair value of the success payment liability of $2.4 million, offset by the increase in the fair value of the contingent consideration of $2.3 million, and the non-cash stock-based compensation expense of $1.9 million. In addition, there was a $5.1 million favorable change in accounts payable and other accrued liabilities due to our overall growth and increased research and development spending.

Net Cash Used in Investing Activities

During the six months ended June 30, 2019 and 2018, net cash used in investing activities was $4,000 and $17,000, respectively, and represented purchases of property and equipment.

Net Cash Provided by Financing Activities

During the six months ended June 30, 2019, net cash provided by financing activities was $21.9 million, which consisted primarily of the net proceeds received from the follow on offering completed in February 2019 of $21.4 million and the net proceeds received from the ATM Offering Program of $0.4 million.

During the six months ended June 30, 2018, net cash provided by financing activities was $30.7 million primarily from the $30.0 million received from the SVB Loan Agreement offset by debt issuance costs of $0.1 million. There was an additional $0.8 million relating to the proceeds from the issuance of common stock from the exercise of stock options and ESPP shares purchased.

Contractual Obligations and Contingent Liabilities

There have been no material changes to our contractual obligations and commitments compared to the disclosures in our Annual Report on Form 10-K for the year ended December 31, 2018.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our certificate of incorporation and bylaws, we have indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes in the source and effects of our market risk compared to the disclosures in our Annual Report on Form 10-K for the year ended December 31, 2018.

Interest Rate Risk

As of June 30, 2019, the outstanding principal amount of the term loans under the SVB Loan Agreement was $30.0 million. The interest payments under our term loans may be subject to interest rate risk and our interest expense could increase if market interest rates increase. The interest on the term loans accrue at a per annum rate of the greater of (i) the Wall Street Journal prime rate plus 2.50% and (ii) 7.25%. Accordingly, increases in these published rates would increase our interest payments under the term loans. The rate at June 30, 2019 was 8.00%. A hypothetical 1% change in interest rates would increase expense by approximately $0.2 million annually and would not have a material impact on our results of operations.

Cash, Cash Equivalents and Restricted Cash

As of June 30, 2019, we had cash and cash equivalents of $49.2 million and restricted cash of $0.2 million, which consist of bank deposits and cash invested in U.S. Treasury money market funds. As of December 31, 2018, we had cash and cash equivalents of $48.5 million and restricted cash of $0.2 million, which consist of bank deposits and cash invested in U.S. Treasury money market funds. Currently, a portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 1% change in interest rates during any of the periods presented would not have a material impact on our consolidated financial statements, and we do not expect interest rate fluctuations to have a material impact on our results of operations.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars. Our foreign subsidiaries operate with the euro and British pound as its functional currencies. The fluctuation in the value of the U.S. dollar against the euro and British pound affect the reported amounts of expenses, assets and liabilities. If we expand our international operations, our exposure to exchange rate fluctuations will increase. At June 30, 2019 and December 31, 2018, we had cash balances denominated in euros of $0.2 million and $0.1 million, respectively. We currently do not hedge any foreign currency exposure. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, 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, or persons performing similar functions, as appropriate, to allow for timely decisions regarding required or necessary disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives, and we are required to apply judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

Management determined that, as of June 30, 2019, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

We are, and may from time to time continue to be, involved in various legal proceedings of a character normally incident to the ordinary course of our business. There are ongoing legal proceedings with respect to certain of our intellectual property rights relating to SNA-001, as described below.

Interference Proceeding

On October 8, 2015, Patent Interference No. 106,037 was declared by the Patent Trial and Appeal Board, or the PTAB, between our U.S. Patent No. 8,821,941, which is directed to treating hair follicles with plasmonic particles, and U.S. Patent Application No. 13/789,575, which lists Massachusetts General Hospital, or GHC, as assignee. On August 9, 2016, the PTAB entered judgment

against GHC. On October 3, 2016, GHC filed an appeal of the interference judgment with the U.S. Court of Appeals for the Federal Circuit, or Court of Appeals, in matter No. 17-1012, which names GHC and Sebacia, Inc., or Sebacia, as real parties in interest. The parties filed their respective appellate briefs with the Court of Appeals in the first quarter of 2017. On November 6, 2017, the Court of Appeals heard oral arguments in this matter. On May 4, 2018, the Court of Appeals entered its decision which affirmed the PTAB's ruling that GHC's original claims 65-67 are unpatentable and vacated and remanded the PTAB's denial of GHC's motion to add a new claim. On November 20, 2018, the PTAB denied GHC's motion to add a new claim and entered judgement against GHC. On January 18, 2019, GHC filed an appeal of the interference judgment with the U.S. Court of Appeals for the Federal Circuit. On April 22, 2019, GHC filed its opening appellate brief. On July 3, 2019, Sienna filed its responsive brief.

For further information regarding risks regarding these proceedings and patent rights held by third parties, please see "Item 1A. Risk Factors—Risks Related to Our Intellectual Property."

ITEM 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described below, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. You should carefully consider the risks described below and the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

Our activities to evaluate and pursue strategic initiatives may not be successful.

On August 5, 2019, we announced that we have begun a review of strategic alternatives to maximize shareholder value. We may have to devote significant time and resources to identifying and evaluating a strategic transaction; however, there can be no assurance that such activities will result in any agreements or transactions. Further, even if we enter into a binding agreement, there is no guarantee that the transactions will be consummated due to regulatory or other obstacles, and even if executed and consummated, such strategic or financial alternatives may not enhance stockholder value or our financial position.

Any such strategic transaction may require us to incur non-recurring or other charges, may increase our near-and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- incurrence of dilutive issuances of equity securities;
- higher-than-expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any merged businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any merged businesses due to changes in management and ownership; and
- inability to retain our key employees.

Accordingly, although there can be no assurance that we will undertake or successfully complete any strategic transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, financial condition and prospects. In addition, any such strategic transaction may result in substantial dilution to existing stockholders and may not result in consideration to the Company or its stockholders in an amount that enhances stockholder value. If we are unable to complete a strategic transaction of the nature described above, we could experience a drop in stock price and we may be unable to obtain additional financing, which could result in a further slowdown of our pipeline and commercialization efforts, further reductions in force, or other restructuring or bankruptcy protection efforts.

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved or cleared for commercial sale, and we have incurred significant losses since our inception. We anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have no products approved or cleared for commercial sale and have not generated any revenue from product sales and have incurred losses in each year since our inception in July 2010. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience 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. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net losses were approximately $8.3 million and $24.6 million for the three and six months ended June 30, 2019, and $20.2 million and $37.3 million for the three and six months ended June 30, 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $184.1 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our recurring losses from operations and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses and negative cash flows and lack of sufficient capital to fund our operations for the next 12 months raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations or significantly curtail our operations to conserve our capital resources. Further, the perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations, or necessitate that we obtain financing on terms that are more favorable to investors, and could result in the loss of confidence by investors, suppliers and employees.

We will require substantial additional financing for our Phase 3 development program of our lead product candidate and to advance our other product candidate, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, will force us to continue to delay or to terminate our product development and other operations.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities and the acquisition of Creabilis plc, or Creabilis. Nonclinical studies and clinical trials for our product candidates will require substantial funds to complete. As of June 30, 2019, we had capital resources consisting of cash and cash equivalents of $49.2 million. In order to progress the clinical development of our lead product candidate, SNA-120, and develop any other product candidates we will need to raise additional capital. In August 2019, we announced that we do not intend to initiate our planned Phase 3 clinical trials of SNA-120 until we secure sufficient additional capital, and we have engaged Cowen as an independent financial advisor to assist in exploring financial and strategic alternatives.

We may not be successful in raising capital through the issuance of equity securities. In particular, our ability to raise capital through the issuance of equity securities is constrained as a result of the trading price of our common stock under applicable Nasdaq rules. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. Our ability to obtain debt financing may be limited by covenants we have made under our loan and security agreement with Silicon Valley Bank and our pledge to Silicon Valley Bank of substantially all of our assets, other than our intellectual property, as collateral. The negative pledge in favor of Silicon Valley Bank with respect to our intellectual property under the loan and security agreement could further limit our ability to obtain additional debt financing.

Progressing SNA-120 or any other product candidate will require substantial additional capital. These expenditures will include costs associated with conducting nonclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any nonclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our lead product candidates and any future product candidates. In addition, we are obligated to make certain milestone payments to former Creabilis shareholders upon the achievement of predetermined milestones, as well as success payments to certain of our existing stockholders if the market price of our common stock meets or exceeds certain specified share price thresholds. For instance, upon the commencement of the first Phase 3 clinical trials with SNA-120, we will become obligated to issue $18.0 million in shares of our common stock, less certain offsets if applicable, to the former Creabilis shareholders. These payments, to the extent triggered and payable in cash, will also have an effect on our liquidity and capital needs. To the extent these success payment obligations are satisfied in shares of our common stock, holders of our common stock would be diluted.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting nonclinical studies and clinical trials, in particular our planned Phase 3 pivotal clinical trials of SNA-120, and any clinical trials of SNA-125;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our lead product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing of any cash milestone payments to the former Creabilis shareholders if we successfully achieve certain predetermined milestones;
- the timing and amount of any success payments we elect to pay in cash to certain of our existing stockholders if the market price of our common stock meets or exceeds certain specified share price thresholds;
- our ability to maintain compliance with the terms of our agreement with Silicon Valley Bank;
- our ability to successfully partner SNA-001 or other assets;
- the cost of manufacturing our lead product candidates or any future product candidates and any products we successfully commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities if our lead product candidates or any future product candidates are approved or cleared for sale, including marketing, sales and distribution costs;
- the cost of building a sales force in anticipation of any such product commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs associated with maintaining subsidiaries in foreign jurisdictions;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the timing, receipt and amount of sales of any future approved or cleared products, if any.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate nonclinical studies, clinical trials or other development activities for our lead product candidates or any future product candidate;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our efforts to establish sales and marketing capabilities or other activities that may be necessary to commercialize our lead product candidates or any future product candidate, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and commercialization activities relating to our product candidates, which may change from time to time;
- the timing of receipt of approvals or clearances for our product candidates from regulatory authorities in the United States and internationally;
- the timing and status of enrollment for our clinical trials;

- the timing of any cash milestone payments to the former Creabilis shareholders if we successfully achieve certain predetermined milestones;
- the timing and amount of any success payments we elect to pay in cash to certain of our existing stockholders if the market price of our common stock meets or exceeds certain specified share price thresholds, as well as fluctuations in our non-cash expenses related to the periodic revaluations of the fair value of the success payments;
- coverage and reimbursement policies with respect to our product candidates, if approved or cleared, and potential future drugs or devices that compete with our product candidates;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for our products, if approved or cleared, which may vary significantly over time;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of nonclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Our success payment obligations to certain of our existing stockholders may result in dilution to our other stockholders, may be a drain on our cash resources, or may cause us to incur debt obligations to satisfy the payment obligations.

In October 2015, we entered into a Success Payment Agreement with certain of our existing stockholders, pursuant to which we agreed to make success payments to such stockholders. These success payments are based on certain specified threshold per share values of our common stock measured at specific times during the success payment period, which began on the effective date of the Success Payment Agreement and ends on the fifth anniversary of the Success Payment Agreement, in October 2020. Success payments are payable in cash or, in our sole discretion, common stock, and will be owed, if ever, in the event that the value of our common stock meets or exceeds certain specified share price thresholds on any of the following dates during the success payment period: (1) any date after October 30, 2017, the 90th day after we completed our initial public offering, or IPO; (2) the date on which we sell, lease, transfer or exclusively license all or substantially all of our assets to another company; and (3) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity). In the case of our IPO, success payments would be triggered when the per share value of our common stock, as determined based on the average trading price of a share of our common stock over the consecutive 90-day period preceding the date the success payment is triggered, meets or exceeds specified per share thresholds. In the case of an asset sale, license or sale of the company, success payments are triggered when the per share value of our common stock, as determined based on the consideration paid in the transaction for each share of our stock, meets or exceeds specified per share thresholds. Each per share threshold is associated with a success payment, ascending from $10.0 million at $53.71 per share to $35.0 million at $71.61 per share to $60.0 million at $107.42 per share, subject to adjustment for any stock dividend, stock split, combination of shares, or other similar events. Any previous success payments made to stockholders pursuant to the Success Payment Agreement are credited against the success payment owed as of any future valuation date. The first payout is $10.0 million, the second payout is $35.0 million (inclusive of the first $10.0 million success payment, if previously paid) and the third payout is $60.0 million (inclusive of any previous success payments, if made). The success payments paid to such stockholders will not exceed, in aggregate, $60.0 million.

In order to satisfy our obligations to make these success payments, if and when they are triggered, we may issue equity securities that may cause dilution to our stockholders, or we may use our existing cash or incur debt obligations to satisfy the success payment obligation in cash, which may adversely affect our financial position. In addition, these success payments may impede our ability to raise money in future public offerings of debt or equity securities or to obtain a third-party line of credit.

The success payment obligations to certain of our existing stockholders may cause GAAP operating results to fluctuate significantly from quarter to quarter, which may reduce the usefulness of our GAAP financial statements.

Our success payment obligations to certain of our stockholders are recorded as a liability on our balance sheet. Under generally accepted accounting principles in the United States, or GAAP, we are required to remeasure the fair value of this liability as of each quarter end. Factors that may lead to increases or decreases in the estimated fair value of this liability include, among others, changes in the value of our common stock, changes in the volatility of our common stock, changes in the applicable term of the success payments and changes in the risk-free interest rate. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and from year to year and may reduce the usefulness of our GAAP financial statements. The estimated fair value of the liability associated with the success payments was $3,000 at both June 30, 2019 and December 31, 2018.

We may be required to repay the outstanding indebtedness pursuant to the minimum liquidity requirements or in an event of default under our loan and security agreement, which could have a materially adverse effect on our business. In addition, our operating activities may be restricted as a result of covenants related to the indebtedness.

On June 29, 2018, we entered into a loan and security agreement with Silicon Valley Bank, pursuant to which Silicon Valley Bank funded an aggregate principal amount of $30.0 million. On January 28, 2019, we amended the loan and security agreement with Silicon Valley Bank. The loan and security agreement with Silicon Valley Bank, as amended, provides that if our unrestricted cash at Silicon Valley Bank falls below the greater of (i) $30.0 million and (ii) the sum of (x) $15.0 million, plus (y) our six month cash burn, tested monthly as of the last day of each month beginning February 28, 2019, then we have the option to either prepay the term loans in denominations of $15.0 million (plus accrued and unpaid interest and certain fees) or immediately cash secure not less than the lesser of the outstanding balance or $15.0 million of the principal balance of all outstanding indebtedness under the term loans. Accordingly, Silicon Valley Bank may collateralize (or we may choose to prepay) $15.0 million in our existing cash resources if we fail to maintain these minimum liquidity requirements. If the cash is collateralized, we may be required to expedite our strategic transaction plans and/or seek the protection of the Federal Bankruptcy Code, as well as initiate further cost reduction measures including further restructuring of the Company, among other things.

Until we have repaid such indebtedness, the loan and security agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, and to encumber our intellectual property. Our business may be adversely affected by these restrictions on our ability to operate our business.

Additionally, we may be required to repay the outstanding indebtedness under the loan facility if an event of default occurs under the loan and security agreement. Under the loan and security agreement, an event of default will occur if, among other things, we fail to make payments under the loan and security agreement; we breach any of our covenants under the loan and security agreement, subject to specified cure periods with respect to certain breaches; Silicon Valley Bank determines that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit Silicon Valley Bank to accelerate the maturity of such indebtedness or that could have a material adverse change on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Silicon Valley Bank could also exercise its rights as collateral agent to take possession of and to dispose of the collateral securing the term loans, which collateral includes substantially all of our property (excluding intellectual property, which is subject to a negative pledge). Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Risks Related to Our Business

We are substantially dependent on the success of our lead product candidate, SNA-120; however, based on our current operating plans, we are not progressing it into Phase 3 clinical trials until such time as we have secured sufficient capital.

On January 2, 2019, we implemented a corporate restructuring to focus our resources on our lead product candidate, SNA-120 for psoriasis and the associated pruritus, resulting in a reduction in force to reduce operational costs and preserve capital. On February 8, 2019, we announced top-line results from our pivotal trials of SNA-001 for light hair removal and our plans to seek a strategic partner for SNA-001. As a result, we are substantially dependent on the success of SNA-120. In August 2019, we announced that we will not initiate our planned Phase 3 clinical trials of SNA-120 until such time as we secure sufficient additional capital. There can be no assurance that our process to identify and consummate a capital raising transaction, or other financial or strategic transaction will be successful or consummated. As a result, we cannot assure you that we will be able to further the development of SNA-120, which may require us to pursue a strategic sale of the company or other strategic transaction.

In the event we are able to secure additional capital to pursue our planned Phase 3 clinical trials of SNA-120, the clinical and commercial success of SNA-120 and any other product candidates will depend on a number of factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our nonclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of SNA-120 or any other product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals or clearances from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to SNA-120 or any other product candidates or approved products, if any;
- our ability to find a strategic partner to further develop SNA-001;
- the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved or cleared for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved or cleared, including relative to alternative and competing treatments;
- patient demand for our product candidates, if approved or cleared;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or clearances or commercialize our product candidates. Even if regulatory approvals or clearances are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

We may be unable to obtain regulatory approval or clearance for our product candidates under applicable regulatory requirements. The denial or delay of any such approval or clearance would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

To gain approval or clearance to market our product candidates, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication applied for in the applicable regulatory filing. Product development is long, expensive and uncertain processes, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology, pharmaceutical and medical device industries have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway, and safety or efficacy observations made in clinical trials including previously unreported adverse events. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

While our product candidates SNA-120 and SNA-125 will be regulated as drug products under a new drug application, or NDA, pathway, SNA-001 will be regulated as a medical device. In the United States, before we can market SNA-001, or a new use of, new claim for or significant modification to SNA-001, we must first receive clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FDCA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process or a device that was legally marketed prior to May 28, 1976 (pre-amendments device). To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence.

We currently have no products approved or cleared for sale, and we may never obtain regulatory approval or clearance to commercialize our lead product candidates. The research, testing, manufacturing, labeling, approval, clearance, sale, marketing and distribution of drug and medical device products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval or clearance from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that any of our product candidates is safe and effective for the requested indication;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional nonclinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory agency's non-approval of the formulation, labeling or specifications of SNA-120 or SNA-125;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers upon which we rely; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of biopharmaceutical and medical device products in development, only a small percentage successfully complete the FDA or other regulatory approval or clearance processes and are commercialized.

Even if we eventually complete clinical testing and receive approval or clearance from the FDA or applicable foreign agencies for any of our product candidates, the FDA or the applicable foreign regulatory agency may grant marketing authorization contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or the applicable foreign regulatory agency also may approve or clear our lead product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve or clear our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates. For example, SNA-120, if approved, may only receive a label covering psoriasis, but may not receive labeling covering the treatment of pruritus associated with psoriasis.

Any delay in obtaining, or inability to obtain, applicable regulatory approval or clearance would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in nonclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology, pharmaceutical and medical device industries have suffered

significant setbacks in clinical trials, even after positive results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway, and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. Notwithstanding any potential promising results in earlier studies and trials, 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.

We may experience delays in completing ongoing studies or trials and initiating planned studies or trials, and we cannot be certain that studies or trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient quantities of product candidate for use in nonclinical studies or clinical trials from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or as a result of, nonclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, or simply be unable to provide us with sufficient product supply to conduct and complete nonclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct nonclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;

- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the treatment removed from the market after obtaining marketing approval or clearance.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion, or termination, of any nonclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or not realized at all.

In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval or clearance process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval or clearance of our product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient consents.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval or clearance, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved or cleared, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business.

As a company, we have never completed a Phase 3 program or obtained marketing approval for any product candidate and we may be unable to successfully do so for any of our product candidates. Failure to successfully complete any of these activities in a timely manner for any of our product candidates could have a material adverse impact on our business and financial performance.

Conducting a pivotal clinical trial and preparing, and obtaining marketing approval for, a product candidate is a complicated process. Although members of our management team have participated in pivotal trials and obtained marketing approvals for product candidates in the past while employed at other companies, we as a company have not done so. As a result, such activities may require more time and cost more than we anticipate. Failure to successfully complete, or delays in, our pivotal trials or related regulatory submissions would prevent us from or delay us in obtaining regulatory approval for, or clearance of, our product candidates. In addition, it is possible that the FDA may refuse to accept for substantive review any NDAs or medical device marketing applications that we submit for our product candidates or may conclude after review of our applications that they are insufficient to obtain marketing approval or clearance of our product candidates. If the FDA does not accept our applications or issue marketing authorizations for our product candidates, it may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or receipt

of other marketing authorizations for any other applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs or clear our 510(k) submissions or grant other marketing authorizations.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if our lead product candidates or any future product candidates obtain regulatory approval or clearance, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

Even if we obtain FDA or other regulatory approvals or clearances, the commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our product candidates may not be commercially successful. For a variety of reasons, including among other things, competitive factors, pricing or physician preference, the degree and rate of physician and patient adoption of our current or future product candidates, if approved or cleared, will depend on a number of factors, including:

- the clinical indications for which the product is approved or cleared and patient demand for approved or cleared products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our products and overall treatment experience, including, for example, a smaller or no effect on the visual symptoms of psoriasis while relieving the associated pruritus;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved or cleared, on the part of insurance companies and other third-party payers, physicians and patients;
- the willingness of patients to pay for certain of our products, particularly our aesthetic products, such as SNA-001, if approved or cleared, especially during economically challenging times;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved or cleared labeling for our products;
- the compatibility, or clearance for use, of our SNA-001 product with the lasers available in aesthetic professionals' offices;
- the willingness of physicians, operators of clinics and patients to utilize or adopt SNA-001 as a procedural solution;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our product candidates that obtain regulatory approval or clearance to achieve market acceptance or commercial success would adversely affect our results of operations.

We may be unsuccessful in identifying and securing a strategic partner for SNA-001.

In February 2019, we announced top-line results from our pivotal trials of SNA-001 for light hair removal and final pivotal trial of SNA-001 for the treatment of acne and our plans to seek a strategic partner to maximize the value of SNA-001. There can be no assurance that our activities will result in any agreements or transactions that will monetize SNA-001 or that will enhance shareholder value. Further, any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance shareholder value.

SNA-125, if approved for the treatment of psoriasis, may compete with SNA-120, if approved for the treatment of psoriasis, which could reduce the commercial success of SNA-120, if both are approved.

SNA-120 and SNA-125 are both designed to inhibit TrkA. To the extent both SNA-120 and SNA-125 are approved for psoriasis, physicians and patients may prefer to use SNA-125 instead of SNA-120, and the revenue we would derive from SNA-120 could be reduced. If SNA-120 and SNA-125 compete for treatment of the same indications, the incremental revenue derived from SNA-125 may be less than if SNA-125 and SNA-120 did not treat the same indications.

We currently rely on single source third-party suppliers to manufacture nonclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved or cleared product candidate. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not currently have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our nonclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a nonclinical, clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs (or the Quality System Regulation, or QSR, in the case of our device product candidates). If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture or our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

We currently rely on third parties at key stages in our supply chain and use only a single contract manufacturer for each component of the manufacturing process for each of our lead product candidates. There are a limited number of suppliers for materials we use in our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our nonclinical studies and clinical trials, and if approved, ultimately for commercial sale. We currently have no alternative suppliers and expect to continue to depend on third-party contract manufacturers for the foreseeable future. Although we intend to enter into agreements with our primary manufacturers prior to commercial launch of any of our product candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. In the case of SNA-001, we have a commercial supply agreement with nanoComposix to supply the silver nanoplates used to manufacture SNA-001 on an exclusive basis, subject to certain exceptions in the event of certain specified supply failures, and we have an agreement with Unicep to supply SNA-001 finished product on a nonexclusive basis, subject to certain contingencies. In the case of SNA-120 and SNA-125, we currently obtain our supplies of drug substance and drug product through individual purchase orders and have not entered into supply agreements with our current manufacturers.

We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. We generally do not begin a nonclinical study or clinical trial unless we believe we have access to a sufficient supply of a product candidate to complete such study or trial. Prior to submitting an NDA for SNA-120, we must complete nonclinical studies. If our existing manufacturers were unable to supply sufficient drug substance or drug product, this would likely result in a delay of our NDA submission and approval of SNA-120. In addition, any significant delay in, or quality control problems with respect to, the supply of a product candidate, or the raw material components thereof, for an ongoing study or trial could considerably delay completion of our nonclinical studies or clinical trials, product testing and potential regulatory approval of our product candidates. Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into or maintain arrangements for the commercial supply of our product candidates on acceptable terms, we will have no other means of producing our lead product candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our nonclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, political, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

In addition, to manufacture our lead product candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers may need to increase manufacturing capacity and, in some cases, we may attempt to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party

manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the commercial launch of our lead product candidates or any future product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved or cleared.

We rely on third parties in the conduct of all of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We currently do not have the ability to independently conduct nonclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant nonclinical studies and GCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant nonclinical studies and our GCP-compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our nonclinical studies or our clinical trials do not perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our nonclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete.

The biotechnology, pharmaceutical and medical device industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing, including biotechnology companies. We face competition from a number of sources, such as pharmaceutical companies, medical device companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other dermatological products, including over-the-counter, or OTC, treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

If approved for the treatment psoriasis, SNA-120 and SNA-125 will face competition from a number of approved treatments for psoriasis, including branded topical drugs and generic versions where available. In many cases, these products have been developed, and are being marketed, by well-established companies. We believe that SNA-125, if approved for the treatment of atopic dermatitis, will also face potential competition from well-established companies that market, or are expected to market, branded and generic corticosteroids or topical calcineurin inhibitors. If cleared for light-pigmented hair removal or reduction, we anticipate that SNA-001 would compete with hair reduction products designed for at-home use by the patient.

Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles. Additional products and treatments, including numerous injectable biological products which have been approved or are currently in clinical trials, may also receive regulatory approval in one or more territories in which we compete, and these existing and new products may be more effective, more widely used and less costly than ours. Newly developed systemic or non-systemic treatments that replace existing therapies that are currently only utilized in patients suffering from severe disease may also have lessened side effects or reduced prices compared to current therapies, which make them more attractive for patients suffering from mild to moderate disease. Even if a generic product or an OTC product is less effective than our product candidates, a less effective generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience.

If coverage and adequate reimbursement from third-party payors are not available, it may make it difficult for us to sell certain of our products profitably.

Our ability to successfully commercialize our SNA-120 and SNA-125 product candidates and potentially some or all of our future product candidates that we may develop will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish adequate coverage and reimbursement for such product candidates. Patients who are prescribed treatments for their conditions and providers furnishing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and the procedures using our products.

Significant uncertainty exists as to the coverage and reimbursement status of newly approved products. A trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. Therefore, as a result of these cost containment measures, coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be sufficient enough to successfully commercialize any product candidates that we develop.

In the United States, private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy requirement for coverage and reimbursement for products exists among third-party payors and coverage and reimbursement can differ significantly from payor to payor. Each plan determines whether or not it will provide coverage, what amount it will pay, and with respect to pharmaceutical products, on what tier of its formulary such product will be placed. The position of a prescription drug on a formulary generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of a product by patients and physicians. Each plan may separately require us to provide scientific and clinical support for the use of our products and, as a result, the coverage determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Our inability to promptly obtain coverage and adequate reimbursement from both government-funded and private payors for any approved products that we develop could significantly harm our operating results, our ability to raise capital needed to commercialize our product candidates and our overall financial condition.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and foreign jurisdictions, if approved, or generate product revenue.

We currently do not have a sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, 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 any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products or medical devices 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. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our product candidates or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

We restructured the Company in January 2019 to refocus our resources on the Phase 3 clinical trial program for SNA-120 and, given our decision not to initiate our planned Phase 3 clinical trial of SNA-120 until we have sufficient capital combined with our considerably reduced workforce, we may experience difficulties in retaining our existing employees and managing our operations.

On January 2, 2019, we implemented a corporate restructuring to focus our resources on our lead product candidate, SNA-120 for psoriasis and the associated pruritus, resulting in a reduction in force to reduce operational costs and preserve capital. In August 2019, we announced that we will not initiate our planned Phase 3 clinical trials of SNA-120 until we secure sufficient additional capital, and that we have engaged Cowen to assist us in exploring capital raising and other financial and strategic alternatives. As a result, we may have additional difficulty retaining our existing employees. A failure to retain sufficient management and personnel may impair our ability to execute on our strategy.

If we fail to attract and retain, and integrate new, senior management and key scientific personnel, we may be unable to successfully develop our lead product candidates or any future product candidates, conduct our clinical trials and commercialize our current or any future product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our President and Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our lead product candidates or any future product candidates. Although we have entered into employment agreements with our senior management team, these agreements do not provide for a fixed term of service. In addition, we have recently hired new members of our senior management team and intend to continue to build out our organization. Integrating these new members of management, and potential future hires, will require the attention to management and may cause temporary distractions in our operations as these new members are integrated into the organization.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future product candidates we develop. We currently carry product liability insurance covering our clinical trials in the amount of $10 million in the aggregate.

Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, 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. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business and achieve our longer-term strategic objectives would be impaired.

Although a substantial amount of our effort will focus on the continued nonclinical and clinical testing and potential approval or clearance of SNA-120, a key element of our longer-term strategy is to discover, develop and commercialize a diverse portfolio of product candidates to serve the dermatology market. We are seeking to do so through our internal research programs and may explore strategic collaborations for the development or acquisition of new products. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our lead product candidates.

We have in the past engaged and may in the future engage in strategic transactions that could affect our liquidity, dilute our existing stockholders, increase our expenses and present significant challenges in focus and energy to our management or prove not to be successful.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. In December 2016, we acquired the entire issued share capital of Creabilis plc, which became our direct wholly-owned subsidiary. In connection with closing, we made an upfront payment of approximately $0.2 million in cash, issued 1,407,679 shares of our Series A-3 Preferred Stock to the former Creabilis shareholders and settled approximately $6.7 million of Creabilis liabilities. In October 2017, we commenced our additional Phase 2b clinical trial for SNA-120, triggering our first contingent milestone payment of $5.0 million, less certain offsets totaling approximately $0.3 million, which we satisfied by issuing an aggregate of 201,268 shares of common stock to the former Creabilis shareholders in December 2017 pursuant to the terms of the Share Purchase Agreement. Upon the achievement of certain additional clinical, regulatory and approval milestones for SNA-120 and SNA-125, we are obligated to pay the former Creabilis shareholders up to an aggregate of $53.0 million, which consists of an aggregate of $25.0 million in cash and $28.0 million in shares of our common stock and includes our obligation to, upon the commencement of the first Phase 3 clinical trial of SNA-120, issue $18.0 million in shares of our common stock, less certain offsets if applicable. In addition, upon the achievement of certain annual net sales milestone thresholds for qualifying products, including SNA-120 and SNA-125, we are required to pay the former Creabilis shareholders up to an aggregate of $80.0 million in cash as well as one-time royalties of less than 1% on net sales of qualified products that exceed these net sales thresholds in the year such threshold is achieved.

Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. The Creabilis acquisition and any future transactions could result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional

financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition.

The international aspects of our business expose us to a variety of business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States, which could materially adversely affect our business.

We currently have limited international operations in Italy, the United Kingdom and Luxembourg. Doing business internationally, including any future efforts by us or a collaborator to commercialize our product candidates outside the United States, involves a number of risks related to these international markets or business relationships, including but not limited to:

- different regulatory requirements for product approvals in foreign countries;
- different approaches by reimbursement agencies regarding the assessment of the cost effectiveness of our products;
- reduced protection for intellectual property rights in certain foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems for dermatological medications and for clinicians treating patients with dermatological conditions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- multiple, conflicting and changing laws and regulations such as privacy regulations, including General Data Protection Regulation, or GDPR, tax laws, export and import restrictions, employment laws, immigration laws, labor laws, regulatory requirements and other governmental approvals, permits and licenses;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- certain expenses including, among others, expenses for travel, translation and insurance;
- limits in our or our collaboration partners' ability to penetrate international markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from activities conducted on our behalf by distributors or other vendors we engage;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act or the U.K. Bribery Act; and
- business interruptions resulting from natural disasters, outbreak of disease or geopolitical actions, including war, terrorism, political unrest, boycotts, curtailment of trade or other business restrictions.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with our most recent Annual Report on Form 10-K, Section 404 requires that we file with the SEC an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following August 1, 2022, the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

During the course of our review and testing of our internal control over financial reporting, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, as amended. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend, in part, on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the Northern Los Angeles Area, which in the past has experienced severe earthquakes, wildfires and mudslides. We do not carry earthquake insurance. Earthquakes, wildfires, mudslides or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

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, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, government files or penalties and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product 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. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various international, federal and state privacy and security laws, if applicable, including the GDPR, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, 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. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Risks Related to Intellectual Property

Our proprietary platform technology and any future products that we commercialize could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our products.

Our commercial success depends on our ability to develop, manufacture and market candidates from our proprietary platform technology and use our platform technology without infringing the patents and other proprietary rights of third parties. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. We operate in an industry with extensive intellectual property litigation. As the biopharmaceutical and dermatological product industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated.

Whether merited or not, we may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including patents held by our competitors or by non-practicing entities. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether claims that we are infringing patents or other intellectual property rights have merit, the claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our products and features while we develop non-infringing substitutes, or may result in significant settlement costs. For example, litigation can involve substantial damages for infringement (and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees), and the court could prohibit us from selling or licensing our products unless the third-party licenses rights to us, which it is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible at all or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use, or sale.

In addition, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on whether the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the United States Patent and Trademark Office (USPTO) to determine priority of invention in the United States. The costs of any such proceedings could be substantial, and it is possible that such efforts would be unsuccessful if it is determined that the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Although we are not currently subject to any claims from third parties asserting infringement of their intellectual property rights, in the future, we may receive claims from third parties asserting infringement of their intellectual property rights. Future litigation may be necessary to establish our intellectual property rights or to defend ourselves by determining the scope, enforceability and validity of third-party intellectual property rights. There can be no assurance with respect to the outcome of any current or future litigation brought by or against us, and the outcome of any such litigation could have a material adverse impact on our business, operating results and financial condition. Litigation is inherently unpredictable and outcomes are uncertain. Further, as the costs and outcome of these types of claims and proceedings can vary significantly, it is difficult to estimate potential losses that may occur. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

With respect to adverse proceedings in which we are currently involved, we plan to vigorously protect our intellectual property rights. However as with all adverse proceedings, regardless of the merits of third-party claims, such proceedings are time-consuming and costly to litigate or settle and may divert managerial attention and resources away from our business objectives.

Successful pending claims against us could result in monetary liability and/or prevent us from operating our business, or portions of our business. Resolution of claims may require us to obtain rights to third-party intellectual property rights, which may be expensive to procure, or we may be required to cease using certain intellectual property altogether. These and other risks are inherent to adverse proceedings involving intellectual property.

For further information regarding the proceedings in which we are currently involved, please see "Part II, Item 1". Legal Proceedings."

If we are unable to obtain, maintain and enforce intellectual property protection directed to our proprietary platform technology and any future technologies that we develop, others may be able to make, use, or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.

We have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our products in every country or territory in which we may sell our products. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they will issue in a form that will be advantageous to us. The USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with protection for our commercial products. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of our legal actions against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual property may be challenged, invalidated or circumvented, may not provide specific protection and/or may not prove to be enforceable in actions against specific alleged infringers.

The market for biopharmaceuticals and dermatological treatments is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and products for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights in connection therewith. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our technology and/or infringe our intellectual property to unfairly and illegally compete with our products. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use, or sell products that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market. With respect to our Topical Photoparticle Therapy™ technology, under our exclusive license agreement with nanoComposix, we are solely responsible for the prosecution of the licensed patent rights throughout the world, at our expense, and we have the first right to enforce within our licensed field and defend the licensed patent rights throughout the world, at our expense.

We use a combination of patents, trademarks, know-how, confidentiality procedures and contractual provisions to protect our proprietary technology. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our currently pending or any future patent applications, and our issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us.

If we or one of our current or future collaborators were to initiate legal proceedings against a third party to enforce a patent covering one of our lead product candidates or future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make product that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our proposed commercial technologies or the future products that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have dominating, blocking, or other patents relevant to our technology of which we are not aware. There may be prior public disclosures or art that could be deemed to invalidate one or more of our patent claims. Further, we may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many international jurisdictions, policy regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and international legislative bodies. Those changes may materially affect our patents, our ability to obtain patents or the patents and patent applications of our licensors.

Patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The United States Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business and financial condition.

In addition, we have a number of international patents and patent applications and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. The laws of some international jurisdictions may not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in obtaining, protecting, and defending such rights in international jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in international jurisdictions, our business prospects could be substantially harmed. Varying filing dates in international countries may also permit intervening third parties to allege priority to certain technology.

Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates, and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing (including any patent term extension or adjustment filing), whether intentional or unintentional, may also result in the loss of patent rights important to our business. Certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect confidential information and proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or

misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. We may in the future rely on trade secret protection, which would be subject to the risks identified above with respect to confidential information.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products, and may in the future seek to enforce our patents or other rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product or service features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, such as (but not limited to) interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions, or other patent proceedings. We may need to initiate infringement claims or litigation. Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court or other judicial body may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation and may have significantly broader patent portfolios to assert against us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending, and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings (such as litigation) costs.

With respect to our proprietary platform technology, if we do not obtain rights to commercialize certain compounds, there is a risk that such rights will be exploited by another entity. As with all licenses to third parties in specific fields of use, there is a risk of impermissible exploitation by such third parties outside the licensed field.

With respect to our Topical Photoparticle Therapy™ technology, if the nanoComposix license agreement is terminated or narrowed, we could lose intellectual property rights that may be material to our Topical Photoparticle Therapy™ products. This agreement may be terminated by nanoComposix for our nonpayment or material breach, in either case, after the opportunity to cure and final determination in arbitration, or for our failure to receive FDA regulatory approval to sell a licensed product by June 2024, or for our insolvency or bankruptcy, or if we or our affiliate or future sublicensee initiates or voluntarily joins as a party to any legal action that challenges the validity or enforceability of the nanoComposix licensed patent rights, or nanoComposix's title thereto, or by joint written agreement. We may enter into additional licenses and agreements in the future and, as with all such arrangements, if we do not comply with obligations, we may suffer adverse consequences. Likewise, we are party to several agreements that although do not currently have a material impact on intellectual property, may become material if certain obligations are not fulfilled by any of the contracting parties.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates, including all of the licensed rights under our exclusive license agreement with nanoComposix, in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. In addition, third parties may file first for our trademarks in certain countries. If they succeeded in registering such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

We have not yet registered trademarks for a commercial trade name for our lead product candidates in the United States or foreign jurisdictions and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for our lead product candidates in the United States or any foreign jurisdiction, if approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We may not be able to protect our proprietary information and technology adequately. Although we use reasonable efforts to protect our proprietary information, technology, and know-how, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our proprietary information, technology or know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect proprietary information, technology, and know-how. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our proprietary information, technology, and know-how. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop similar or equivalent proprietary information, and third parties may otherwise gain access to our proprietary knowledge.

Risks Related to Government Regulation

The regulatory approval and clearance processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval or other marketing authorizations for our product candidates, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval or any other marketing authorization for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval or clearance. Neither we nor any future collaborator is permitted to market SNA-120, SNA-125 or any future drug product candidates in the United States until we receive regulatory approval of an NDA from the FDA, nor can we or any future collaborator market SNA-001 or any future product candidates under the 510(k) clearance process in the United States until we receive clearance or marketing authorization from the FDA.

Prior to obtaining approval to commercialize SNA-120, SNA-125 and any other drug product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. In addition, the FDA may refer applications for novel drugs, like SNA-120 and potentially other of our future product candidates, to an advisory committee comprised of outside experts. The FDA is not bound by the recommendation of the advisory committee, but it considers such recommendation when making its decision.

We have announced our intent to seek a strategic partner for SNA-001, but may concurrently pursue FDA clearance of SNA-001 for the reduction of light-pigmented hair and the treatment of acne under the FDA's 510(k) premarket notification process. Before we or our partner can market SNA-001 in the United States, we are required to obtain clearance from the FDA under Section 510(k) of the FDCA. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. Under certain conditions, a medical device is required to be received under pre-market approval, or PMA, application from the FDA. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, nonclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down classification based on a *de novo* submission, the FDA will authorize the device for marketing. This device type can then be used as a predicate device for future 510(k) submissions. The process of obtaining regulatory clearances or approvals, or completing the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

If the FDA requires us to go through a lengthier, more rigorous examination for our products than we expect, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that SNA-001 or other future medical device product candidates for which we pursue 510(k) clearance will require us to obtain approval

through the PMA process, which is generally more costly and uncertain and can take from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. Further, even where a PMA is not required, we cannot assure you that we will be able to obtain 510(k) clearances with respect to such product candidates or modifications to previously cleared products.

The FDA or any foreign regulatory bodies can delay, limit or deny approval or clearance of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory agency's disagreement with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication, or in the case of the 510(k) clearance process, that our product candidate is substantially equivalent to a predicate device;
- the FDA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional nonclinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory agency's disagreement regarding the formulation, labeling or the specifications of our product candidates;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval or clearance of an FDA or foreign marketing application for our product candidates, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials, and/or the implementation of a REMS, in the case of SNA-120, SNA-125 and any other drug product candidates, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Moreover, obtaining FDA clearance under the FDA's 510(k) clearance process can be expensive and uncertain, and generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in marketing authorization. Even if we were to obtain the requisite marketing authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

In order to market any product in the European Economic Area (which is composed of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), or EEA, and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products, such as SNA-120 and SNA-125, can only be commercialized after obtaining a Marketing Authorization, or MA. Before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

There is currently no premarket government review of medical devices in the EEA. However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive 93/42/EEC concerning medical devices (the "Medical Devices Directive"). Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene, or CE, mark to such products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements for such product candidates, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its product candidates with the essential requirements of the EU Medical Device Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, a regulation is directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will not become fully applicable until three years following its entry into force but medical device manufacturers, including our company, are already adjusting their conformity assessment procedures and working with their Notified Bodies to meet the more stringent requirements of the EU Medical Devices Regulation with respect to their product candidates.

The EU Medical Devices Regulation explicitly provides that high intensity electromagnetic radiation (e.g., infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment, falls under its scope. This affects the regulatory approval pathway of candidate SNA-001 which would thus need to comply with the requirements of the Medical Devices Regulation before it can be commercialized for removal of light-pigmented hair in the EEA. If we are unable to demonstrate conformity of SNA-001 and our manufacturers with the requirements of the Medical Devices Regulation, or otherwise fail to remain in compliance with applicable European laws and directives, we would be unable to affix (or continue to affix) the CE mark to SNA-001, which would prevent us from selling SNA-001 within the EEA.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file we may not receive necessary approvals to commercialize our products in any market.

In addition, the FDA and other regulatory authorities may change their policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance or other marketing authorizations of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals or marketing authorizations, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. For example, as part of the Food and Drug Administration Safety and Innovation Act enacted in 2012, Congress enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are intended to clarify and improve medical device regulation both pre- and post-clearance and approval.

Modifications to our product candidates cleared under the 510(k) clearance process, if any, may require new 510(k) clearances or other marketing authorizations, and if we make modifications to such products without obtaining requisite marketing authorization, we may be required to cease marketing or recall the modified products until clearances or other marketing authorizations are obtained.

Any modification to a 510(k)-cleared product or a device authorized for marketing that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We may make modifications or add features to any of our product candidates that are cleared under the 510(k) clearance process in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required clearances or approvals for such changes would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Any of these actions would harm our operating results.

We have requested a special protocol assessment, from the FDA relating to our planned Phase 3 program for SNA-120, and we cannot guarantee that the FDA will issue an agreement on the SPA. Even if we do obtain FDA's agreement, an SPA would not guarantee approval of SNA-120 or any other particular outcome from regulatory review.

We have requested agreement from the FDA under a special protocol assessment, or SPA, for our planned Phase 3 clinical trials of SNA-120 in patients with psoriasis and associated pruritus. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of certain clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

However, an SPA agreement does not guarantee approval of a product candidate, even if the trial is conducted in accordance with the protocol. Moreover, even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

There is no assurance that the FDA will agree with the design and size of any Phase 3 clinical program for which we request an SPA. Even if we do obtain agreement on an SPA, we cannot assure you that our planned Phase 3 clinical trial will succeed, will be deemed binding by the FDA under an SPA, if granted, or will result in any FDA approval for SNA-120. Moreover, if the FDA revokes or alters its agreement under an SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals or other marketing authorizations we obtain for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or the conditions of approval or marketing authorization, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our drug product candidates, such as SNA-120 and SNA-125, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority authorizes our product candidates for marketing, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and

ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs (including the QSR in the case of any of our product candidates cleared under the 510(k) clearance process), and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to accept new marketing applications or supplements, approve or otherwise authorize for marketing pending applications or supplements to applications filed by us or suspension or revocation of approvals or other marketing authorizations;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our future products under development. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. These proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our product candidates, if authorized for marketing, may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our product candidates, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, if such products are marketed, could have a negative impact on us.

With respect to any of our product candidates cleared under the 510(k) clearance process, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. There are similar reporting requirements for our drug product candidates, if and when they are approved. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls involving our product candidates, if and when they are cleared or approved or otherwise authorized for marketing, could be particularly harmful to our business, financial condition and results of operations.

Depending on the corrective action we take to redress a device product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals, clearances, or other marketing authorizations for the device before we may market or distribute the corrected device. Seeking such authorizations may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. If we obtain marketing authorizations and market our medical device product candidates, we may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

We may be subject to healthcare laws and regulations relating to our business and could face substantial penalties if we are determined not to have fully complied with such laws, which would have an adverse impact on our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, customers and patients, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;

- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities may conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on the pricing of medical items and services, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States which, due to subsequent legislative amendments, has been suspended through December 31, 2019, and, absent further legislative action, will be reinstated starting January 1, 2020;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which, through subsequent legislative amendments, was increased to 70%, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, the Tax Act was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. The current Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include the Budget Control Act of 2011, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year and will remain in effect through 2027, and the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved or cleared product. Any reduction in reimbursement from Medicare or other government programs may result in a similar

reduction in payments from private payors. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Recent U.S. tax legislation and future changes to applicable U.S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

We are subject to income and other taxes in the United States and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, on December 22, 2017, the U.S. government enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, (i) a federal corporate tax rate decrease from 34% to 21% for tax years beginning after December 31, 2017, (ii) the transition of U.S. international taxation from a worldwide tax system to a partially territorial system, (iii) limitation of the deduction for net operating losses generated in tax years beginning after December 31, 2017 to 80% of current year taxable income, and (iv) eliminating carryback and providing for indefinite carryforwards for net operating losses generated in tax years beginning after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

Risks Related to Our Common Stock

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section and others such as:

- results from, and any delays in or suspension of, our clinical trials for our lead product candidates, or any other future clinical development programs, including as a result of unforeseen safety events or side effects;
- announcements of regulatory approval or disapproval of our current or any future product candidates;
- failure or discontinuation of any of our research and development programs;
- announcements of capital raising events or activities;
- announcements relating to future licensing, collaboration or development agreements;
- delays in the commercialization of our current or any future product candidates;
- acquisitions and sales of new products, technologies or businesses;
- manufacturing and supply issues related to our product candidates for clinical trials or future product candidates for commercialization;
- results or announcements (if any) from, or any delays in, our exploration of financial or strategic alternatives for the Company focusing on maximizing stockholder value and the timing and nature of any strategic transactions that we undertake (if any);
- quarterly variations in our results of operations or those of our future competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- any major changes in our board of directors or management;
- new legislation in the United States, or governmental announcements of proposed legislation, relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;

- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- ability to meet Nasdaq minimum listing requirements; and
- general economic conditions in the United States and abroad.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical, medical device and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

If we fail to continue to meet all applicable Nasdaq Global Select Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on the Nasdaq Global Select Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a "public shell company." As of the date of the filing of this Quarterly Report on Form 10-Q, the closing bid price of our common stock has been below $1.00 per share for 30 consecutive business days. Accordingly, we anticipate that we will receive a deficiency letter from the Listing Qualifications Department of the Nasdaq Global Select Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1). Upon receipt of any such notice, we would have an initial period of 180 calendar days to regain compliance with this listing rule. If, at any time before the close of the initial 180 day period, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days as required under Listing Rule 5810(c)(3)(A), Nasdaq will provide written notification to us that it is in compliance with the listing rule. If we receive a deficiency letter, we intend to actively monitor the bid price for our common stock between now and the end of such 180 day period, and will consider available options, including a reverse stock split, to resolve the deficiency and regain compliance with the listing rule. If we are unable to comply with Nasdaq's listing standards, Nasdaq may determine to delist our common stock from the Nasdaq Global Select Market. If our common stock is delisted for any reason, it could reduce the value of our common stock and its liquidity.

An active market for our common stock may not be maintained.

Prior to our IPO in July 2017, there had been no public market for shares of our common stock. Our stock only recently began trading on the Nasdaq Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market on the Nasdaq Global Select Market or any other exchange in the future. If an active market for our common stock does not develop or is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have very limited research coverage by securities and industry analysts. If no additional securities or industry analysts commence coverage of us, the trading price or trading volume for our stock could be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and a "smaller reporting company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations

regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We also qualify as a "smaller reporting company," as defined in the Exchange Act. As a smaller reporting company and so long as we remain a smaller reporting company, we benefit from similar exemptions and exclusions as an emerging growth company, including: (1) scaled executive compensation disclosures; and (2) the requirement to provide only two years of audited financial statements, instead of three years. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company and/or smaller reporting company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following August 1, 2022, the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We will remain a smaller reporting company until (1) the market value of our common stock held by non-affiliates is greater than $250.0 million as of the prior June 30th and our annual revenue exceeds $100 million, or (2) the market value of our common stock held by non-affiliates is greater than $700.0 million, regardless of our annual revenue.

If we sell shares of our common stock in future financings or issue shares pursuant to our agreement with the former shareholders of Creabilis, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, including pursuant to the terms of the Share Purchase Agreement with the former Creabilis shareholders, our common stockholders would experience additional dilution and, as a result, our stock price may decline. For instance, upon our commencement of the first Phase 3 clinical trial with SNA-120, we will become obligated to issue $18.0 million in shares of our common stock, less certain offsets if applicable, to the former Creabilis shareholders.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the number of shares outstanding as of June 30, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 43.49% of our voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future and/or subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer or the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and the indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We do not currently intend to pay dividends on our common stock, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. In addition, our loan and security agreement with Silicon Valley Bank prohibits us from paying dividends without their consent. Therefore, our stockholders are not likely to receive any dividends on their common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our stockholders have purchased it.

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

Covenants in our loan and security agreement with Silicon Valley Bank limit our ability to pay dividends (or make other distributions) without Silicon Valley Bank's consent. For additional information refer to Note 8, "Long-Term Debt" in the notes to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10 Q.

Unregistered Sales of Equity Securities

Information relating to the issuance of warrants to purchase shares of our common stock in January 2019 was included in our Current Report on Form 8-K (File No. 001-38155) filed with the U.S. Securities and Exchange Commission, or SEC, on January 30, 2019, and is accordingly omitted. No other equity securities of the Company that were not registered under the Securities Act were sold during the six months ended June 30, 2019.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

The information set forth below is included herein for the purpose of providing the disclosure required under "Item 2.05 – Costs Associated with Exit or Disposal Activities," of Form 8-K.

Review of Strategic Alternatives and Corporate Restructuring

On August 5, 2019, we announced that we retained Cowen and Company, LLC ("Cowen") as an independent financial advisor to assist in exploring financial and strategic alternatives designed to maximize shareholder value. With Cowen's assistance, we will continue to explore capital raising to enable the initiation of our planned Phase 3 pivotal clinical trials for SNA-120, in addition to exploring a wide range of financial and strategic alternatives. We may be unable to identify or execute such financial or strategic alternatives, and, even if executed, such financial or strategic alternatives may not enhance stockholder value or our financial position. We do not intend to initiate our planned Phase 3 clinical trials of SNA-120 until we secure sufficient additional capital.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation, as amended.	8-K	8-1-2017	3.1	
3.2	Amended and Restated Bylaws.	8-K	8-1-2017	3.2	
4.1	Reference is made to exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	7-17-2017	4.2	
10.1#	Non-Employee Director Compensation Program, as amended and restated effective May 30, 2019.				X
31.1	Certification of Chief Executive Officer of Sienna Biopharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Chief Financial Officer of Sienna Biopharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
32.1*	Certification by the Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

# Indicates management contract or compensatory plan.

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Sienna Biopharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Sienna Biopharmaceuticals, Inc.

Date: August 8, 2019

By: /s/ Alexander Azoy
Alexander Azoy
Chief Financial Officer
(Principal Financial Officer)

SIENNA BIOPHARMACEUTICALS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM
(AS AMENDED AND RESTATED EFFECTIVE MAY 30, 2019)

This Sienna Biopharmaceuticals, Inc. (the "Company") Non-Employee Director Compensation Program (this "Program") has been adopted under the Company's 2017 Incentive Award Plan (the "Plan") and became effective upon the closing of the Company's initial public offering of its common stock (the "IPO"), and further amended and restated effective as of May 30, 2019. The Equity Compensation portion of this Program is intended to constitute the Non-Employee Director Equity Compensation Program contemplated by Section 4.6 of the Plan. Capitalized terms not otherwise defined herein shall have the meaning ascribed in the Plan.

Cash Compensation

Effective upon the IPO, annual retainers will be paid in the following amounts to Non-Employee Directors:

Non-Employee Director:	$35,000
Non-Executive Chair:	$30,000
Chair of Audit Committee:	$15,000
Chair of Compensation Committee:	$12,500
Chair of Nominating and Corporate Governance Committee:	$ 7,500
Audit Committee Member (other than Chair):	$ 7,500
Compensation Committee Member (other than Chair):	$ 6,250
Nominating and Corporate Governance Committee Member (other than Chair):	$ 3,750

All annual retainers will be paid in cash quarterly in arrears promptly following the end of the applicable calendar quarter, but in no event more than thirty (30) days after the end of such quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described above, for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

Equity Compensation

Initial Stock Option Grant: Each Non-Employee Director who is initially elected or appointed to serve on the Board after the IPO shall be granted an Option to purchase 50,000 shares of Common Stock under the Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "Initial Option").

	The Initial Option will be automatically granted on the date on which such Non-Employee Director commences service on the Board, and will vest as to 1/36th of the shares subject thereto on each monthly anniversary of the applicable date of grant such that the shares subject to the Initial Option are fully vested on the third anniversary of the grant, subject to the Non-Employee Director continuing in service on the Board through each vesting date.
Annual Stock Option Grant:	Each Non-Employee Director who is serving on the Board as of the date of each annual shareholder meeting of the Company (each, an "Annual Meeting") shall be granted an Option to purchase 25,000 shares of Common Stock under the Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "Annual Option").
	The Annual Option will be automatically granted on the date of the applicable Annual Meeting, and will vest as to 1/12th of the shares subject thereto on each monthly anniversary of the applicable date of grant such that the shares subject to the Annual Option are fully vested on the first anniversary of the grant, subject to the Non-Employee Director continuing in service on the Board through such vesting date.

The per share exercise price of each Option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Plan) of a share of common stock on the date the Option is granted.

The term of each Option granted to a Non-Employee Director shall be ten (10) years from the date the Option is granted.

No portion of an Initial Option or Annual Option which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board shall become vested and exercisable thereafter.

Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Option, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Annual Options as described above.

Change in Control

Upon a Change in Control of the Company, all outstanding equity awards granted under the Plan or any other equity incentive plan maintained by the Company that are held by a Non-Employee Director shall become fully vested and/or exercisable, irrespective of any other provisions of the Non-Employee Director's Award Agreement.

Reimbursements

The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

Miscellaneous

The other provisions of the Plan shall apply to the Options granted automatically pursuant to this Program, except to the extent such other provisions are inconsistent with this Program. All applicable terms of the Plan apply to this Program as if fully set forth herein, and all grants of Options hereby are subject in all respect to the terms of such Plan. The grant of any Option under this Program shall be made solely by and subject to the terms set forth in a written agreement in a form to be approved by the Board and duly executed by an executive officer of the Company.

Effectiveness, Amendment, Modification and Termination

This Program shall become effective upon the consummation of the IPO. This Program may be amended, modified or terminated by the Board in the future at its sole discretion. No Non-Employee Director shall have any rights hereunder, except with respect to an Option granted pursuant to the Program.

Exhibit 31.1

Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Frederick Beddingfield III, M.D., Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sienna Biopharmaceuticals, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 8, 2019

By: /s/ Frederick C. Beddingfield III
Frederick C. Beddingfield III, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Alexander Azoy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sienna Biopharmaceuticals, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 8, 2019

By: /s/ Alexander Azoy
Alexander Azoy
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION 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 on Form 10-Q of Sienna Biopharmaceuticals, Inc. (the "Company") for the period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Frederick C. Beddingfield III, M.D., Ph.D., President and Chief Executive Officer of the Company, and Alexander Azoy, Chief Financial Officer of the Company, respectively, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 8, 2019

/s/ Frederick C. Beddingfield III
Frederick C. Beddingfield III, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2019

/s/ Alexander Azoy
Alexander Azoy
Chief Financial Officer
(Principal Financial Officer)