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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from _____ to _____

Commission file number: 001-38155

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)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

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

As of August 6, 2018, there were 20,799,794 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

Sienna Biopharmaceuticals, Inc.
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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, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 74,887	$ 74,467
Restricted cash	181	181
Prepaid expenses and other current assets	2,573	2,698
Total current assets	77,641	77,346
Property and equipment, net	371	432
In-process research and development	46,501	47,597
Goodwill	11,207	11,472
Total assets	$ 135,720	$ 136,847
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,180	$ 2,357
Accrued personnel costs	1,875	2,646
Other accrued expenses	7,077	3,007
Early exercise liability, current portion	213	231
Total current liabilities	13,345	8,241
Early exercise liability—net of current portion	151	258
Contingent consideration	25,200	22,900
Success payment liability	881	3,285
Long-term debt, net	29,897	—
Deferred tax liability	10,712	10,964
Total liabilities	80,186	45,648
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000 shares authorized, no shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.0001 par value, 300,000 shares authorized, 20,800 and 20,740 shares issued and 20,365 and 20,194 shares outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Additional paid in capital	174,523	171,726
Accumulated other comprehensive income	4,250	5,370
Accumulated deficit	(123,239)	(85,897)
Total stockholders' equity	55,534	91,199
Total liabilities and stockholders' equity	$ 135,720	$ 136,847

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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 15,692	$ 6,704	$ 28,672	$ 11,622
General and administrative	5,976	4,562	11,473	8,638
Total operating expenses	21,668	11,266	40,145	20,260
Loss from operations	(21,668)	(11,266)	(40,145)	(20,260)
Other income (expense), net	1,429	(1,672)	2,803	(2,833)
Net loss before taxes	(20,239)	(12,938)	(37,342)	(23,093)
Income tax benefit	—	81	—	127
Net loss	$ (20,239)	$ (12,857)	$ (37,342)	$ (22,966)
Other comprehensive income (loss):				
Cumulative translation adjustment	(2,494)	2,706	(1,120)	3,477
Comprehensive loss	$ (22,733)	$ (10,151)	$ (38,462)	$ (19,489)
Per share information:				
Net loss, basic and diluted	$ (1.00)	$ (6.50)	$ (1.84)	$ (11.81)
Basic and diluted weighted average shares outstanding	20,289	1,978	20,258	1,944

See accompanying notes.

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

	Six Months Ended June 30,	
	2018	**2017**
Operating activities		
Net loss	$(37,342)	$(22,966)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	78	53
Amortization of debt discount	—	729
Stock-based compensation	1,896	313
Fair value adjustment of success payment liability	(2,404)	2,073
Fair value adjustment of contingent consideration	2,300	2,090
Non-cash interest expense	—	34
Loss on disposal of property and equipment	—	5
Changes in assets and liabilities:		
Prepaid expenses and other current assets	122	(2,137)
Accounts payable and other accrued liabilities	5,145	2,275
Net cash used in operating activities	(30,205)	(17,531)
Investing activities		
Investment in property and equipment	(17)	(74)
Proceeds from sale of property and equipment	—	8
Net cash used in investing activities	(17)	(66)
Financing activities		
Proceeds from issuance of common stock, net of early exercise liability	407	206
Repurchase of unvested early exercise stock options	(18)	—
Net proceeds from issuance of long-term debt	29,897	—
Proceeds from issuance of common stock upon ESPP purchase	388	—
Proceeds from issuance of convertible promissory notes	—	3,906
Net proceeds from issuance of Series B preferred stock	—	36,306
Net cash provided by financing activities	30,674	40,418
Effect of exchange rate changes on cash	(32)	(121)
Net increase in cash, cash equivalents and restricted cash	420	22,700
Cash, cash equivalents and restricted cash at beginning of period	74,648	9,200
Cash, cash equivalents and restricted cash at end of period	$ 75,068	$ 31,900

See accompanying notes.

Sienna Biopharmaceuticals, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
June 30, 2018

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 innovations in biotechnology to the discovery, development and commercialization of first-in-class, targeted, topical products in medical dermatology and aesthetics.

On July 20, 2017, the Company amended and restated its certificate of incorporation, giving effect to a 1-for-5.87 reverse stock split of the Company's capital stock. All share and per share information included in the accompanying unaudited condensed consolidated financial statements has been adjusted to reflect this reverse stock split.

On August 1, 2017, the Company completed its initial public offering, or IPO, of 4,983,333 shares of common stock, which included the exercise in full by the underwriters of their option to purchase up to 650,000 additional shares of common stock, at an offering price to the public of $15.00 per share. The Company received net proceeds of approximately $66.4 million after deducting underwriting discounts, commissions and offering related transaction costs. In connection with the IPO, the Company's outstanding shares of convertible preferred stock were automatically converted into 12.8 million shares of common stock. As of June 30, 2018, the Company had 20.8 million shares of common stock outstanding. See Note 13, "Stockholders' Equity."

In connection with the completion of its IPO, on August 1, 2017, the Company's certificate of incorporation was amended and restated to provide for 300.0 million authorized shares of common stock with a par value of $0.0001 per share and 10.0 million authorized shares of preferred stock with a par value of $0.0001 per share.

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 and $10.0 million of which remains available for borrowing, subject to the satisfaction of certain conditions set forth in the SVB Loan Agreement.

2. Liquidity Risks

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 $123.2 million and $85.9 million as of June 30, 2018 and December 31, 2017, respectively. The Company had net losses of $20.2 million and $37.3 million for the three and six months ended June 30, 2018 and $12.9 million and $23.0 million for the three and six months ended June 30, 2017, respectively, and net cash used in operating activities of $30.2 million and $17.5 million for the six months ended June 30, 2018 and 2017, respectively.

The Company has historically financed its operations primarily through private equity issuances and debt offerings, and more recently through its IPO and term loans, under the SVB Loan Agreement. The Company had cash and cash equivalents of $74.9 million and $74.5 million at June 30, 2018 and December 31, 2017, respectively. The Company believes that its current capital resources will be sufficient to fund operations through at least the next twelve months based on the expected cash burn rate. 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. If the Company is unable to obtain additional funding from these or other sources when needed, or to the extent needed, it may be necessary to significantly reduce its current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require the Company to relinquish rights to product candidates at an earlier stage of development or on less favorable terms to it or its stockholders than the Company would otherwise choose.

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.

Unaudited Condensed Consolidated Financial Statements

The accompanying financial information for the three and six months ended June 30, 2018 and 2017 are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual 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, 2018 and its results of operations for the three and six months ended June 30, 2018 and 2017 and cash flows for the six months ended June 30, 2018 and 2017. The results 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 in consolidation.

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 the valuation of equity awards and the success payment liability, clinical trial accruals and the valuation of the contingent consideration obligations 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.

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, 2018, 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, 2018 and December 31, 2017, the Company held $0.2 million of restricted cash related to cash collateralized standby letters of credit in connection with obligations under the Company's facility lease.

Fair Value Measurements

The Company's financial instruments, in addition to those presented in Note 7, "Fair Value Measurements", include cash and cash equivalents, restricted cash, accounts payable, accrued liabilities and long-term debt. The carrying amount of cash and cash equivalents, 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 impairments recognized during the six months ended June 30, 2018 and the year ended December 31, 2017.

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, or IPR&D, 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 indefinite-lived intangible assets for the six months ended June 30, 2018 and the year ended December 31, 2017.

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. Goodwill will not be amortized but will be evaluated for impairment annually 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. There was no impairment of goodwill for the six months ended June 30, 2018 and the year ended December 31, 2017.

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. Stock options issued to non-employees are valued on their grant date and remeasured at the current fair value at the end of each reporting period until they vest. 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, 2018, 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 $4.3 million and $0.9 million as of June 30, 2018 and December 31, 2017, respectively. At December 31, 2017, prepaid expenses and other current assets include prepaid clinical trial costs of $1.1 million.

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, 2018 and 2017. Shares excluded from the calculation were 2.5 million and 14.4 million at June 30, 2018 and 2017, 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.

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, "Creabilis Acquisition". 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 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 March 2018, the FASB issued ASU 2018-05, "*Income Taxes (Topic 740)—Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118",* a new accounting standard to incorporate Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 118 (SAB 118), which addresses the accounting implications of the major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (the 2017 Tax Act), enacted on December 22, 2017. The SEC issued SAB 118 to address concerns about reporting entities' ability to timely comply with the accounting requirements to recognize all of the effects of the 2017 Tax Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Act are incomplete by the due date of the financial statements and if possible provide a reasonable estimate. The Company will continue to analyze the 2017 Tax Act and, in certain areas, has made reasonable estimates of the effects on the condensed consolidated financial statements and tax disclosures.

In January 2017, the FASB issued ASU 2017-01 *"Business Combinations (Topic 805): Clarifying the Definition of a Business",* which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. The Company adopted this standard as of January 1, 2018 and will apply it prospectively. Adoption of this new standard may result in more transactions being accounted for as asset acquisitions versus business combinations. The impact on the consolidated financial statements in future periods will depend on the facts and circumstances of future transactions.

In November 2016, the FASB issued ASU 2016-18, *"Statement of Cash Flows (Topic 230): Restricted Cash"* ("ASU 2016-18"). The update is effective for fiscal years beginning after December 15, 2017, including interim reporting periods within those fiscal years. Early adoption is permitted. The purpose of Update No. 2016-18 is to clarify guidance and presentation related to restricted cash in the statement of cash flows. The amendment requires beginning-of-period and end-of-period total amounts shown on the statement of cash flows to include cash and cash equivalents as well as restricted cash and restricted cash equivalents. This amended guidance was retrospectively adopted on January 1, 2018. As a result of adopting ASU 2016-18, the Company includes its restricted cash balance in the cash, cash equivalents and restricted cash reconciliation of operating, investing and financing activities. The adoption of this guidance did not have a significant impact on the statement of cash flows.

In August 2016, the FASB issued ASU 2016-15, *"Statement of Cash Flows (Topic 230)"* ("ASU 2016-15"), which seeks to reduce the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows, including contingent consideration cash payments made after a business combination. The Company adopted this standard on January 1, 2018 with no impact on the consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, "*Revenue from Contracts with Customers (Topic 606)*" ("ASU 2014-09") which amended the existing accounting standards for revenue recognition. ASU 2014-09 establishes principles for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. This guidance is effective for fiscal years beginning after December 15, 2017, with an option to early adopt for fiscal years beginning after December 15, 2016. The Company adopted this standard on January 1, 2018 and as the Company has no revenues, there was no impact on the consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

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. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, *Revenue from Contracts with Customers.* The Company is currently evaluating the impact of adopting this standard on the consolidated financial statements and disclosures.

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 new authoritative guidance will be effective for all entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the impact of adopting this standard on the consolidated financial statements and disclosures, but does not expect it to have a significant impact.

In May 2017, the FASB issued ASU 2017-09, "*Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*", which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. Early adoption is permitted. The Company is currently evaluating the impact of adopting this standard on the consolidated financial statements and disclosures, but does not expect it to have a significant impact.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (ASC 842),* which requires lessees to recognize most leases on the balance sheet. This is expected to increase both reported assets and liabilities. The standard will be effective for the first interim reporting period within annual periods beginning after December 15, 2018, although early adoption is permitted. Lessees and lessors will be 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 will be the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. The requirements of this standard include a significant increase in required disclosures. The Company is in the process of identifying and analyzing all agreements which may be affected by the new guidance and is currently evaluating the update and assessing the impact it may have on its consolidated financial statements and disclosures.

4. Creabilis Acquisition

Pursuant to the acquisition of Creabilis in December 2016, the Company obtained SNA-120, SNA-125 and the related intellectual property. SNA-120 is a first-in-class inhibitor of TrkA in Phase 2b clinical development for the treatment of pruritus, or itch, associated with psoriasis, as well as for psoriasis itself. SNA-125 is a dual JAK3/TrkA inhibitor being developed for the treatment of atopic dermatitis, psoriasis and pruritus. The transaction was accounted for as a business combination under the acquisition method of accounting and as such, the tangible assets and identifiable intangible assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill.

Upon closing, the Company became obligated 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. In addition, the Company became 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.

On October 19, 2017, the Company achieved the first dosing of a human subject in a Phase 2b clinical trial for SNA-120, triggering the obligation to settle the first contingent payment of $5.0 million to the former Creabilis shareholders, subject to certain offsets. As a result, the Company issued 201,268 shares of its common stock valued at $20.86 per share for the aggregate value of $4.2 million to the former Creabilis shareholders. Accordingly, the shares were issued to the former Creabilis shareholders for no additional cash consideration. The Company recognized the additional change in fair value of the contingent consideration liability through the date of settlement and reclassified the related contingent consideration liability balance to equity in the condensed consolidated balance sheet.

The agreement to pay the future milestones and potential one-time royalties resulted in the recognition of a contingent consideration liability, 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 condensed consolidated statement of operations in general and administrative expense. The fair value of the contingent consideration is based on preliminary cash flow projections, based on expected product sales, probabilities around the achievement of certain development, approval and sales milestones and other assumptions. Based on the assumptions, the fair value of the contingent consideration liability was determined to be $25.2 million and $22.9 million at June 30, 2018 and December 31, 2017, respectively. The fair value of the contingent consideration was 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.

As a result of the acquisition of Creabilis, the Company recorded a deferred tax liability of $9.4 million for the non-deductible in-process research and development intangible assets acquired on the date of the acquisition. The deferred tax liability is a foreign denominated liability subject to translation at each balance sheet date and had a carrying value of $10.7 million and $11.0 million at June 30, 2018 and December 31, 2017, respectively. The change in carrying value during the six months ended June 30, 2018 was related to $0.3 million of translation adjustments. The recording of the deferred tax liability resulted in goodwill in the amount of $9.8 million on the date of acquisition. Goodwill is also foreign denominated and subject to translation at each balance sheet date and had a carrying value of $11.2 million and $11.5 million at June 30, 2018 and December 31, 2017, respectively. The change in carrying value during the six months ended June 30, 2018 was due to translation adjustments of $0.3 million. The net impact of all translation adjustments is included in other comprehensive income (loss).

5. Identifiable Intangible Assets

The Company’s only identifiable intangible assets as of June 30, 2018 and December 31, 2017 are indefinite-lived IPR&D assets related to SNA-120 and SNA-125. The total intangible IPR&D assets were recorded at an initial value of $42.3 million as a result of the Company’s acquisition of Creabilis. These IPR&D assets are foreign denominated and subject to translation and had a carrying value of $46.5 million and $47.6 million as of June 30, 2018 and December 31, 2017, respectively. The Company uses the income approach to derive the fair value of IPR&D assets. This approach calculates fair value by estimating future cash flows attributable to the assets, using several unobservable inputs such as future revenues and expenses, time and resources need 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”.

Indefinite-lived 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. Changes in value as a result of foreign currency translation adjustments are included in other comprehensive income (loss).

6. Property and Equipment

Property and equipment consisted of the following as of June 30, 2018 and December 31, 2017 (in thousands):

	Estimated Useful Life (in years)	June 30, 2018	December 31, 2017
Lab equipment	5	$ 307	$ 307
Computer hardware	3	129	116
Capital lease equipment	3	46	46
Furniture and fixtures	5	95	91
Leasehold improvements		105	105
Total		682	665
Less accumulated depreciation		(311)	(233)
Property and equipment, net		$ 371	$ 432

Leasehold improvements are depreciated over the lease term. Depreciation expense was $39,000 and $78,000 for the three and six months ended June 30, 2018, and $27,000 and $53,000 for the three and six months ended June 30, 2017, respectively.

7. Fair Value Measurements

We determine 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, 2018 and December 31, 2017 (in thousands):

	June 30, 2018		
	Level 1	Level 2	Level 3
Assets:			
Cash and cash equivalents	$74,887	$ —	$ —
Total	$74,887	$ —	$ —
Liabilities:			
Success payment liability	$ —	$ —	$ 881
Contingent consideration	—	—	25,200
Total	$ —	$ —	$26,081

	December 31, 2017		
	Level 1	Level 2	Level 3
Assets:			
Cash and cash equivalents	$74,467	$ —	$ —
Total	$74,467	$ —	$ —
Liabilities:			
Success payment liability	$ —	$ —	$ 3,285
Contingent consideration	—	—	22,900
Total	$ —	$ —	$26,185

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

	Success Payment Liability	Contingent Consideration
Balance at December 31, 2017	$ 3,285	$ 22,900
Change in fair value due to remeasurement	(2,404)	2,300
Balance at June 30, 2018	$ 881	$ 25,200

Cash equivalents

At June 30, 2018, 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 IPR&D assets at the acquisition date 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 when required as part of the related impairment test.

Contingent consideration

The Company also 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 5.43% to 17.6%, projected future revenues and expenses based on the cumulative probabilities of multiple scenarios with individual probabilities ranging from 0.1% to 25.0%, and estimates of the 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 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.

In October 2017, the Company commenced the additional Phase 2b clinical trial for SNA-120, triggering the first contingent milestone payment of $5.0 million, less certain offsets totaling approximately $0.3 million, which was satisfied by issuing an aggregate of 201,268 shares of common stock to the former Creabilis shareholders. The number of shares issued was based on the volume weighted average price of the Company's common stock over the 20-day trading period preceding the commencement of the trial. Concurrently, the Company recognized the additional change in fair value of the contingent consideration liability in general and administrative expense and recognized the settlement of the first contingent milestone in shares of common stock totaling $4.2 million by reclassifying the related contingent consideration liability balance to equity in the condensed consolidated balance sheet. The increase in value during the three and six months ended June 30, 2018 was $0.8 million and $2.3 million, respectively, and was primarily related to the passage of time and progress toward milestone dates as well as changes in external market factors. The increase in value during the three and six months ended June 30, 2017 was $0.7 million and $2.1 million, respectively, and was related to changes in external market factors partially offset by decreases in the value related to assumptions regarding milestone payments.

Success payment liability

In October 2015, as a result of an agreement in which the Company agreed to pay certain stockholders success payments if the stock price of the Company's common stock reached certain thresholds, the Company recorded a success payment liability. The success payment liability was recorded at fair value based on significant unobservable inputs, as discussed in Note 9, "Success Payment Liability". The change in fair value during the three and six months ended June 30, 2018 resulted in other income of $1.2 million and $2.4 million, respectively. During the three and six months ended June 30, 2017, the change in fair value resulted in other expense of $1.0 million and $2.1 million, respectively. The changes in fair value were recorded to other income (expense), net in the condensed consolidated statements of operations. The valuation of the fair value of the success payment liability uses assumptions the Company believes would be made by a market participant and the Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. In evaluating the fair value information, judgement is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates. Significant increases or decreases in the probabilities of meeting the common stock price thresholds or in the timing or likelihood of achieving the triggering events and other inputs would result in a significantly higher or lower fair value measurement, respectively.

There were no transfers of assets or liabilities between the fair value measurement levels during the six months ended June 30, 2018 or the year ended December 31, 2017.

8. Convertible Notes

In January 2017, the Company entered into a note purchase agreement pursuant to which the Company issued, in two tranches, subordinated convertible promissory notes (the "Series B Bridge Notes" and together with the note purchase agreement, the "Series B Bridge Note Agreements") in an aggregate principal amount of $3.9 million. The Series B Bridge Notes provided for an annual interest rate of 6.0% and a maturity date of January 27, 2018. Under the terms of the Series B Bridge Note Agreements, under certain circumstances, the unpaid principal of the Series B Bridge Notes, including any accrued but unpaid interest thereon, would convert into shares of convertible preferred stock upon the closing of a future preferred stock financing that met specified criteria. Such conversion would be at a 15% discount to the per share price of the convertible preferred stock sold in the financing. In addition, the notes were voluntarily convertible into shares upon the occurrence of a non-qualified financing or upon maturity, and such conversion would still be at a 15% discount to the per share price of the convertible preferred stock sold in the financing.

The conversion feature included a 15% discount in the convertible notes, which constituted a beneficial conversion feature that was bifurcated and allocated to additional paid in capital. The intrinsic value of the beneficial conversion feature due to the 15% discount on conversion of the principal and accrued interest was calculated to be $0.7 million. This resulted in a discount of $0.7 million being allocated to the Series B Bridge Notes which was being amortized to interest expense in the condensed consolidated statement of operations on an effective interest method from the date of issuance of each Series B Bridge Notes through the maturity date of January 27, 2018.

In April 2017, in connection with the Company's Series B convertible preferred stock financing, the outstanding principal under the Series B Bridge Notes of $3.9 million, plus $34,000 of accrued interest, converted into an aggregate of 0.4 million shares of Series B convertible preferred stock at a rate of $10.40 per share and the Series B Bridge Notes were cancelled. In connection with the IPO, the Series B convertible preferred stock was automatically converted into 0.4 million shares of common stock. The remaining unamortized discount was recognized in interest expense in the condensed consolidated statement of operations. Included in other income (expense), net for the three and six months ended June 30, 2017 is amortization of the debt discount of $0.6 million and $0.7 million and accrued interest expense of $7,000 and $34,000, respectively.

9. 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 "Success Payment Agreement"). 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 any of the following dates during the success payment period: (1) any date after the 90th day after the date on which the Company completes an initial public offering of its common stock; (2) the date on which the Company sells, leases, transfers, or exclusively licenses all or substantially all of its assets to another company; and (3) the date on which the Company merges or consolidates with or into another entity (other than a merger in which the pre-merger stockholders own a majority of the shares of the surviving entity). In the case of an initial public offering, the success payments are triggered when the value of the Company's common stock, as determined by the average daily volume-weighted average trading price per share over the preceding consecutive 90-day period, meets or exceeds the specified share price thresholds. In the case of an asset sale, license or sale of the Company, the success payment is triggered when the value of the Company's common stock, as determined by the per share consideration paid in the transaction, is in excess of the specified share price thresholds.

The amount of the success payment is determined based on whether the value of the common stock of the Company meets or exceeds certain specified share price thresholds, subject to adjustment for any stock dividend, stock split, combination of shares, or other similar events. 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 remeasures the liability each reporting period, with changes being recognized in the consolidated statements of operations. 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. The following variables were incorporated in the estimated fair value of the success payment liability: estimated term of the success payments, fair value of the Company's common stock, expected volatility, and risk-free interest rate. The computation of expected volatility was estimated using a combination of available information about the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term assumption. During the three and six months ended June 30, 2018, the Company recorded other income of $1.2 million and $2.4 million, respectively, and during the three and six months ended June 30, 2017, the Company recorded other expense of $1.0 million and $2.1 million, respectively, due to re-measurement of the liability.

10. Long-Term Debt

On June 29, 2018 the Company entered into a Loan and Security Agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"). Under the SVB Loan Agreement, SVB will provide 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.

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 29, 2018, the rate was 7.50%. If the Company fails to receive positive Phase 2b data for SNA-120 by March 31, 2019, the Company must immediately cash secure at least the lesser of the outstanding principal balance of the term loans or $15.0 million, until such time that the Company raises at least $50.0 million in equity financing and has received positive Phase 1 data for SNA-125 in atopic dermatitis on or prior to April 30, 2019.

An additional term loan, of a principal amount of up to $10.0 million, can be drawn down at the Company's option during the period of time commencing on the date the Company has received positive pivotal data for SNA-001 and positive Phase 2b data for SNA-120 and ending on the earlier of June 30, 2019 or the occurrence of an event of default that continues; provided, however, that such period of time shall not commence if, on the date of the occurrence of either the Company's receipt of positive pivotal data for SNA-001 or receipt of positive Phase 2b data for SNA-120, an event of default has occurred and is continuing. Interest and principal for the additional tranche is repayable upon the same schedule as the repayment for the initial credit extension, including the same interest-only period.

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 5.50% of the total term loans advanced, due upon the earliest of maturity, acceleration, prepayment or termination of the SVB Loan Agreement.

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, investments and dividends, but no financial covenants), 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, 2018, the carrying value of the term loan consists of $30.0 million principal outstanding less the debt issuance costs of approximately $0.1 million. 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. 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 related to the amortization of capitalized loan costs. At June 30, 2018, the effective interest rate was 9.32%. The final maturity payment of $1.7 million is recognized over the life of the term loan through interest expense using the effective interest method.

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

	June 30, 2018
2018	$ —
2019	—
2020	4,530
2021	9,613
2022	10,370
2023	5,487
Total principal payments	30,000
Final fee due at maturity in 2023	1,650
Total principal and final fee payments	31,650
Unamortized discount and debt issuance costs	(1,753)
Long-term debt, net	$ 29,897

11. Commitments and Contingencies

Operating Lease

In May 2016, the Company entered into a 40-month lease obligation for office space in Westlake Village, California, which commenced on October 10, 2016, and terminates on February 29, 2020. In June 2017, the Company amended the lease agreement to include an additional 5,973 square feet and an allowance for leasehold improvements of up to $0.1 million. The lease is subject to fixed rate escalation increases and includes a period of free rent. As a result, the Company recognizes rent expense on a straight-line basis for the full amount of the commitment including the minimum rent increases over the life of the lease and the free rent period. The lease contains a renewal option for an additional three-year term.

During the three and six months ended June 30, 2018, the Company incurred $0.1 million and $0.2 million, respectively, for rent expense and $0.1 million and $0.3 million, for the three and six months ended June 30, 2017, respectively.

License and Supply Agreement

The Company has an exclusive license and supply 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.

Indemnifications

The Company has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to some 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 believes the fair value of these indemnification agreements is minimal. Accordingly, the Company did not record liabilities for these agreements as of June 30, 2018 and December 31, 2017.

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, 2018, there are no matters where there is at least a reasonable probability that a material loss has been or will be incurred.

12. 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 no management or voting rights in respect of Venvest (including no voting or investment power with respect to shares of the Company's capital stock held by 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 0.6 million 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 0.5 million 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 49,000 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 49,000 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. 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 $0.1 million recognized as compensation expense for the three and six months ended June 30, 2018, respectively and $37,000 and $0.1 million recognized during the three and six months ended June 30, 2017, 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 by providing a promissory note to the Company in the principal amount of $1.3 million, with an interest rate of 1.43% per annum. The promissory note was considered to be substantively non-recourse and, as such, the issuance of the unvested restricted shares in exchange for the note continued to constitute a stock option for accounting purposes. As the promissory note was non-recourse, it was not reflected on the Company's balance sheet at December 31, 2016. In June 2017, the Company forgave all outstanding principal and accrued interest under the related party non-recourse promissory note effective as of July 2, 2017, and the note was cancelled. The total outstanding principal balance and accrued but unpaid interest forgiven on the promissory note was $1.3 million. As of December 31, 2017, 0.2 million shares subject to the award had vested and an additional 57,000 shares vested during the six months ended June 30, 2018.

Success Payments

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

13. Stockholders' Equity

As of June 30, 2018, 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.

Pursuant to the automatic increase provisions of our 2017 Incentive Award Plan, ("the 2017 Plan") and 2017 Employee Stock Purchase Plan, ("ESPP"), 829,606 additional shares were reserved for future issuance under the 2017 Plan and 207,401 additional shares under the ESPP on January 1, 2018.

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

	June 30, 2018
Common stock awards outstanding	2,103
Common stock awards available for grant under the ESPP	376
Common stock awards available for grant under the 2017 Plan	1,191
Total shares of common stock reserved for future issuance	3,670

Convertible Preferred Stock

As of June 30, 2018, there was no convertible preferred stock outstanding. In connection with the Company's IPO, all outstanding shares of convertible preferred stock were automatically converted into 12.8 million shares of common stock.

In April 2017, the Company issued an aggregate of 3.0 million shares of Series B convertible preferred stock at a price per share of $12.24 for aggregate proceeds of $36.5 million, exclusive of 0.4 million shares of Series B convertible preferred stock issued upon conversion of the Series B Bridge Notes. See Note 8 "Convertible Notes". All of the Company's outstanding Series B convertible preferred stock was automatically converted into common stock in connection with the IPO.

Stock Awards and Stock-Based Compensation

In July 2017, the Company's board of directors approved the 2017 Plan, which became effective upon the completion of the 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 1.2 million shares of common stock available 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 will increase 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 2018 and 2017 was estimated on the grant date using the Black-Scholes option-pricing model. The fair value of each non-employee option granted was estimated on the grant date and subsequently remeasured each reporting period using the Black-Scholes option-pricing model. The following assumptions were used for grant date fair value for the six months ended June 30, 2018 and the year ended December 31, 2017:

	Six Months Ended June 30, 2018	Year Ended December 31, 2017
Expected stock price volatility	66.72%–74.21%	59.13%–64.09%
Expected dividend yield	— %	— %
Expected term (in years)	5.0–6.08	5.3–10.0
Risk-free interest rate	2.55%–2.84%	1.77%–2.60%

Due to limited historical data, the Company estimates stock price volatility based on the actual volatility 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 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 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 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.

The table below summarizes the stock option activity for the six months ended June 30, 2018:

	Number of Shares (in thousands)	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	1,159	$ 8.19	$ 11,795
Granted	1,123	16.57	
Exercised	(37)	11.04	—
Cancelled	(142)	12.55	
Outstanding at June 30, 2018	2,103	$ 12.32	$ 8,146
Exercisable at June 30, 2018	337	$ 4.51	$ 3,659

The aggregate intrinsic value of the options outstanding is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of June 30, 2018.

The Company did not grant any non-employee options to purchase shares of its common stock during the six months ended June 30, 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 nonemployees subject to vesting, the value of stock and options issued to nonemployees 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,	
	2018	2017	2018	2017
Research and development	$ 287	$ 44	$ 730	$ 78
General and administrative	708	136	1,166	235
	$ 995	$ 180	$1,896	$313

As of June 30, 2018, there was $15.5 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 3.52 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.

The weighted-average grant date fair value of all stock options granted during the six months ended June 30, 2018 was $10.62. The weighted-average remaining contractual life of options outstanding at June 30, 2018 is 9.2 years. The total fair value of the shares vested during the six months ended June 30, 2018 was $1.2 million. Additionally, stock compensation expense includes $0.1 million, $0.3 million, $39,000 and $0.1 million related to non-employee option grants during the three and six months ended June 30, 2018 and 2017, 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 condensed consolidated balance sheets and will be transferred to common stock and additional paid in capital as such shares vest. As of June 30, 2018 and December 31, 2017, 0.4 million and 0.5 million 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, 2018 and December 31, 2017, of $0.4 million and $0.5 million, respectively, of which $0.2 million and $0.2 million is included in current liabilities, and $0.2 million and $0.3 million is included in non-current liabilities in the condensed consolidated balance sheets at June 30, 2018 and December 31, 2017, respectively. During the six months ended June 30, 2018, the Company repurchased 7,775 shares of unvested early exercise shares at $2.35 per share.

2017 Employee Stock Purchase Plan

The Company adopted 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 structured 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 Company recognized $0.1 million and $0.2 million in compensation expense related to the ESPP for the three and six months ended June 30, 2018. During the three months ended June 30, 2018, 30,486 shares of common stock were issued under the ESPP.

14. Income Taxes

There is no provision for income taxes for the three and six months ended June 30, 2018 as the Company has incurred operating losses since inception. Intraperiod tax allocation rules require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings. As a result, for the three and six months ended June 30, 2017 the Company recorded a $0.1 million income tax benefit in the consolidated statement of operations.

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 U.S. 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, 2018, 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.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act, or the Act. The Act amends the Internal Revenue Code of 1986, as amended, or the Code, to reduce tax rates and modify policies, credits and deductions for individuals and businesses. For businesses, the Act reduces the corporate tax rate from a maximum of 35% to a flat 21% rate. The rate reduction is effective on January 1, 2018.

Due to the uncertainties which currently exist in the interpretation of the provisions of the Act regarding Code Section 162(m), the Company has not evaluated all of the potential impacts as amended by the Act on its consolidated financial statements.

On December 22, 2017, Staff Accounting Bulletin No. 118, or SAB 118, was issued to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, the Company has determined that there is no deferred tax benefit or expense with respect to the remeasurement of certain deferred tax assets and liabilities due to the full valuation allowance against net deferred tax assets. Additional analysis of the law and the impact to the Company will be performed and any impact will be recorded in the respective quarters, within the available measurement period in 2018.

15. Subsequent Events

On July 30, 2018, the Company announced top-line data from two pivotal trials with SNA-001 for the treatment of acne. The two pivotal acne trials with SNA-001 in conjunction with 1064 nm and 810 nm lasers did not show statistical significance on the primary and secondary endpoints. SNA-001 is a topical medical product derived from Sienna's proprietary Topical Photoparticle Therapy™ platform.

2018 Sales Agreement

On August 3, 2018 the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("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"). 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. In addition, the Company has agreed to reimburse a portion of the expenses of Cowen in connection with the offering up to a maximum of $0.1 million.

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 shares to be sold under the Sales Agreement, if any, may be issued and sold pursuant to the Shelf Registration Statement, after such time as it is declared effective by the SEC.

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, 2017 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, 2017, 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 innovations in biotechnology to the discovery, development and commercialization of first-in-class, targeted, topical products in medical dermatology and aesthetics. Our objective is to develop our multi-asset pipeline of topical therapies that enhance the health, appearance and quality of life of dermatology patients. We are advancing multiple product candidates derived from our Topical by Design™ platform, all of which are designed to be suitable for chronic administration in patients with inflammatory skin diseases and other dermatologic and aesthetic conditions. Our lead candidate from this platform, SNA-120, is a first-in-class inhibitor of Tropomyosin receptor kinase A, or TrkA, in Phase 2b clinical development for the treatment of pruritus, or itch, associated with psoriasis, as well as for psoriasis itself. Our second Topical by Design™ product candidate, SNA-125, is a dual JAK3/TrkA inhibitor being developed for the treatment of atopic dermatitis, psoriasis and pruritus. Additionally, we have advanced SNA-001, a silver particle treatment derived from our Topical Photoparticle Therapy™ platform, into pivotal clinical trials for both acne vulgaris and the reduction of unwanted light-pigmented hair. We believe our management team is well-positioned to execute on our objectives, having served in clinical and commercial leadership roles at several marquee dermatology, aesthetics and biotechnology companies, including Kythera, Allergan, Medicis and Amgen.

Since our inception in 2010, 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, in December 2016. We have not generated any revenue from product sales and, to date, have funded our operations primarily through private and public equity issuances and debt offerings. At June 30, 2018, we had cash and cash equivalents of $74.9 million. In August 2017, we completed our initial public offering, or IPO, of our common stock pursuant to which we issued 4,983,333 shares of our common stock at a price to the public of $15.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 650,000 additional shares. Our net proceeds, after deducting underwriting discounts, commissions and offering related transaction costs, were $66.4 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. On August 3, 2018, we entered into a sales agreement (the "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").

We have incurred net losses in each year since inception, including net losses of $20.2 million and $37.3 million for the three and six months ended June 30, 2018, and $12.9 million and $23.0 million and for the three and six months ended June 30, 2017, respectively. As of June 30, 2018, we had an accumulated deficit of $123.2 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, or 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 that our expenses will increase substantially as we continue nonclinical studies and clinical trials for, and research and development of, our product candidates and maintain, expand 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. We currently anticipate that we will seek to fund our operations through equity or debt financings or other sources, such as potential collaboration agreements. 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 and the Topical by Design™ platform and related product candidates, SNA-120 and SNA-125, we will be required to make contingent payments in cash and stock upon the achievement of certain development, approval and sales milestones. 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 in December 2017 to the former Creabilis shareholders pursuant to the terms of the Share Purchase Agreement. 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 an additional $53.0 million, which consists of an aggregate of $25.0 million in cash and $28.0 million in shares of our common stock. 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—Creabilis Acquisition" below.

On July 30, 2018, we announced top-line data from two pivotal acne trials with SNA-001 in conjunction with 1064 nm and 810 nm lasers, noting that SNA-001 did not show statistical significance on the primary and secondary endpoints.

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.

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.

We expect to continue to incur substantial research and development expenses in the future as we develop our product candidates. In particular, we expect to incur substantial research and development expenses for the additional Phase 2b trials for SNA-120, the nonclinical studies and clinical trials for SNA-125 and the completion of our ongoing pivotal trials for SNA-001. We also expect to continue investing in our internal research and development efforts to develop new product candidates for dermatology, aesthetics and other therapeutic areas.

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, SNA-125 and SNA-001 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 and general legal services, and the changes in the fair value of our contingent consideration liability. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and prepare for potential commercialization of our product candidates, increase our headcount and

support our operations as a public company, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or 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 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, 2017, 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, 2018, 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, or 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 during the six months ended June 30, 2018 or the year ended December 31, 2017.

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. There was no impairment of goodwill during the six months ended June 30, 2018 or the year ended December 31, 2017.

Success Payments

We have certain payment obligations related to the Success Payment Agreement that we entered into with certain of our existing stockholders in October 2015. These success payments are based on certain specified threshold per share values of our common stock measured at specific times through 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 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.

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, we recorded an initial liability at fair value and will remeasure 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. The following variables were incorporated in the estimated fair value of the success payment liability: estimated term of the success payments, fair value of our common stock, expected volatility, and risk-free interest rate. The computation of expected volatility was estimated using a combination of available information about the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term assumption. Due to the remeasurement of the liability, we recorded other income of $1.2 million and $2.4 million during the three and six months ended June 30, 2018, respectively, and other expense of $1.0 million and $2.1 million, during the three and six months ended June 30, 2017, respectively.

In determining the fair value of the success payments, judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates. Significant increases or decreases in our common stock price and other inputs could result in a significantly higher or lower fair value measurement, respectively.

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. Stock options issued to non-employees are valued on their grant date and remeasured at the current fair value at the end of each reporting period until they vest.

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, 2018 and the year ended December 31, 2017.

	Six Months Ended June 30, 2018	Year Ended December 31, 2017
Expected stock price volatility	66.72–74.21%	59.13–64.09%
Expected dividend yield	—%	—%
Expected term (in years)	5.0–6.08	5.3–10.0
Risk-free interest rate	2.55–2.84%	1.77–2.60%

Due to limited historical data, we estimate stock price volatility based on the actual volatility 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 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, 2018 and 2017, as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Research and development	$ 287	$ 44	$ 730	$ 78
General and administrative	708	136	1,166	235
	$ 995	$ 180	$1,896	$313

As of June 30, 2018, there was $15.5 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 3.52 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 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, 2018 and December 31, 2017, 0.4 million and 0.5 million unvested shares were issued and outstanding, respectively. In connection with these unvested shares, we recorded an early exercise liability as of June 30, 2018 and December 31, 2017 of $0.4 million and $0.5 million, respectively, of which $0.2 million and $0.2 million is included in other current liabilities and $0.2 million and $0.3 million is included in other non-current liabilities in the condensed consolidated balance sheets at June 30, 2018 and December 31, 2017, 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.

Creabilis Acquisition

As a result of the Creabilis acquisition we became obligated to make certain contingent payments. 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 additional $53.0 million, which consists of an aggregate of $25.0 million in cash and $28.0 million in shares of our common stock. 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 condensed consolidated statement of operations. The fair value of the contingent consideration is based on preliminary cash flow projections, which are based on expected product sales, probabilities around the achievement of certain development, approval and sales milestones and other assumptions. Based on these assumptions, the fair value of the contingent consideration was determined to be $25.2 million as of June 30, 2018 and $22.9 million at December 31, 2017. The fair value of the contingent consideration was 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.

As a result of the acquisition of Creabilis, we recorded a deferred tax liability of $9.4 million for the non-deductible in-process research and development intangible assets acquired on the date of the acquisition. The deferred tax liability is a foreign denominated liability subject to translation at each balance sheet date and had a carrying value of $10.7 million and $11.0 million at June 30, 2018 and December 31, 2017, respectively. The change in carrying value during the six months ended June 30, 2018 was related to $0.3 million of translation adjustments. The recording of the deferred tax liability resulted in goodwill in the amount of $9.8 million on the date of acquisition. Goodwill is also foreign denominated and subject to translation at each balance sheet date and had a carrying value of $11.2 million and $11.5 million at June 30, 2018 and December 31, 2017, respectively. The change in carrying value during the six months ended June 30, 2018 was due to translation adjustments of $0.3 million. The net impact of all translation adjustments is included in other comprehensive income (loss). Goodwill will not be amortized but will be tested at least annually for impairment. No impairment has been recognized as of June 30, 2018 or December 31, 2017.

Net Operating Loss and Research and Development Carryforwards

As of December 31, 2017, we had deferred tax assets of $27.2 million and deferred tax liabilities of approximately $11.0 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 net operating loss, or NOL carryforwards. As of December 31, 2017, we had federal and state NOL carryforwards of $44.4 million and foreign NOL carryforwards of $38.1 million available to potentially offset future taxable income. As of December 31, 2017, we also had federal research and development tax credit carryforwards of approximately $1.4 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 2037. 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, 2018 and 2017

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

	(unaudited) Three Months Ended June 30,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 15,692	$ 6,704	$ 8,988	134%
General and administrative	5,976	4,562	1,414	31
Total operating expenses	21,668	11,266	10,402	92
Loss from operations	(21,668)	(11,266)	(10,402)	92
Other income (expense), net	1,429	(1,672)	3,101	(185)
Net loss before taxes	(20,239)	(12,938)	(7,301)	56
Income tax benefit	—	81	(81)	(100)
Net loss	$(20,239)	$(12,857)	$ (7,382)	57%

Research and development expenses

Research and development expenses were $15.7 million for the three months ended June 30, 2018, compared to $6.7 million for the three months ended June 30, 2017. The increase of $9.0 million in research and development expenses is due to the increased costs for the initiation of clinical studies for SNA-120 of $5.5 million and SNA-125 of $1.7 million, and increased costs associated with an increase in personnel of $0.9 million, the additional increase of $0.9 million in early stage research activities, partially offset by decreased costs associated with ongoing SNA-001 clinical studies of $0.1 million.

General and administrative expenses

General and administrative expenses were $6.0 million for the three months ended June 30, 2018, compared to $4.6 million for the three months ended June 30, 2017. The increase of $1.4 million is primarily due to an increase in costs associated with an increase in personnel of $0.9 million, an increase in marketing expenses of $1.0 million, and $0.1 million of expense recognized related to the change in the contingent consideration liability, partially offset by decreased legal costs of $0.4 million and decreased public company costs of $0.2 million.

Other income (expense), net

Other income (expense), net was a net income of $1.4 million and a net expense of $1.7 million for the three months ended June 30, 2018 and 2017, respectively. The other net income of $1.4 million for the three months ended June 30, 2018 is primarily due to the change in the fair value of the success payment liability of $1.2 million and interest earned on the proceeds from our IPO during 2017 of $0.2 million. The other net expense of $1.7 million for the three months ended June 30, 2017 is primarily due to the increase in the fair value of the success payment liability of $1.0 million, plus $0.7 million for the amortization of the debt discount relating to the convertible promissory notes that we issued in January and March 2017, the Series B Bridge Notes, which converted into shares of our Series B Preferred Stock in April 2017.

Income tax benefit

Income tax benefit for the three months ended June 30, 2017 was $0.1 million. The income tax benefit resulted from a deferred tax liability recorded in additional paid in capital in the condensed consolidated balance sheet during the first quarter of 2017 relating to the beneficial conversion feature due to the 15% discount on conversion of the convertible notes that was bifurcated and allocated to additional paid in capital during the first quarter of 2017. See further discussion in Note 8, “Convertible Notes” and Note 14, “Income Taxes” of our unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Comparison of the Six Months Ended June 30, 2018 and 2017

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

	(unaudited) Six Months Ended June 30,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 28,672	$ 11,622	$ 17,050	147%
General and administrative	11,473	8,638	2,835	33
Total operating expenses	40,145	20,260	19,885	98
Loss from operations	(40,145)	(20,260)	(19,885)	98
Other income (expense), net	2,803	(2,833)	5,636	(199)
Net loss before taxes	(37,342)	(23,093)	(14,249)	62
Income tax benefit	—	127	(127)	(100)
Net loss	$(37,342)	$(22,966)	$(14,376)	63%

Research and development expenses

Research and development expenses were $28.7 million for the six months ended June 30, 2018, compared to $11.6 million for the six months ended June 30, 2017. The increase of $17.1 million in research and development expenses is primarily due to increased costs for the initiation of clinical studies for SNA-120 of $9.0 million and SNA-125 of $2.2 million, an increase in costs associated with the increase in personnel of $2.4 million, increased costs associated with ongoing SNA-001 clinical studies of $0.5 million, and increased manufacturing costs for SNA-120 of $0.8 million and SNA-125 of $1.0 million. There was also an additional increase in expenses of $1.2 million related to early stage research activities.

General and administrative expenses

General and administrative expenses were $11.5 million for the six months ended June 30, 2018, compared to $8.6 million for the six months ended June 30, 2017. The increase of $2.9 million in general and administrative expenses is primarily due to the increased costs associated with an increase in personnel of $1.9 million, increased costs related to being a public company of $0.4 million, increased marketing expenses of $0.9 million and $0.2 million of expense recognized related to the change in the contingent consideration liability, offset by decreased legal costs of $0.4 million.

Other income (expense), net

Other income (expense), net was a net income of $2.8 million and a net expense of $2.8 million for the six months ended June 30, 2018 and 2017, respectively. The other net income of $2.8 million for the six months ended June 30, 2018 was mainly due to the $2.4 million gain recognized on the decrease in success payment liability and interest earned on the proceeds from our IPO of $0.4 million. The other net expense of $2.8 million for the six months ended June 30, 2017 was primarily due to the $2.1 million expense recognized on the increase in success payment liability and $0.7 million of amortization of the debt discount relating to the Series B Bridge Notes.

Income tax benefit

Income tax benefit for the six months ended June 30, 2017 was $0.1 million. The income tax benefit resulted from a deferred tax liability recorded in additional paid in capital in the condensed consolidated balance sheet during the first quarter of 2017 relating to the beneficial conversion feature due to the 15% discount on conversion of the convertible notes that was bifurcated and allocated to additional paid in capital during the first quarter of 2017. See further discussion in Note 8, “Convertible Notes” and Note 14, “Income Taxes” of our unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

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 $123.2 million and $85.9 million as of June 30, 2018 and December 31, 2017, respectively. We had net losses of $20.2 million and $37.3 million for the three and six months ended June 30, 2018, and $12.9 million and $23.0 million for the three and six months ended June 30, 2017, respectively. We had net cash used in operating activities of $30.2 million and $17.5 million for the six months ended June 30, 2018 and 2017, respectively. We anticipate that operating losses and net cash used in operating activities will increase over the next several years as we further develop SNA-120 and SNA-125, move into later and more costly stages of product development, develop new product candidates, hire personnel and prepare for regulatory submissions and the commercialization of our product candidates.

We have historically financed our operations primarily through private placements of preferred stock and debt securities and more recently through our IPO and term loans and will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from our operations.

In January 2017, we entered into a note purchase agreement pursuant to which we issued, in two tranches, the Series B Bridge Notes in an aggregate principal amount of $3.9 million, with an annual interest rate of 6.0%. In April 2017, in connection with the issuance of Series B Preferred Stock, the entire outstanding principal under the Series B Bridge Notes, plus accrued interest, converted into 378,838 shares of Series B Preferred Stock. In April 2017, we issued an aggregate of 2,985,422 shares of our Series B Preferred

Stock for aggregate proceeds to us of $36.5 million, excluding the shares of Series B Preferred Stock issued upon conversion of the Series B Bridge Notes. In August 2017, we completed our IPO of 4,983,333 shares of common stock, which included the exercise in full by the underwriters of their option to purchase up to 650,000 additional shares of common stock, at an offering price to the public of $15.00 per share, and raised net proceeds of approximately $66.4 million after deducting underwriting discounts, commissions and estimated offering expenses payable by us.

In June 2018 we entered into the SVB Loan Agreement, pursuant to which SVB will provide us with access to term loans in an aggregate principal amount of up to $40.0 million. On June 29, 2018, we drew down the first credit extension of a 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. If we fail to receive positive Phase 2b data for SNA-120 by March 31, 2019, we must immediately cash secure at least the lesser of the outstanding principal balance of the term loans or $15.0 million, until such time that we raise at least $50.0 million in equity financing and have received positive Phase 1 data for SNA-125 in atopic dermatitis on or prior to April 30, 2019.

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 shares to be sold under the Sales Agreement, if any, may be issued and sold pursuant to the Shelf Registration Statement, after such time as it is declared effective by the SEC.

We believe that our current capital resources will be sufficient to fund operations through at least the next twelve months based on our expected cash burn rate. 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. There can be no assurance that sufficient funds will be available to us at all or on attractive terms when needed from these sources. 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 lead product candidates or any future product candidates, and conducting nonclinical studies and clinical trials, in particular our ongoing additional Phase 2b and planned Phase 3 pivotal clinical trials of SNA-120, our ongoing and planned clinical trials of SNA-125 and our ongoing pivotal trials for SNA-001;
- 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, 2018 and 2017

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

	(unaudited) (in thousands) Six Months Ended June 30,	
	2018	2017
Net cash provided by (used in)		
Operating activities	$ (30,205)	$ (17,531)
Investing activities	(17)	(66)
Financing activities	30,674	40,418
Effect of exchange rate changes on cash	(32)	(121)
Net increase in cash, cash equivalents and restricted cash	$ 420	$ 22,700

Net Cash Used in Operating Activities

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.

During the six months ended June 30, 2017, net cash used in operating activities was $17.5 million and consisted primarily of a net loss of $23.0 million, offset by the increase in fair value of both the success payment liability and the contingent consideration of $2.1 million and $2.1 million, respectively, the amortization of the debt discount of $0.7 million associated with the Series B Bridge Notes, and the non-cash stock-compensation expense of $0.3 million. In addition, there was an increase in prepaid expenses and other current assets of $2.1 million primarily relating to deferred financing costs associated with our IPO. This was offset by the $2.3 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, 2018 and 2017, net cash used in investing activities was $17,000 and $66,000, respectively, and represented purchases of property and equipment.

Net Cash Provided by Financing Activities

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.

During the six months ended June 30, 2017, net cash provided by financing activities was $40.4 million from the proceeds received from the issuance of our Series B Bridge Notes and the issuance of our Series B Preferred Stock.

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, 2017, except as noted below:

* In June 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. 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.

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, 2017.

Interest Rate Risk

As of June 30, 2018, 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, 2018 was 7.50%. 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, 2018 and December 31, 2017, we had cash and cash equivalents of $74.9 million and $74.5 million, respectively and restricted cash of $0.2 million as of both periods, which consisted 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 pound affect the reported amounts of expenses, assets and liabilities. As we expand our international operations, our exposure to exchange rate fluctuations will increase. Our balance sheet as of June 30, 2018 includes cash balances of $0.1 million and $0.1 million denominated in euros and pounds, respectively. At December 31, 2017 we had cash balances of $0.7 million and $0.2 million denominated in euros and pounds, respectively. We carry out some of our clinical development and supportive activities in foreign countries and payments may be due in foreign currencies. We do not participate in any foreign currency hedging activities and we do not have any other derivative financial instruments. We did not recognize any significant exchange rate losses during the three and six months ended June 30, 2018. 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, 2018, 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, 2018, 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.

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.

Inter Partes Review Proceedings

On October 7, 2016, we filed a petition with the PTAB for IPR challenging validity of certain claims of U.S. Patent No. 6,530,944, or the '944 patent, naming William Marsh Rice University, or Rice University, as patent owner. On October 18, 2016, the PTAB assigned the proceeding case number IPR2017-00045 and accorded the petition the filing date of October 7, 2016. On November 21, 2016, Rice University filed its mandatory notices, which name Rice University, exclusive licensee Nanospectra Biosciences, Inc., or Nanospectra, and sublicensee Sebacia as real parties in interest. Rice University filed a patent owner's preliminary response on January 18, 2017 contesting institution of the IPR. On April 11, 2017, the PTAB issued a decision instituting the IPR proceeding. Rice University filed a patent owner response on June 28, 2017. We filed a reply on September 20, 2017. On December 18, 2017, the PTAB heard oral arguments in this matter. On April 5, 2018, the PTAB issued its decision finding all of the challenged claims unpatentable. On June 4, 2018, Rice University agreed not to appeal the PTAB's decision.

On March 4, 2017, Rice University filed a request at the United States Patent and Trademark Office, or the USPTO, for *ex parte* reexamination of certain claims of the '944 patent. The USPTO assigned serial number 90/013,924 to the request, or the '924 Reexam, and ordered reexamination on April 26, 2017. On June 23, 2017, the PTAB issued an order staying the '924 Reexam pending resolution of our IPR challenging the validity of the '944 patent. On June 4, 2018, the PTAB entered an order lifting the stay.

On October 7, 2016, we filed a petition with the PTAB for IPR challenging validity of certain claims of U.S. Patent No. 6,685,730, or the '730 patent, naming Rice University as patent owner. On October 27, 2016, the PTAB assigned the proceeding case number IPR2017-00046 and accorded the petition the filing date of October 7, 2016. On November 21, 2016, Rice University filed its mandatory notices, which name Rice University, Nanospectra, and Sebacia as real parties in interest. Rice University filed a patent owner's preliminary response to the IPR petition on January 27, 2017 contesting institution of the IPR. On April 21, 2017, the PTAB issued a decision instituting the IPR proceeding. Rice University filed a patent owner response on July 7, 2017. We filed a reply on September 27, 2017. On December 18, 2017, the PTAB heard oral arguments in this matter. On April 18, 2018, the PTAB issued its decision finding all of the challenged claims unpatentable. On June 4, 2018, Rice University agreed not to appeal the PTAB's decision.

On December 21, 2016, Rice University filed a request at the USPTO for *ex parte* reexamination of certain claims of the '730 patent. The USPTO assigned serial number 90/013,883 to the request, or the '883 Reexam, and ordered reexamination on January 26, 2017. On April 24, 2017, the PTAB issued an order staying the '883 Reexam pending resolution of our IPR challenging the validity of the '730 patent. On June 4, 2018, the PTAB entered an order lifting the stay.

European Opposition Proceeding

On July 22, 2016, we filed a notice of opposition with the European Patent Office, or EPO, against European patent EP2343047, which patent names Rice University as applicant. On May 18, 2017, Rice University filed a response to the opposition. On December 21, 2017, we filed a response to Rice University's May 18, 2017 submission. On February 2, 2018 Rice University filed a response to our December 21, 2017 submission. On February 28, 2018 the EPO heard oral arguments in this matter and rendered a decision restricting the claims of the Rice University patent. On April 10, 2018, the EPO issued its written decision with the reasons for the decision made at the oral proceedings on February 28, 2018. On June 19, 2018, Rice University filed an appeal of the EPO decision and we filed a cross appeal.

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

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 $20.2 million and $37.3 million for the three and six months ended June 30, 2018, and $12.9 million and $23.0 million for the three and six months ended June 30, 2017, respectively. As of June 30, 2018, we had an accumulated deficit of $123.2 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.

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

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, 2018, we had capital resources consisting of cash and cash equivalents of $74.9 million. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the nonclinical and clinical development of our lead product candidates, SNA-120 and SNA-125, as well as our ongoing pivotal trials for SNA-001, and the development of any other product candidates we may choose to pursue. 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. 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.

We believe our existing cash, will allow us to fund our operating plan for at least the next twelve months. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. 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. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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 ongoing additional Phase 2b and planned Phase 3 pivotal clinical trials of SNA-120, our ongoing and planned clinical trials of SNA-125 and our ongoing pivotal trials for SNA-001;
- 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;
- 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 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.

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.

Our IPO triggered the potential for success payments to the stockholders party to the Success Payment Agreement. However, we will not be required to make any success payments triggered by the per share market value of our common stock until August 1, 2018, the first anniversary of the closing of our IPO (or a 90-day grace period following such anniversary, at our option if we are contemplating a capital market transaction during such grace period). 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. As of June 30, 2018 and December 31, 2017, the estimated fair value of the liability associated with the success payments was $0.9 million and $3.3 million, respectively.

We may be required to repay the outstanding indebtedness 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 the SVB Loan Agreement, 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, $30.0 million of which was funded on June 29, 2018 and $10.0 million of which remains available for borrowing, subject to our satisfaction of certain conditions. If we fail to receive positive Phase 2b data for SNA-120 by March 31, 2019, we must immediately cash secure at least the lesser of the outstanding principal balance of the term loans or $15.0 million, until such time that we raise at least $50.0 million in equity financing and have received positive Phase 1 data for SNA-125 in atopic dermatitis on or prior to April 30, 2019.

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; the 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

Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates.

Our portfolio includes our lead product candidates: SNA-120, a topical tropomyosin receptor kinase A, or TrkA, inhibitor in clinical development for the treatment of pruritus associated with psoriasis as well as the underlying psoriasis; SNA-125, a topical Janus kinase 3 (JAK3)/TrkA inhibitor in clinical trials for the treatment of atopic dermatitis, psoriasis and pruritus; and SNA-001, a topical suspension of silver particles in pivotal trials for the reduction of unwanted light-pigmented hair and for acne vulgaris. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval or clearance and commercialization of our product candidates. In the future, we may also become dependent on other product candidates that we may develop or acquire. The clinical and commercial success of our 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 our lead product candidates or any future 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 our lead product candidates or any future product candidates or approved products, if any;
- the willingness of physicians, operators of clinics and patients to utilize or adopt SNA-001 as a procedural solution;
- 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 or clinical studies. These setbacks have been caused by, among other things, nonclinical findings made while clinical studies were underway, and safety or efficacy observations made in clinical studies, 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.

Our product candidates SNA-120, SNA-125 and SNA-001 are currently in clinical development. 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 pruritus, a symptom of psoriasis, but may not receive labeling covering the treatment of 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. For example, on July 30, 2018, we announced the top-line data from two pivotal acne trials with SNA-001 in conjunction with 1064 nm and 810 nm lasers noting that SNA-001 did not show statistical significance on the primary and secondary endpoints. In light of the results of these trials, we do not anticipate a different result in our third pivotal trial evaluating SNA-001's efficacy in combination with lasers for the treatment of acne.

Although our lead product candidates, SNA-120, SNA-125 and SNA-001, are in clinical development, 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.

For example, the FDA has recommended that, for the future Phase 3 pivotal trials of SNA-120 for the treatment of pruritus associated with psoriasis, we utilize the 11-point itch Numeric Rating Scale, or I-NRS, as the primary endpoint for assessing efficacy, rather than the pruritus visual analog scale, or VAS, used in the completed Phase 2b trial of SNA-120, despite the similarity between the two scales. The I-NRS scale requires patients to select a number between zero (no itch) to ten (the worst possible itch), but unlike a VAS, which uses a continuous scale, patients must select a specific whole number and not mark a point on the usual scale. It is possible that using the I-NRS scale could produce results that differ from results we saw in the prior Phase 2b trial in which the VAS scale was used.

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. We are currently conducting pivotal trials for SNA-001 and we anticipate commencing pivotal Phase 3 clinical trials for SNA-120 after the completion of our additional Phase 2b clinical trial. 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 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.

SNA-125, if approved for the treatment of pruritus or the underlying psoriasis, may compete with SNA-120, if approved for the treatment of pruritus or the underlying 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. We believe that SNA-125, by inhibiting both JAK3 and TrkA, has the potential to offer enhanced efficacy over SNA-120 in the treatment of pruritus and the underlying psoriasis, which could make SNA-125 a more compelling treatment for pruritus or the underlying psoriasis. To the extent both SNA-120 and SNA-125 are approved for pruritus or the underlying 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 an agreement with nanoComposix to supply the silver nanoplates used to manufacture SNA-001 for nonclinical studies and clinical trials 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 toxicity 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 such as Menlo Therapeutics, Inc. and Dermira, Inc. 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 of pruritus, or the underlying 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 such as Leo, Eli Lilly, Maruho, Valeant, Incyte, GlaxoSmithKline and Pfizer. 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 approved for the treatment of acne vulgaris, SNA-001 will face competition from a number of branded and generic oral and topical antimicrobials, oral and topical retinoids and oral contraceptives, including branded therapeutics, as well as potential competition from a similar procedure using gold particles that is currently in development by a third party. We believe SNA-001 would also face competition from a number of currently available procedural solutions for the treatment of acne, including chemical peels, laser or light-based treatments, and photodynamic therapy. If approved for light-pigmented hair removal or reduction, we also anticipate that SNA-001 would compete with hair reduction procedures using laser or intense pulsed light, which are available in dermatologist offices, medical spas and laser treatment centers, as well as against 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 will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of June 30, 2018, we had 54 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our lead product candidates or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including sales personnel;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

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. In addition, we may be required to defend ourselves in the event an injury occurs from the negligent use of a laser in a procedure using SNA-001 or a laser malfunction causing injury during an aesthetic procedure. 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 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 our lead product candidates, a key element of our 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. 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.

If we do not successfully integrate Creabilis into our business operations, our business could be adversely affected.

The process of integrating an acquired business' technology, service, intellectual property, products or product candidates into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. Our ability as an organization to integrate acquisitions, including Creabilis' business, is relatively unproven. As a result of our acquisition of Creabilis in December 2016, we have undergone substantial changes in a short period of time and our business has changed and broadened in size and the scope of products we are developing. In addition, our business immediately shifted from being fully domestic to including international employees, entities, operations and facilities. Integrating the operations of a new business with that of our own is a complex, costly and time-consuming process, which requires significant management attention and resources to integrate the business practice and operations. The integration process may disrupt the businesses and, if implemented ineffectively, would preclude realization of the full benefits expected by us. Our failure to meet the challenges involved in integrating the Creabilis business in order to realize the anticipated benefits of the acquisitions could cause an interruption of, or a loss of momentum in, our activities and could adversely affect our results of operations. Prior to the acquisition, Creabilis operated independently, with its own business, corporate culture, locations, employees and systems. There may be substantial difficulties, costs and delays involved in any integration of other businesses, including Creabilis, with that of our own. These may include:

- distracting management from day-to-day operations;
- an ability to retain key executives and employees of Creabilis, which may reduce the value of the acquisition or give rise to additional integration costs;
- challenges associated with integrating Creabilis' intellectual property and prosecuting the acquired intellectual property;
- risks associated with the assumption of the liabilities of Creabilis;
- inheriting and uncovering previously unknown issues, problems and costs from Creabilis;
- risks and costs associated with inheriting a supply chain of third-party manufacturers with whom Creabilis had not yet established long-term contractual relationships;
- realization of assets and settlement of liabilities at amounts equal to estimated fair value as of the acquisition date of any acquisition or disposition;
- costs and delays in implementing common systems and procedures, including technology, compliance programs, financial systems, distribution and general business operations, among others; and
- increased difficulties in managing our business due to the addition of international locations.

These risks may be heightened in the case of Creabilis because the majority of the business' operations and employees are located in Europe. Any one or all of these factors may increase operating costs or lower anticipated financial performance. Many of these factors are also outside of our control. In addition, dispositions of certain key products, technologies and other rights may affect our business operations.

In addition, even if the operations of Creabilis are integrated successfully, we may not realize the full benefits of the acquisition, including the cost savings or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frames, or at all. Additional unanticipated costs may be incurred in the integration of the business. All of these factors could cause a reduction to our earnings, decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our common stock.

The failure to successfully integrate the business operations of Creabilis and any other business we may acquire would have a material adverse effect on our business, financial condition and results of operations.

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 the second annual report that we will be required to file with the SEC, Section 404 requires 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.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, 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 to 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. In particular, we do not currently plan to pursue coverage and reimbursement for procedures using SNA-001, if cleared, for acne or other clinical indications and, as a result, demand for this product will be tied to discretionary spending levels of our targeted patient population. 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 Topical by Design™ and Topical Photoparticle Therapy™ technologies 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 our Topical by Design™ and Topical Photoparticle Therapy™ technologies and use our proprietary 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, to determine priority of invention in the United States. For example, in October 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. Although the PTAB entered judgment against GHC in October 2016, GHC filed an appeal with the U.S. Court of Appeals for the Federal Circuit and 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. The costs of this and other 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 Topical by Design™ and/or Topical Photoparticle Therapy™ 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 United States Patent and Trademark Office, or 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 Photopartical Therapy™ technology , under our exclusive supply and 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 Topical by Design™ 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 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 August 2022, 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 supply and 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 typically refers 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.

If our pivotal trials for SNA-001 are successful, we expect to pursue FDA clearance of SNA-001 for the treatment of acne and the reduction of light-pigmented hair under the FDA's 510(k) premarket notification process. Before we can market SNA-001 for these indications 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 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.

Our medical device product candidates must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). 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 Devices 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. If we are unable to demonstrate conformity of SNA-001 and our manufacturers with these requirements, 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.

Further, based on our preliminary discussions with our Notified Body, the National Standards Authority of Ireland, SNA-001, when intended for the removal of light-pigmented hair, may currently not fall under the EU Medical Devices Directive but under EU Regulation (EC) 1223/2009 on cosmetic products, or the EU Cosmetics Products Regulation. As a result, SNA-001, when intended for removal of light-pigmented hair, may need to comply with the requirements of the EU Cosmetics Products Regulation, which are generally not more burdensome than those imposed by the Medical Devices Directive. However, this may change with the application of the new EU Medical Devices Regulation, which was adopted on April 5, 2017. 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. The EU Medical Devices Regulation will however not become fully applicable until three years from its entry into force, and it is not yet clear whether the inclusion within its scope of high intensity electromagnetic radiation emitting equipment for hair removal would result in SNA-001 (which is a topical product applied in combination with commercially available lasers) falling under the EU Medical Devices Regulation when intended for removal of light-pigmented hair.

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 intend to request 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.

If we successfully complete our planned Phase 2b trial of SNA-120, we intend to request agreement from the FDA under a special protocol assessment, or SPA, for our planned Phase 3 clinical trials of SNA-120 in patients with pruritus associated with psoriasis vulgaris. 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.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and medical devices and to spur innovation, but its ultimate implementation is unclear. 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.

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, 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 U.S. 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 from January 1, 2016 to 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. 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 2025, 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 bills 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 U.S. 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;
- 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; 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.

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 as a result of the reduced disclosure and governance requirements applicable to emerging growth 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 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. 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.

If we sell shares of our common stock in future financings, 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, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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, 2018, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 51.5% 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of June 30, 2018, we had outstanding a total of approximately 20.8 million shares of common stock, of which 5.5 million shares are held by current directors, executive officers and their respective affiliates and may be subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, as of June 30, 2018, approximately 3.7 million shares of our common stock that are either subject to outstanding stock awards or reserved for future issuance under our employee benefit plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of approximately 4.6 million shares of our common stock, or approximately 22.0% of our total outstanding common stock as of June 30, 2018 will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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. 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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

On July 26, 2017, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-219142), as amended, filed in connection with our IPO. The IPO closed on August 1, 2017 and we issued and sold 4,983,333 shares of our common stock at a price to the public of $15.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received net proceeds from the IPO of approximately $66.4 million, after deducting underwriting discounts and commissions of approximately $5.2 million, and estimated offering expenses of approximately $3.0 million. The managing underwriters of the offering were J.P. Morgan Securities LLC and Cowen and Company, LLC. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

The net proceeds from the IPO have been invested in United States treasury money market funds. There has been no material change in the expected use of the net proceeds from our IPO as described in our registration statement on Form S-1.

Issuer Purchases of Equity Securities

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

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	Loan and Security Agreement, dated as of June 29, 2018, by and between Silicon Valley Bank and Sienna Biopharmaceuticals, Inc.	8-K	7-2-2018	10.1	
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

* 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 9, 2018

By: /s/ John W. Smither
John W. Smither
Chief Financial Officer
(Principal Financial Officer)

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)) 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. 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

c. 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 9, 2018

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, John W. Smither, 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)) 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. 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

c. 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 9, 2018

By: /s/ John W. Smither
John W. Smither
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, 2018, 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 John W. Smither, 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 9, 2018

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

Date: August 9, 2018

/s/ John W. Smither
John W. Smither
Chief Financial Officer
(Principal Financial Officer)