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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2019

or

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

For the transition period from ___ to ___
Commission File No. 001-36297

Revance Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**77-0551645**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

7555 Gateway Boulevard, Newark, California, 94560
(Address, including zip code, of principal executive offices)

(510) 742-3400
(Registrant's telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	RVNC	Nasdaq Global Market

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

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

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

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Smaller reporting 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 statement accounting standards provide pursuance 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 ☒

Number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of July 26, 2019: 44,102,532

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. Condensed Consolidated Financial Statements

REVANCE THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 90,034	$ 73,256
Short-term investments	151,858	102,556
Accounts receivable	—	27,000
Prepaid expenses and other current assets	8,013	5,110
Total current assets	249,905	207,922
Property and equipment, net	15,263	14,449
Operating lease right of use assets	27,602	—
Restricted cash	730	730
Other non-current assets	2,392	3,247
TOTAL ASSETS	$ 295,892	$ 226,348
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 7,966	$ 8,434
Accruals and other current liabilities	14,737	14,948
Deferred revenue, current portion	18,825	8,588
Operating lease liabilities, current portion	3,168	—
Total current liabilities	44,696	31,970
Derivative liability associated with the Medicis settlement	2,824	2,753
Deferred revenue, net of current portion	32,169	42,684
Operating lease liabilities, net of current portion	27,661	—
Deferred rent	—	3,319
TOTAL LIABILITIES	107,350	80,726
Commitments and Contingencies (Note 7)		
STOCKHOLDERS' EQUITY		
Convertible preferred stock, par value $0.001 per share — 5,000,000 shares authorized, and no shares issued and outstanding as of June 30, 2019 and December 31, 2018	—	—
Common stock, par value $0.001 per share — 95,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 44,105,474 and 36,975,203 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	44	37
Additional paid-in capital	945,851	830,368
Accumulated other comprehensive income (loss)	116	(8)
Accumulated deficit	(757,469)	(684,775)
TOTAL STOCKHOLDERS' EQUITY	188,542	145,622
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 295,892	$ 226,348

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

REVANCE THERAPEUTICS, INC.

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

	Three Months Ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Revenue	$ —	$ 686	$ 278	$ 880
Operating expenses:				
Research and development	25,526	22,871	49,521	45,111
General and administrative	13,596	12,734	26,506	26,350
Total operating expenses	39,122	35,605	76,027	71,461
Loss from operations	(39,122)	(34,919)	(75,749)	(70,581)
Interest income	1,596	1,081	3,166	2,103
Interest expense	—	—	—	(44)
Change in fair value of derivative liability associated with the Medicis settlement	21	(70)	(71)	(104)
Other income (expense), net	115	(172)	(40)	(492)
Net loss	(37,390)	(34,080)	(72,694)	(69,118)
Unrealized gain (loss) and adjustment on securities included in net loss	46	52	124	(224)
Comprehensive loss	$ (37,344)	$ (34,028)	$ (72,570)	$ (69,342)
Basic and diluted net loss	$ (37,390)	$ (34,080)	$ (72,694)	$ (69,118)
Basic and diluted net loss per share	$ (0.86)	$ (0.94)	$ (1.71)	$ (1.92)
Basic and diluted weighted-average number of shares used in computing net loss per share	43,260,317	36,123,659	42,434,137	36,037,604

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

REVANCE THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019		2018		2019		2018	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Convertible Preferred Stock	—	$ —	—	$ —	—	$ —	—	$ —
Common Stock								
Balance — Beginning of period	44,004,658	44	36,742,847	37	36,975,203	37	36,516,075	37
Issuance of common stock in connection with the 2019 follow-on offering	—	—	—	—	6,764,705	7	—	—
Issuance of common stock upon exercise of stock options	5,416	—	150,698	—	8,240	—	233,088	—
Issuance of restricted stock awards, net of cancellation	67,997	—	10,345	—	391,023	—	205,686	—
Net settlement of restricted stock awards for employee taxes	(7,763)	—	(4,962)	—	(68,863)	—	(55,921)	—
Issuance of common stock relating to employee stock purchase plan	35,166	—	18,795	—	35,166	—	18,795	—
Balance — End of period	44,105,474	44	36,917,723	37	44,105,474	44	36,917,723	37
Additional Paid-In Capital								
Balance — Beginning of period	—	941,068	—	814,084	—	830,368	—	810,975
Issuance of common stock in connection with the 2019 follow-on offering, net of issuance costs of $521	—	—	—	—	—	107,572	—	—
Stock-based compensation expense	—	4,420	—	4,172	—	8,579	—	8,330
Issuance of common stock upon exercise of stock options	—	75	—	2,779	—	93	—	3,395
Net settlement of restricted stock awards for employee taxes	—	(99)	—	(147)	—	(1,148)	—	(1,813)
Issuance of common stock relating to employee stock purchase plan	—	387	—	438	—	387	—	439
Balance — End of period	—	945,851	—	821,326	—	945,851	—	821,326
Other Accumulated Comprehensive Gain (Loss)								
Balance — Beginning of period	—	70	—	(276)	—	(8)	—	—
Unrealized gain (loss) and adjustment on securities included in net loss	—	46	—	52	—	124	—	(224)
Balance — End of period	—	116	—	(224)	—	116	—	(224)
Accumulated Deficit								
Balance — Beginning of period	—	(720,079)	—	(577,204)	—	(684,775)	—	(542,167)
Net loss	—	(37,390)	—	(34,080)	—	(72,694)	—	(69,117)
Balance — End of period	—	(757,469)	—	(611,284)	—	(757,469)	—	(611,284)
Total Stockholders' Equity	44,105,474	$ 188,542	36,917,723	$ 209,855	44,105,474	$ 188,542	36,917,723	$ 209,855

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

REVANCE THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (72,694)	$ (69,118)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,418	807
Amortization of discount on investments	(1,481)	(610)
Stock-based compensation expense	8,579	8,330
Other non-cash operating activities	338	263
Changes in operating assets and liabilities:		
Accounts receivable	27,000	—
Prepaid expenses and other current assets	(2,903)	(6,970)
Operating lease right of use assets	(2,938)	—
Other non-current assets	853	(2,291)
Accounts payable	(321)	(958)
Accruals and other liabilities	(914)	(1,274)
Deferred revenue	(278)	24,120
Operating lease liabilities	2,637	—
Net cash used in operating activities	(40,704)	(47,701)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(164,970)	(212,197)
Purchases of property and equipment	(1,466)	(2,335)
Proceeds from maturities of investments	117,000	18,000
Proceeds from sales of property and equipment	7	146
Payment for acquisition of in-process research and development	—	(100)
Net cash used in investing activities	(49,429)	(196,486)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock in connection with the 2019 follow-on offering, net of commissions and discount	108,100	—
Proceeds from the exercise of stock options and employee stock purchase plan	480	3,834
Net settlement of restricted stock awards for employee taxes	(1,148)	(1,813)
Payment of offering costs	(521)	(366)
Principal payments made on financing obligations	—	(932)
Net cash provided by financing activities	106,911	723
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	16,778	(243,464)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — Beginning of period	73,986	283,476
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — End of period	$ 90,764	$ 40,012
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 3,000	$ —
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Property and equipment purchases included in accounts payable and accruals	$ 1,408	$ 2,128

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. The Company and Summary of Significant Accounting Policies

The Company

Revance Therapeutics, Inc. ("the Company" or "Revance") is a biotechnology company developing new innovations in neuromodulators for aesthetic and therapeutic indications. The Company's lead product candidate, DaxibotulinumtoxinA for Injection ("DAXI"), combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. The Company has successfully completed a Phase 3 program for DAXI in glabellar (frown) lines, demonstrating efficacy and long-lasting duration of effect, and is pursuing U.S. regulatory approval in 2020. The Company is also evaluating DAXI in forehead lines and lateral canthal lines (crow's feet), as well as three therapeutic indications including cervical dystonia, adult upper limb spasticity, and plantar fasciitis, with plans to study migraine. Beyond DAXI, the Company has begun development of a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. Revance is dedicated to making a difference by transforming patient experiences.

Since inception, the Company has devoted substantially all of its efforts to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel, raising capital, conducting preclinical and clinical development of, and manufacturing development for DAXI, DaxibotulinumtoxinA Topical and the biosimilar to BOTOX®. The Company has incurred losses and negative cash flows from operations. The Company has not commenced commercial operations, has not generated product revenue to date, and will continue to incur significant research and development and other expenses related to its ongoing operations. For the three and six months ended June 30, 2019, the Company had a net loss of $37.4 million and $72.7 million, respectively. As of June 30, 2019, the Company had a working capital surplus of $205.2 million and an accumulated deficit of $757.5 million. The Company has funded its operations primarily through the issuance and sale of common stock, convertible preferred stock, notes payable, and convertible notes. As of June 30, 2019, the Company had capital resources of $241.9 million consisting cash, cash equivalents, and investments. The Company believes that its existing capital resources will fund the operating plan through at least the next 12 months following the issuance of this Form 10-Q, and may identify additional capital resources to fund its operations.

Basis of Presentation

The accompanying Condensed Consolidated Financial Statements are unaudited, and reflect all adjustments which are, in the opinion of management, of a normal recurring nature and necessary for a fair statement of the results for the interim periods presented.

The Condensed Consolidated Balance Sheet for the year ended December 31, 2018 was derived from audited Consolidated Financial Statements, but does not include all disclosures required by U.S. generally accepted accounting principles ("U.S. GAAP"). The interim results presented herein are not necessarily indicative of the results of operations that may be expected for the full fiscal year ending December 31, 2019, or any other future period. The Condensed Consolidated Financial Statements should be read in conjunction with the Company's audited Consolidated Financial Statements contained in its Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the Securities and Exchange Commission ("SEC"), on February 28, 2019.

The Condensed Consolidated Financial Statements include the Company's accounts and those of its wholly-owned subsidiaries, and have been prepared in conformity with U.S. GAAP. The Company operates in one segment.

Principles of Consolidation

The Condensed Consolidated Financial Statements include the accounts of the company and its wholly-owned subsidiaries. All intercompany transactions have been eliminated.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

Use of Estimates

The preparation of the Condensed Consolidated Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the Condensed Consolidated Financial Statements and accompanying notes. Such management estimates include revenue recognition, deferred revenue, accruals including clinical trial accruals, stock-based compensation, fair value of derivative liability, and the valuation of deferred tax assets. The Company bases its estimates on historical experience and on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* which requires an entity to recognize right-of-use asset and lease liabilities arising from a lease for both financing and operating leases with terms greater than twelve months. In July 2018, the FASB issued ASU 2018-10, *Leases (Topic 842), Codification Improvements* and ASU 2018-11, *Leases (Topic 842), Targeted Improvements*, to provide additional guidance for the Topic 842 adoption. ASU 2018-10 clarifies certain provisions and correct unintended applications of the guidance such as the application of implicit rate, lessee reassessment of lease classification, and certain transition adjustments that should be recognized to earnings rather than to stockholders' equity. ASU 2018-11 provides an alternative transition method to allow entities initially applying Topic 842 at the adoption date, rather than at the beginning of the earliest comparative period presented, and recognizing the cumulative effect of applying the new standard as an adjustment to beginning retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting guidance. ASU 2018-11 also provides a number of optional practical expedients in transition. In March 2019, the FASB issued *ASU 2019-01, Leases (Topic 842): Codification Improvements*. The Company evaluated ASU 2019-01 in its entirety and determined that Issue 3, *Transition disclosures related to Topic 250, Accounting Changes and Error Corrections*, is the only provision that currently applies to the Company. Issue 3 of ASU 2019-01 exempts certain interim disclosures in the fiscal year of adoption. ASU 2018-11, ASU 2018-10, ASU 2016-02, and Issue 3 of ASU 2019-01 (collectively, "the new lease standards") are effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company has elected the transition method under ASU 2018-11 at the adoption date of January 1, 2019 on a modified retrospective basis and will not restate comparative periods. The Company has also elected all of the available practical expedients except the practical expedient allowing the use of hindsight in determining the lease term and assessing impairment of right-of-use assets based on all facts and circumstances through the effective date of the new standard. The Company has elected the recognition exemption for short-term leases for all leases that qualify. Under this exemption, the Company will not recognize right-of-use assets or lease liabilities for those leases that qualify as a short-term lease. For real estate leases, the Company did not elect the practical expedient to combine lease and non-lease components, therefore the Company accounts for lease and non-lease components separately. For equipment leases, lease and non-lease components are accounted for as a single lease component. The Company recognized $24.7 million and $28.2 million as total right-of-use assets and total lease liabilities, respectively, on its Condensed Consolidated Balance Sheet as of January 1, 2019 for its existing operating lease agreements for the office and manufacturing spaces in Newark, California and equipment leases. The existing deferred rent liabilities of $3.5 million associated with the same lease agreements was reversed as of January 1, 2019.

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40) Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The amendments in ASU 2018-15 align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). Accordingly, the amendments require an entity (customer) in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. ASU 2018-15 is effective for fiscal years beginning after December 15, 2019 with early adoption permitted. The Company is evaluating the impact of this standard on its Condensed Consolidated Financial Statements and disclosures.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

2. Revenue

Mylan Collaboration and License Agreement

The Company and Mylan entered into a collaboration agreement in February 2018 (the "Mylan Collaboration"), pursuant to which the companies will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture, and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®.

Under the Mylan Collaboration, Mylan paid the Company a non-refundable upfront payment of $25.0 million with additional contingent payments of up to $100.0 million in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to $225.0 million. The upfront payment does not represent a financing component for the transfer of goods or services. The contingent payments would be payable following Mylan's decision to continue development services for Initial Phase and Phase 3 clinical trials and upon meeting certain milestones. In addition, Mylan would pay the Company low to mid double-digit royalties on any sales of the biosimilar in the U.S., mid double-digit royalties on any sales in Europe, and high single-digit royalties on any sales in other areas excluding Japan. However, the Company agreed to waive royalties for U.S. sales, up to a limit of $50.0 million in annual sales, during the first approximately four years after commercialization to defray launch costs.

Revenue Recognition

In accordance with ASC 606, transaction price is defined as the amount of consideration to which an entity expects to be entitled in exchange for promised goods or services to a customer. The initial estimated transaction price was $81.0 million which included a $25.0 million upfront payment, $40.0 million of development milestones, and the estimated variable consideration for cost-sharing payments from Mylan. The Company re-evaluates the transaction price at each reporting period. As of June 30, 2019, the transaction price allocated to the unfulfilled performance obligations is $76.4 million.

The Company recognizes revenue and estimates deferred revenue based on the cost of services incurred over the total estimated cost of services to be provided for the development period. For revenue recognition purposes, the development period is estimated to extend through 2022. However, it is possible that this period will change and is assessed at each reporting date.

For the three months ended June 30, 2019, the Company recognized no revenue as no development services were provided during this period, and for the six months ended June 30, 2019, the Company recognized revenue related to development services provided of $0.3 million. For the three and six months ended June 30, 2018, the Company recognized revenue related to development services of $0.7 million and $0.9 million, respectively. As of June 30, 2019 and December 31, 2018, the Company estimated short-term deferred revenue of $18.8 million and $8.6 million, respectively; and long-term deferred revenue of $2.2 million and $12.7 million, respectively.

Fosun License Agreement

The Company and Fosun entered into a license agreement (the "Fosun License Agreement") in December 2018, whereby the Company has granted Fosun the exclusive rights to develop and commercialize the Company's proprietary DAXI in mainland China, Hong Kong and Macau (the "Fosun Territory") and certain sublicense rights.

Under the Fosun License Agreement, the Company received a non-refundable upfront payment of $30.0 million net of foreign withholding tax of $3.0 million from Fosun in January 2019. The Company is also eligible to receive (i) additional contingent payments of up to $230.5 million upon the achievement of specified milestones, and (ii) tiered royalty payments in low double-digit to high-teen percentages on annual net sales.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

Revenue Recognition

In accordance with ASC 606, transaction price is defined as the amount of consideration to which an entity expects to be entitled in exchange for promised goods or services to a customer. The Company estimated the transaction price for the Fosun License Agreement using the most likely amount method. The Company evaluated all of the variable payments to be received during the duration of the contract, which included payments from specified milestones, royalties, and estimated supplies to be delivered, and concluded only a certain milestone of $1.0 million was included in the transaction price. The Company will re-evaluate the transaction price at each reporting period and upon a change in circumstances. As of June 30, 2019, the transaction price allocated to unfulfilled performance obligation is $31.0 million. The Company will recognize revenue on the single performance obligation as control of the manufactured product is supplied to Fosun.

For the six months ended June 30, 2019, no revenue has been recognized from the Fosun License Agreement. As of June 30, 2019 and December 31, 2018, substantially all of the $30.0 million non-refundable upfront payment was included in long-term deferred revenue.

3. Medicis Settlement

In July 2009, the Company and Medicis Pharmaceutical Corporation ("Medicis") entered into a license agreement granting Medicis worldwide aesthetic and dermatological rights to the Company's investigational botulinum toxin type A product candidate. In October 2012, the Company entered into a settlement and termination agreement with Medicis. The terms of the settlement provided for the reacquisition of the rights related to all territories of DAXI and DaxibotulinumtoxinA Topical from Medicis and for consideration payable by the Company to Medicis of up to $25.0 million, comprised of (i) an upfront payment of $7.0 million, which was paid in 2012, (ii) a proceeds sharing arrangement payment of $14.0 million due upon specified capital raising achievements by the Company, of which $6.9 million was paid in 2013 and $7.1 million in 2014, and (iii) a product approval payment of $4.0 million to be paid upon the achievement of regulatory approval for DAXI or DaxibotulinumtoxinA Topical by the Company. In December 2012, Medicis was subsequently acquired by Valeant Pharmaceuticals International Inc., now known as Bausch Health Companies Inc.

The Company determined that the settlement provisions related to the proceeds sharing arrangement payment in (ii) above and product approval payment in (iii) above were derivative instruments that require fair value accounting as a liability and periodic fair value remeasurements until settled.

As of June 30, 2019, the fair value of the Company's liability for the product approval payment was $2.8 million, which was measured using a term of 1.4 years, a risk-free rate of 1.8% and a credit risk adjustment of 7.5%. As of December 31, 2018, the fair value of the Company's liability for the product approval payment was $2.7 million, which was measured using a term of 1.5 years, a risk-free rate of 2.6% and a credit risk adjustment of 8.0%. The term is based on an expected Biologics License Application ("BLA") approval in 2020. For the six months ended June 30, 2019 and 2018, no payment was made for the product approval payment.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

4. Cash Equivalents and Investments

The Company's cash equivalents and investments consist of money market funds, U.S. treasury securities, U.S. government agency obligations, and commercial paper which are classified as available-for-sale securities.

The following table is a summary of amortized cost, unrealized gains and losses, and fair value:

	June 30, 2019			December 31, 2018			
		Unrealized			Unrealized		
(in thousands)	Cost	Gains	Fair Value	Cost	Gains	Losses	Fair Value
Money market funds	$ 81,734	$ —	$ 81,734	$ 38,354	$ —	$ —	$ 38,354
U.S. treasury securities	113,991	116	114,107	80,844	5	(5)	80,844
U.S. government agency obligations	—	—	—	52,586	—	(8)	52,578
Commercial paper	44,730	—	44,730	—	—	—	—
Total cash equivalents and available-for-sale securities	$ 240,455	$ 116	$ 240,571	$ 171,784	$ 5	$ (13)	$ 171,776
Classified as:							
Cash equivalents			$ 88,713				$ 69,220
Short-term investments			151,858				102,556
Total cash equivalents and available-for-sale securities			$ 240,571				$ 171,776

As of June 30, 2019 and December 31, 2018, the Company has no other-than-temporary impairments on its available-for-sale securities.

Related Party Transactions

The Company had no related party transactions for the six months ended June 30, 2019.

As of December 31, 2018, JPMorgan Chase & Co. and its wholly owned subsidiaries JPMorgan Chase Bank, National Association (NA), J.P. Morgan Investment Management Inc., and JPMorgan Asset Management (UK) Limited held approximately 3.8 million shares or 10.3% of the Company's outstanding common stock. J.P. Morgan Securities LLC is an affiliate of JPMorgan Chase Bank, NA, and it acts as a custodian and trustee for certain investments of the Company. As of December 31, 2018, cash, cash equivalents, and investments of $87.7 million were held in an investment account with J.P. Morgan Securities LLC. As of June 30, 2019, JPMorgan Chase & Co. and its wholly owned subsidiaries owned less than 10% of the Company's outstanding common stock.

5. Fair Value Measurements

The Company determines the fair value of certain financial assets and liabilities using three levels of inputs as follows:

- Level 1 — Observable inputs, such as 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, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3 — Valuations based on unobservable inputs to the valuation methodology and including data about assumptions market participants would use in pricing the asset or liability based on the best information available under the circumstances.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

The following table summarizes, for assets and liabilities measured at fair value, the respective fair value and the classification by level of input within the fair value hierarchy:

	June 30, 2019			
(in thousands)	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds	$ 81,734	$ 81,734	$ —	$ —
U.S. treasury securities	114,107	114,107	—	—
Commercial paper	44,730	—	44,730	—
Total assets measured at fair value	$ 240,571	$ 195,841	$ 44,730	$ —
Liabilities				
Derivative liability associated with the Medicis settlement	$ 2,824	$ —	$ —	$ 2,824
Total liabilities measured at fair value	$ 2,824	$ —	$ —	$ 2,824

	December 31, 2018			
(in thousands)	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds	$ 38,354	$ 38,354	$ —	$ —
U.S. treasury securities	80,844	80,844	—	—
U.S. government agency obligations	52,578	—	52,578	—
Total assets measured at fair value	$ 171,776	$ 119,198	$ 52,578	$ —
Liabilities				
Derivative liability associated with the Medicis settlement	$ 2,753	$ —	$ —	$ 2,753
Total liabilities measured at fair value	$ 2,753	$ —	$ —	$ 2,753

The Company classifies U.S. government agency obligations and commercial paper within Level 2 because it uses alternative pricing sources and models utilizing market observable inputs to determine their fair values.

The following table summarizes the change in the fair value of the Company's Level 3 financial instrument:

(in thousands)	**Derivative Liability Associated with the Medicis Settlement**
Fair value as of December 31, 2018	$ 2,753
Change in fair value	71
Fair value as of June 30, 2019	$ 2,824

The fair value of the derivative liability associated with the Medicis settlement was determined by estimating the timing and probability of the related regulatory approval and multiplying the payment amount by this probability percentage and a discount factor based primarily on the estimated timing of the payment and a credit risk adjustment (Note 3). Generally, increases or decreases in these unobservable inputs would result in a directionally similar impact to the fair value measurement of this derivative instrument. The significant unobservable inputs used in the fair value measurement of the product approval payment derivative are the expected timing and probability of the payments at the valuation date and the credit risk adjustment.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

6. Leases

The Company has non-cancelable operating leases for facilities for research, manufacturing, and administrative functions, and equipment operating leases. One of the facility operating leases commenced in February 2019. As of June 30, 2019, the weighted average remaining lease term is 7.2 years. The monthly payments for the facility lease escalate over the facility lease term with the exception of a decrease in payments at the beginning of 2022. The Company has options to extend the facility operating leases for up to 14 years. The Company's lease contracts do not contain termination options, residual value guarantees or restrictive covenants.

The operating lease costs are summarized as follows:

(in thousands)	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Operating lease cost	$ 1,425	$ 2,768
Variable lease cost [1]	298	588
Total operating lease costs	$ 1,723	$ 3,356

[1] Variable lease cost includes management fees, common area maintenance, property taxes, and insurance, which are not included in the lease liabilities and are expensed as incurred.

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

Year Ending December 31,	(in thousands)
2019 remaining six months	$ 3,268
2020	6,735
2021	6,942
2022	5,464
2023	5,557
2024 and thereafter	17,959
Total operating lease payments	45,925
Less imputed interest [1]	(15,096)
Present value of operating lease payments	$ 30,829

[1] The Company's lease contracts do not provide a readily determinable implicit rate. The imputed interest was based on a weighted average discount rate of 12.0%, which represents the estimated incremental borrowing based on the information available at the adoption or commencement dates.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

As of December 31, 2018, the aggregate total future minimum lease payments under non-cancelable operating leases were as follows:

Year Ending December 31,	(in thousands)
2019	$ 5,826
2020	6,011
2021	6,196
2022	4,696
2023 and thereafter	20,173
Total payments	$ 42,902

Supplemental cash flow information related to the operating leases was as follows:

(in thousands)	Six Months Ended June 30, 2019
Cash paid for amounts included in the measurement of operating lease liabilities	$ 3,069
Right-of-use assets obtained in exchange for operating lease liabilities	$ 3,890

7. Commitments and Contingencies

Purchase Commitments

The Company and Ajinomoto Althea, Inc. ("Althea") are parties to a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement (the "Althea Services Agreement"), under which Althea provides the Company a contract development and manufacturing organization, which allows the Company to have expanded capacity and a second source for drug product manufacturing in order to support a global launch of DAXI. Under the Althea Services Agreement, the initial term is to 2024, unless terminated sooner by either company, and the Company has minimum purchase obligations based on its production forecasts. As of June 30, 2019, the Company made non-refundable advanced payments of $1.9 million under the Althea Services Agreement. The remaining services can be canceled at any time, with the Company required to pay costs incurred through the cancellation date.

Contingencies

The Company is obligated to pay $2.0 million milestone payment to a developer of botulinum toxin, List Biological Laboratories, Inc. ("List Laboratories"), when a certain regulatory milestone is achieved. As of June 30, 2019, the milestone has not been achieved. The Company is also obligated to pay royalties to List Laboratories on future sales of botulinum toxin products.

The Company and Botulinum Toxin Research Associates, Inc. ("BTRX") are parties to an asset purchase agreement (the "BTRX Purchase Agreement"), under which the Company is obligated to pay up to $16.0 million to BTRX upon the satisfaction of milestones relating to the Company's product revenue, intellectual property, and clinical and regulatory events. As of June 30, 2019, a one-time intellectual property development milestone liability of $1.0 million has been recorded in accruals on the Company's Condensed Consolidated Balance Sheets.

The Company and BioSentinel, Inc. ("BioSentinel") are parties to an agreement under which the Company in-licenses BioSentinel's technology and expertise for research, development and manufacturing purposes. The Company is obligated to pay BioSentinel minimum quarterly use fees, and a one-time milestone payment of $0.3 million when regulatory approval is achieved. As of June 30, 2019, the milestone has not been achieved.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

Indemnification

The Company has standard indemnification agreements in the ordinary course of business. Under these indemnification agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual after the execution of the agreements. The maximum potential amount of future payments the Company is obligated to pay under these indemnification agreements is not determinable because it involves claims that may be made against the Company in the future, but have not been made. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

The Company has indemnification agreements with its directors and officers that may require the Company to indemnify them against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

For the six months ended June 30, 2019, no amounts associated with the indemnification agreements have been recorded.

8. Stockholders' Equity

Common Stock Warrants

As of June 30, 2019 and December 31, 2018, 34,113 common stock warrants were outstanding at an exercise price of $14.95 per share, which expire in 2020.

Stock Option Plan

2014 Equity Incentive Plan ("2014 EIP")

On January 1, 2019, the number of shares of common stock reserved for issuance under the 2014 EIP increased by 1,479,008 shares. For the six months ended June 30, 2019, 1,070,950 stock options and 460,325 restricted stock awards were granted under the 2014 EIP. As of June 30, 2019, 1,984,483 shares were available for issuance under the 2014 EIP.

2014 Inducement Plan (the "2014 IN")

For the six months ended June 30, 2019, no stock options or restricted stock awards were granted under the 2014 IN. As of June 30, 2019, 170,019 shares were available for issuance under the 2014 IN.

2014 Employee Stock Purchase Plan (the "2014 ESPP")

On January 1, 2019, the number of shares of common stock reserved for issuance under the 2014 ESPP increased by 300,000 shares. As of June 30, 2019, 1,443,774 shares were available for issuance under the 2014 ESPP.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2019	2018	2019	2018
Research and development	$ 2,253	$ 1,868	$ 4,332	$ 3,791
General and administrative	2,167	2,304	4,247	4,539
Total stock-based compensation expense	$ 4,420	$ 4,172	$ 8,579	$ 8,330

Net Loss per Share

The Company's basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, which includes the vested restricted stock awards. The diluted net loss per share is calculated by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, outstanding stock options, outstanding common stock warrants, unvested restricted stock awards, and shares of common stock expected to be purchased under 2014 ESPP are considered common stock equivalents, which were excluded from the computation of diluted net loss per share because including them would have been antidilutive.

Common stock equivalents that were excluded from the computation of diluted net loss per share are presented as below:

	As of June 30,	
	2019	2018
Outstanding common stock options	4,438,894	3,530,799
Outstanding common stock warrants	34,113	34,113
Unvested restricted stock awards	797,190	668,619

Follow-On Public Offering

In January 2019, the Company completed the 2019 follow-on public offering, pursuant to which the Company issued 6,764,705 shares of common stock at $17.00 per share, including the exercise of the underwriters' over-allotment option to purchase 882,352 additional shares of common stock, for net proceeds of $107.6 million, after underwriting discounts, commissions and other offering expenses.

At-The-Market Offering

The Company and Cantor Fitzgerald & Co. ("Cantor Fitzgerald") are parties to a Controlled Equity Offering sales agreement (the "2018 ATM Agreement"), under which the Company may offer and sell common stock having aggregate proceeds of up to $125.0 million through Cantor Fitzgerald as its sales agent. Under the 2018 ATM Agreement, sales of common stock through Cantor Fitzgerald will be made by means of ordinary brokers' transactions on the Nasdaq Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by the Company and Cantor Fitzgerald. From time to time, Cantor Fitzgerald may sell the common stock based upon the Company's instructions, and the Company will pay a commission to Cantor Fitzgerald of up to 3.0% of the gross sales proceeds of any common stock sold through Cantor Fitzgerald. For the six months ended June 30, 2019 and 2018, no common stock was sold under the 2018 ATM Agreement.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

9. Income Taxes

California State Apportionment

In 2018, the Company petitioned the California Franchise Tax Board for an alternative apportionment percentage due to the insignificant apportionment percentage derived from the single sales factor methodology for California. In January 2019, the California Franchise Tax Board approved the use of an alternative apportionment method. The Company's net operating losses ("NOL") in California is estimated to increase by approximately $209 million as a result of the change in apportionment model. The Company has increased its deferred tax assets by $15 million with a corresponding offsetting adjustment to its valuation allowance. There is no impact to the Company's net loss in the period as a result of the adjustment.

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 Condensed Consolidated Financial Statements and the accompanying notes appearing elsewhere in this Quarterly Report on this Form 10-Q and in our other Securities and Exchange Commission ("SEC") filings, including our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 28, 2019. The words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. The following discussion and analysis contains forward-looking statements within meaning of the Private Securities Litigation Reform Act of 1995.

These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations regarding the results, timing and completion of our clinical trials and regulatory submissions needed for the approval of DAXI, including but not limited to, for the treatment of glabellar (frown) lines, forehead lines, lateral canthal lines, cervical dystonia, plantar fasciitis, and adult upper limb spasticity in the United States ("U.S."), Europe and other countries;
- our expectations regarding our future development of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates for other indications, including but not limited to, migraine;
- our expectations regarding the development of future product candidates;
- the potential for commercialization by us of DAXI, if approved;
- our expectations regarding the potential market size, opportunity and growth potential for DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, if approved for commercial use;
- our belief that DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates can expand overall demand for botulinum toxin;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners including distributors, to commercialize our product candidates, if approved;
- our ability to manufacture in our facility and to scale up our manufacturing capabilities and those of future third-party manufacturers if our product candidates are approved;
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals;

- our ability to advance product candidates into, and successfully complete, clinical trials;
- the implementation of our business model, and strategic plans for our business, product candidates and technology;
- the initiation, timing, progress and results of future preclinical studies and clinical trials and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to establish collaborations or obtain additional funding;
- our financial performance, including future revenue targets; and
- developments and projections relating to our competitors and our industry.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in "Risk Factors" included in Part II, Item 1A and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is neither possible for management to predict all risks nor assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this report may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

Overview

We are a biotechnology company developing new innovations in neuromodulators for aesthetic and therapeutic indications. Our lead product candidate, DaxibotulinumtoxinA for Injection ("DAXI"), combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. We have successfully completed a Phase 3 program for DAXI in glabellar (frown) lines, demonstrating efficacy and long-lasting duration of effect, and is pursuing U.S. regulatory approval in 2020. We are also evaluating DAXI in forehead lines and lateral canthal lines (crow's feet), as well as three therapeutic indications including cervical dystonia, adult upper limb spasticity, and plantar fasciitis, with plans to study migraine. Beyond DAXI, we have begun development of a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. We are dedicated to making a difference by transforming patient experiences.

Since inception, we have devoted substantially all of our effort to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel, raising capital, conducting preclinical and clinical development of, and manufacturing development for DAXI, DaxibotulinumtoxinA Topical and the biosimilar to BOTOX®. We have incurred losses and negative cash flows from operations. We have not commenced commercial operations, have not generated product revenue to date, and will continue to incur significant research and development and other expenses related to our ongoing operations. For the three and six months ended June 30, 2019, we had a net loss of $37.4 million and $72.7 million, respectively. As of June 30, 2019, we had a working capital surplus of $205.2 million and an accumulated deficit of $757.5 million. We have funded our operations primarily through the issuance and sale of common stock, convertible preferred stock, notes payable, and convertible notes. As of June 30, 2019, we had capital resources of $241.9 million consisting of cash, cash equivalents, and investments. We believe that our existing capital resources will fund the operating plan through at least the next 12 months following the issuance of this Form 10-Q, and may identify additional capital resources to fund our operations.

Neuromodulator Pipeline

DAXI Aesthetics

Glabellar lines. In December 2018, we announced top-line results for the SAKURA 3 open-label, long-term safety study. DAXI appeared to be generally well-tolerated with no new tolerability or safety concerns reported. We held a pre-BLA meeting with the U.S. Food and Drug Administration ("FDA") in December 2018 to agree upon the content and format of the BLA. We are in the process of compiling one of the largest clinical data packages for an aesthetic indication. We have been working in parallel to develop a 100-unit vial in addition to an initial 50-unit vial. This added additional work streams for process validation and stability. We expect to submit the BLA in the Fall of 2019, and are on track for a 2020 approval and launch for DAXI for the treatment of glabellar lines. We plan to file marketing applications in the European Union, Canada, and certain Latin American and Asian countries after filing in the U.S.

Forehead lines. In January 2019, we initiated a Phase 2 multicenter, open-label, dose-escalation study to evaluate treatment of moderate or severe dynamic forehead lines ("FHL" or "frontalis") in conjunction with treatment of the glabellar complex. The objective is to understand the potential dosing and injection patterns of DAXI in other areas of the upper face in addition to the lead indication in glabellar lines. We completed enrollment for the study in July 2019. We expect to release top-line results in the first half of 2020.

Lateral canthal lines. In March 2019, we initiated a Phase 2 multicenter, open-label, dose-escalation study to evaluate the treatment of moderate or severe lateral canthal lines (also known as "crow's feet"). Similar to the FHL study above, the objective is to understand the potential dosing and injection patterns of DAXI in other areas of the upper face in addition to the lead indication in glabellar lines. We expect to complete enrollment for the study in the summer of 2019 and release top-line results in the first half of 2020.

DAXI Therapeutics

Cervical dystonia. In June 2018, we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program based on the Phase 2 safety and efficacy results and guidance from the FDA and European Medicines Agency ("EMA"). The ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DAXI for the treatment of cervical dystonia in adults including: a randomized, double-blind, placebo-controlled, parallel group trial, and an open-label, long-term safety trial. We plan to complete the ASPEN Phase 3 pivotal trial enrollment by the end of 2019, and release topline results in the second half of 2020.

Adult upper limb spasticity. In December 2018, we initiated a Phase 2 trial for the treatment of adult upper limb spasticity (JUNIPER). This is a randomized, double-blind, placebo-controlled, parallel group, dose-ranging trial to evaluate the efficacy and safety of DAXI for the treatment of ULS in adults after stroke or traumatic brain injury. We expect to complete Phase 2 trial enrollment in the first half of 2020.

Plantar fasciitis. In September 2018, we completed a Type C meeting with the FDA discussing the design of the Phase 2 dose-finding study. We initiated another Phase 2 trial in December 2018. The Phase 2 prospective, randomized, double-blind, multi-center, placebo-controlled study will evaluate the safety and efficacy of two doses of administration of our investigational drug candidate DAXI in reducing the signs and symptoms of plantar fasciitis. We expect to complete Phase 2 trial enrollment by the end of 2019 and release topline results in the second half of 2020.

Migraine. We are in the process of finalizing our migraine clinical development strategy. We plan to initiate a study with DAXI for the treatment of migraine in 2020.

OnabotulinumtoxinA Biosimilar

We and Mylan entered into the Mylan Collaboration in February 2018, under which the companies will collaborate exclusively, on a worldwide basis (excluding Japan), to develop, manufacture, and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. Under the Mylan Collaboration, we are responsible for conducting initial non-clinical development activities with the goal of preparing for and conducting a scientific advice meeting with the FDA to receive feedback as to whether a biosimilar biological pathway is feasible for BOTOX®.

In February 2019, Revance had a biosimilar initial advisory meeting (BIAM) with the FDA and Mylan on a proposed biosimilar to BOTOX®. In this meeting, the FDA provided guidance on their expectations for a development program to establish biosimilarity to BOTOX®. Based on the FDA's feedback, the companies believe that a 351(k) pathway for the development of a biosimilar to onabotulinumtoxinA is viable and provides the opportunity to develop and commercialize the first biosimilar product for potentially all thirteen currently approved indications of BOTOX® and BOTOX® Cosmetic. In April 2019, we received the official FDA minutes from the BIAM and have met with Mylan to discuss the development program going forward, which could lead to a near-term milestone payment to Revance.

Fosun License Agreement

We and Fosun entered into the Fosun License Agreement in December 2018, whereby we granted Fosun the exclusive rights to develop and commercialize our proprietary DAXI in the Fosun Territory and certain sublicense rights. Additionally, our proprietary peptide excipient technology can be used for molecules other than botulinum toxin. We plan to partner or license the peptide excipient technology opportunistically to monetize our technology platform.

Under the Fosun License Agreement, we received a non-refundable upfront payment of $30.0 million, net of foreign withholding tax of $3.0 million, from Fosun in January 2019.

Follow-On Public Offering

In January 2019, we completed the 2019 follow-on public offering, pursuant to which we issued 6,764,705 shares of common stock at $17.00 per share, including the exercise of the underwriters' over-allotment option to purchase 882,352 additional shares of common stock, for net proceeds of $107.6 million, after underwriting discounts, commissions and other offering expenses.

Results of Operations

Revenue

For the three and six months ended June 30, 2019, our total revenue decreased $0.7 million or 100%, and $0.6 million or 68%, respectively, compared to the same periods in 2018, due to the timing of the initial development activities from the Mylan Collaboration which was completed in February 2019.

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses. The largest component of our operating expenses is our personnel costs including stock-based compensation. We expect our expenses to increase in the near term as we initiate and complete additional clinical trials and associated programs related to DAXI for the treatment of glabellar lines and indications in muscle movement and other disorders, such as cervical dystonia, plantar fasciitis, upper limb spasticity, migraine, and our biosimilar product candidate.

Research and Development Expenses

We recognize research and development expenses as they are incurred. Since our inception, we have focused on our clinical development programs and the related research and development. Since 2002, we have been developing one or more of DAXI, DaxibotulinumtoxinA Topical, and our biosimilar product candidate and have typically shared our employees, consultants and infrastructure resources across all programs. We believe that the strict allocation of costs by product candidate would not be meaningful, therefore, we generally do not track these costs by product candidates.

Research and development expenses consist primarily of:

- salaries and related expenses for personnel in research and development functions, including stock-based compensation;
- expenses related to the initiation and completion of clinical trials and studies for DAXI, DaxibotulinumtoxinA Topical and our biosimilar candidate, including expenses related to production of clinical supplies;
- fees paid to clinical consultants, CROs and other vendors, including all related fees for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- other consulting fees paid to third parties;
- expenses related to establishment and maintenance of our own manufacturing facilities;
- expenses related to the manufacture of drug substance and drug product supplies for ongoing and future preclinical and clinical trials and other pre-commercial supplies;
- expenses to support our product development and establish manufacturing capabilities to support potential future commercialization of any products for which we may obtain regulatory approval;
- expenses related to license fees and milestone payments under in-licensing agreements;
- expenses related to compliance with drug development regulatory requirements in the U.S., the European Union and other foreign jurisdictions; and
- depreciation and other allocated expenses.

Our research and development expenses are subject to numerous uncertainties primarily related to the timing and cost needed to complete our respective projects. Further, the development timelines, probability of success and development expenses can differ materially from expectations and the completion of clinical trials may take several years or more depending on the type, complexity, novelty and intended use of a product candidate. Accordingly, the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development. We expect our research and development expenses to maintain or increase as we continue our clinical development of DAXI for the treatment of facial wrinkles and other neuroscience indications, such as cervical dystonia, plantar fasciitis, adult upper limb spasticity, and migraine, any future new indications, and our biosimilar product candidate or if the FDA requires us to conduct additional clinical trials for approval.

Our research and development expenses fluctuate as projects transition from one development phase to the next. Depending on the stage of completion and level of effort related to each development phase undertaken, we may reflect variations in our research and development expense. We expense both internal and external research and development expenses as they are incurred.

Our research and development expenses are summarized as follows:

(in thousands, except percentages)	Three Months Ended June 30, 2019	2018	Change	Six Months Ended June 30, 2019	2018	Change
Clinical and regulatory	$ 12,747	$ 11,891	7%	$ 25,114	$ 23,776	6 %
Manufacturing and quality	7,727	6,499	19%	15,089	12,495	21 %
Other research and development expenses	2,799	2,613	7%	4,986	5,049	(1)%
Stock-based compensation	2,253	1,868	21%	4,332	3,791	14 %
Total research and development expenses	$ 25,526	$ 22,871	12%	$ 49,521	$ 45,111	10 %

Clinical and regulatory

Clinical and regulatory expenses include personnel costs, external clinical trial costs for clinical sites, clinical research organizations, central laboratories, data management, contractors and regulatory activities associated with the development of DAXI. For the three months ended June 30, 2019 and 2018, clinical and regulatory costs totaled $12.7 million, or 50%, and $11.9 million, or 52%, respectively, of the total research and development expenses for the respective periods. For the six months ended June 30, 2019 and 2018, clinical and regulatory costs totaled $25.1 million, or 51%, and $23.8 million, or 53%, respectively, of the total research and development expenses for the respective periods.

For the three and six months ended June 30, 2019, clinical and regulatory expenses increased by $0.9 million, or 7%, and $1.3 million, or 6%, respectively, compared to the same period in 2018. This increase is primarily due to increased costs related to hiring additional personnel and outside services to support BLA preparation activities. We expect to maintain or increase our clinical and regulatory expenses in the near term as we initiate and complete clinical trials and other associated programs related to DAXI for the treatment forehead lines, lateral canthal lines, cervical dystonia, plantar fasciitis, adult upper limb spasticity, and migraine, and our anticipated BLA submission for DAXI for the treatment of glabellar (frown) lines.

Manufacturing and quality

Manufacturing and quality expenses include personnel and occupancy expenses, external contract manufacturing costs and pre-approval manufacturing of drug product used in our research and development of DAXI. Manufacturing and quality expenses also include raw materials, lab supplies, and storage and shipment of our product to support quality control and assurance activities. These expenses do not include clinical expenses associated with the development of DAXI. For the three months ended June 30, 2019 and 2018, manufacturing and quality expenses were $7.7 million, or 30%, and $6.5 million, or 28%, respectively, of the total research and development expenses for the respective periods. For the six months ended June 30, 2019 and 2018, manufacturing and quality expenses were $15.1 million, or 30%, and $12.5 million, or 28%, respectively, of the total research and development expenses for the respective periods.

For the three and six months ended June 30, 2019, manufacturing and quality expenses increased by $1.2 million, or 19%, and $2.6 million, or 21%, respectively, compared to the same period in 2018, primarily due to increased costs related to pre-BLA manufacturing and quality activities, hiring additional personnel and outside services to address compliance requirements, and infrastructure build-out. We expect to increase our manufacturing and quality efforts as we approach commercialization.

Other research and development expenses

Other research and development expenses include expenses for personnel, contract research organizations, consultants, raw materials, and lab supplies used to conduct preclinical research and development of DAXI and our biosimilar product candidate. We expect to maintain these activities to continue developing DAXI and our biosimilar product candidate. For the three months ended June 30, 2019 and 2018, other research and development expenses were $2.8 million, or 11%, and $2.6 million, or 11%, respectively, of the total research and development expenses for the respective periods. For the six months ended June 30, 2019 and 2018, other research and development expenses were $5.0 million, or 10%, and $5.0 million, or 11%, respectively, of the total research and development expenses for the respective periods.

Stock-based compensation

For the three and six months ended June 30, 2019, stock-based compensation included in research and development expenses increased by $0.4 million, or 21%, and $0.5 million, or 14%, respectively, compared to the same periods in 2018, primarily due to increased employee headcount, offset by an average decrease in fair value of stock options granted during these periods.

General and Administrative Expenses

General and administrative expenses consist primarily the following:

- pre-commercial activities including market research, public relations, promotion and advertising;
- personnel and service costs in our finance, information technology, commercial, investor relations, legal, human resources, and other administrative functions; and
- professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents and litigation.

We expect that our general and administrative expenses will maintain or increase with the continued development of, and if approved, the commercialization of DAXI.

Our general and administration expenses are summarized as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands, except percentages)	**2019**	**2018**	**Change**	**2019**	**2018**	**Change**
General and administrative expenses before stock-based compensation	$ 11,429	$ 10,430	10 %	$ 22,259	$ 21,811	2 %
Stock-based compensation	2,167	2,304	(6)%	4,247	4,539	(6)%
Total general and administrative expenses	$ 13,596	$ 12,734	7 %	$ 26,506	$ 26,350	1 %

General and administrative expenses before stock-based compensation

For the three months ended June 30, 2019, general and administrative expenses before stock-based compensation increased by $1.0 million, or 10%, compared to the same period in 2018, primarily due to increased personnel in administrative functions and costs related to infrastructure build-out. For the six months ended June 30, 2019, general and administrative expenses before stock-based compensation increased by $0.4 million, or 2% compared to the same period in 2018, primarily due to increased personnel in administrative functions, costs related to first-year effort to comply with Sarbanes-Oxley 404(b) requirements, and costs related to infrastructure build-out.

Stock-based compensation

For the three and six months ended June 30, 2019, stock-based compensation included in general and administrative expenses decreased by $0.1 million, or 6%, and $0.3 million, or 6%, respectively, compared to the same period in 2018, primarily due to an average decrease in fair value of stock option granted during the period, offset by higher employee headcount.

Net Non-Operating Income and Expense

Interest Income

Interest income primarily consists of interest income earned on our deposit, money market fund, and investment balances. We expect interest income to vary each reporting period depending on our average deposit, money market fund, and investment balances during the period and market interest rates.

Interest Expense

Interest expense primarily consists of the interest charges associated with our financing obligations and capitalized interest. Interest expense includes cash and non-cash components with the non-cash components consisting of effective interest recognized on the financing obligations and interest capitalized for assets constructed for use in operations.

Change in Fair Value of Derivative Liability associated with the Medicis settlement

The product approval payment associated with the Medicis settlement is classified as a liability on our Condensed Consolidated Balance Sheet. This liability is remeasured to fair value at each balance sheet date with the corresponding gain or loss recorded. We will continue to record adjustments to the fair value of the Medicis settlement derivative liability until the product approval payment is paid.

Other Expense, net

Other expense, net primarily consists of miscellaneous tax and other expense items.

Our net non-operating income and expense are summarized as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands, except percentages)	**2019**	**2018**	**Change**	**2019**	**2018**	**Change**
Interest income	$ 1,596	$ 1,081	48 %	$ 3,166	$ 2,103	51 %
Interest expense	—	—	— %	—	(44)	(100)%
Change in fair value of derivative liability associated with the Medicis settlement	21	(70)	(130)%	(71)	(104)	(32)%
Other income (expense), net	115	(172)	(167)%	(40)	(492)	(92)%
Total net non-operating income	$ 1,732	$ 839	106 %	$ 3,055	$ 1,463	109 %

For the three months ended June 30, 2019, our total net non-operating income increased by $0.9 million compared to the same period in 2018, primarily due to an increase in interest income of $0.5 million from our investments and an increase of $0.3 million in other income. For the six months ended June 30, 2019, our total net non-operating income increased by $1.6 million compared to the same period in 2018, primarily due to our higher cash, cash equivalents, and investments balance and higher interest rates in 2019.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(in thousands)	**June 30, 2019**	**December 31, 2018**	**Increase**
Cash, cash equivalents, and investments	$ 241,892	$ 175,812	$ 66,080
Working capital	$ 205,209	$ 175,952	$ 29,257
Total stockholders' equity	$ 188,542	$ 145,622	$ 42,920

Sources and Uses of Cash

We hold our cash, cash equivalents, and investments in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in money market funds, U.S. treasury securities, U.S. government agency securities, and commercial paper. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs.

As of June 30, 2019 and December 31, 2018, we had cash, cash equivalents and investments of $241.9 million and $175.8 million, respectively, which represented an increase of $66.1 million. The increase was primarily driven by the proceeds from issuance of common stock (net of commissions and discount) of $108.1 million in connection with the 2019 follow-on offering, the upfront payment (net of withholding tax) received under the Fosun License Agreement of $27.0 million, and the proceeds from maturity of investments of $117.0 million. These increases were primarily offset by cash used in other operating activities of $67.7 million, purchases of investments of $165.0 million, and purchases of property and equipment of $1.5 million.

Through June 30, 2019, we have funded substantially all of our operations through the issuance and sale of common stock, convertible preferred stock, notes payable, and convertible notes. Since our inception, we have generated significant net loss due to our substantial research and development expenses. We expect to continue to incur net loss for at least the next several years as we advance DAXI through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. As a result, we will need additional capital to fund our operations which we may obtain from additional financings, public offerings, or other sources.

We derived the following summary of our Condensed Consolidated Cash Flows for the periods indicated from our unaudited Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q:

	Six Months Ended June 30,	
(in thousands)	**2019**	**2018**
Net cash provided by (used in):		
Operating activities	$ (40,704)	$ (47,701)
Investing activities	$ (49,429)	$ (196,486)
Financing activities	$ 106,911	$ 723

Cash Flows from Operating Activities

Our cash used in operating activities is primarily driven by personnel, manufacturing costs, clinical development, and facility related expenditures. The changes in net cash used in operating activities are primarily related to our net loss, working capital fluctuations and changes in our non-cash expenses, all of which are highly variable. Our cash flows from operating activities will continue to be affected principally by our working capital requirements and the extent to which we increase spending on personnel and research and development activities as our business grows.

For the six months ended June 30, 2019, net cash used in operating activities was $40.7 million, which was primarily due to clinical spend of approximately $17 million to advance our clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately $24 million; professional services and consulting of approximately $17 million; and rent, supplies and utilities of $10 million; offset by the upfront payment, net with withholding tax, received under the Fosun License Agreement of $27 million. The remaining balance of operating activities related primarily to other supplies.

For the six months ended June 30, 2018, net cash used in operating activities was $47.7 million, which was primarily due to clinical spend of more than $25 million to advance our clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately $15 million; and professional services and consulting of more than $15 million, offset by cash receipts of $25 million from Mylan upfront payment. The remaining balance of operating activities related primarily to rent, utilities, and other supplies, offset by interest income.

Cash Flows from Investing Activities

For the six months ended June 30, 2019 and 2018, net cash used in investing activities was primarily due to purchases of property and equipment, and fluctuations in the timing of purchases and maturities of investments.

Cash Flows from Financing Activities

For the six months ended June 30, 2019, net cash provided by financing activities was primarily driven by proceeds from the issuance of our common stock in connection with the 2019 follow-on offering (as described below) and proceeds from the exercise of stock options and employee stock purchase plan, offset by net settlement of restricted stock awards for employee taxes and payment of offering costs. For the six months ended June 30, 2018, net cash provided by financing activities was primarily driven by proceeds from the exercise of stock options and employee stock purchase plan, offset by net settlement of restricted stock awards for employee taxes, principal payments made on financing obligations, and payment of offering costs.

Follow-On Public Offering

In January 2019, we completed the 2019 follow-on public offering, pursuant to which we issued 6,764,705 shares of common stock at $17.00 per share, including the exercise of the underwriters' over-allotment option to purchase 882,352 additional shares of common stock, for net proceeds of $107.6 million, after underwriting discounts, commissions and other offering expenses.

ATM Offering

We entered into a Controlled Equity Offering sales agreement (the "2018 ATM Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") in March 2018, under which we may offer and sell common stock having aggregate proceeds of up to $125.0 million through Cantor Fitzgerald as our sales agent. Under the 2018 ATM Agreement, sales of common stock through Cantor Fitzgerald will be made by means of ordinary brokers' transactions on the Nasdaq Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon with Cantor Fitzgerald. From time to time, Cantor Fitzgerald will sell the common stock based upon our instructions, and we will pay a commission to Cantor Fitzgerald of up to 3.0% of the gross sales proceeds of any common stock sold through Cantor Fitzgerald. For the six months ended June 30, 2019 and 2018, no common stock was sold under the 2018 ATM Agreement with Cantor Fitzgerald & Co.

Common Stock and Common Stock Equivalents

As of July 26, 2019, outstanding shares of common stock were 44,102,532, outstanding stock options were 4,395,557, outstanding common stock warrants were 34,113, unvested restricted stock awards were 790,395.

Operating and Capital Expenditure Requirements

We have not achieved profitability on a quarterly or annual basis since our inception and we expect to continue to incur net losses for the foreseeable future. We expect to make additional capital outlays to increase operating expenditures to support the completion of the clinical trials and other associated programs relating to DAXI for the treatment of facial wrinkles, cervical dystonia, plantar fasciitis, adult upper limb spasticity, and migraine, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We believe that our existing capital resources will be sufficient to fund our operations for at least the next 12 months following the filing of this Form 10-Q. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or issue debt, convertible debt or other securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of debt or convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay clinical trials or other development activities for DAXI and our biosimilar product candidate, and any future product candidates, or delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if we obtain marketing approval. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable. Our future capital requirements depend on many factors, including:

- the results of our clinical trials for DAXI and preclinical trials of DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing and conducting preclinical and clinical trials of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the cost of commercialization activities if DAXI or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, Fosun licensing, and the terms of and timing such arrangements;
- the degree and rate of market acceptance of any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- any litigation, including litigation costs and the outcome of such litigation;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Please see Part II, Item 1A. “Risk Factors” for additional risks associated with our substantial capital requirements.

Critical Accounting Policies

For the six months ended June 30, 2019, there have been no material changes in our critical accounting policies as compared to those disclosed in Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019, except as described in Note 1 to our Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

Contractual Obligations

Our minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on February 28, 2019. Our future minimum contractual commitments have not changed materially from the amounts previously reported.

Recent Accounting Pronouncements

Refer to “Recent Accounting Pronouncements” in Note 1 to the Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

Off-Balance Sheet Arrangements

As of June 30, 2019, we did not have any off-balance sheet arrangements or any relationships with any entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes. For the six months ended June 30, 2019, our exposure to market risk has not changed materially since that disclosed in Item 7A in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q, our principal executive officer and principal 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

During the three months ended June 30, 2019, we implemented a new enterprise resource planning ("ERP") system. Accordingly, we modified the design and operation of certain internal control processes and procedures relating to the new ERP system. Other than the ERP system implementation described above, there were no changes in our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all other information included in this Form 10-Q, including our Condensed Consolidated Financial Statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before you decide to purchase shares of our common stock. If any of the following risks actually occurs, our business, prospects, financial condition and operating results could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2018.

Risks Related to Our Business and Strategy

We are substantially dependent on the clinical and commercial success of our product candidate DAXI.*

To date, we have invested substantial efforts and financial resources in the research and development of botulinum toxin-based product candidates. Our success as a company is substantially dependent on the clinical and commercial success of DAXI.

We completed Phase 3 clinical development for DAXI in North America for the treatment of glabellar lines. From 2016 to 2018, we conducted and announced results relating to multiple pivotal and safety trials in our SAKURA Phase 3 program. The SAKURA 1 and SAKURA 2 trials were designed to evaluate the safety and efficacy of a single administration of DAXI for the treatment of moderate-to-severe glabellar lines in adults. In addition to the two pivotal trials, the Phase 3 program includes a long-term open-label safety trial (SAKURA 3), which is designed to evaluate the long-term safety and duration of DAXI for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration. SAKURA 3 was designed to support a safety database adequate for both domestic and international marketing applications. We plan to file marketing applications for DAXI for the treatment of glabellar lines first in the U.S. in the fall of 2019, followed by the European Union, Canada, and certain Latin American and Asian countries.

In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of DAXI for the treatment of cervical dystonia. The Phase 2 study evaluated the safety, preliminary efficacy, and duration of effect of DAXI in subjects with moderate to severe isolated cervical dystonia. Based on the Phase 2 safety and efficacy results and subsequent guidance from the FDA and EMA, in June 2018 we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program. The ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DAXI for the treatment of cervical dystonia in adults including: a randomized, double-blind, placebo-controlled, parallel group trial and an open-label, long-term safety trial.

In 2016, we also initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of DAXI in the therapeutic indication of plantar fasciitis. This study evaluated the safety and efficacy of a single administration of DAXI in reducing the signs and symptoms of plantar fasciitis. The study's primary efficacy endpoint is the improvement in the American Orthopedic Foot and Ankle Score. In January 2018, we announced interim 8-week results from this study. We completed the 16-week trial which showed a 58 percent reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant. We initiated another Phase 2, double-blind, placebo-controlled trial utilizing two doses of DAXI in the fourth quarter of 2018.

In April 2018, we announced two new clinical programs for DAXI, including adult upper limb spasticity and migraine. We initiated a Phase 2 study in adult upper limb spasticity in the fourth quarter of 2018 and we expect to complete Phase 2 trial enrollment in the first half of 2020. In 2020, we plan to initiate a study with DAXI for the treatment of migraine.

Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of DAXI. Our longer-term prospects will depend on the successful development, regulatory approval and commercialization of DAXI, as well as DaxibotulinumtoxinA Topical, biosimilar or any future product candidates. The preclinical, clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- timely completion of, or need to conduct additional, clinical trials, including our clinical trials for DAXI, DaxibotulinumtoxinA Topical, biosimilar and any future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the number and design of such trials and the accurate and satisfactory performance of third-party contractors;
- our ability to demonstrate the effectiveness and differentiation of our products on a consistent basis as compared to existing or future therapies;
- our ability to demonstrate to the satisfaction of the FDA, the safety and efficacy of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates through clinical trials;
- whether we are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- our success in educating physicians and patients about the benefits, administration and use of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, if approved;
- the prevalence and severity of adverse events experienced with our product candidates or future approved products;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the ability to raise additional capital on acceptable terms and in the time frames necessary to achieve our goals;
- achieving and maintaining compliance with all regulatory requirements applicable to DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates or approved products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative treatments;
- the effectiveness of our own or our current and any future potential strategic collaborators' marketing, sales and distribution strategy and operations;

- our ability to effectively and reliably manufacture clinical trial supplies of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;

- our ability to successfully commercialize DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, if approved for marketing and sale, whether alone or in collaboration with others;

- our ability to enforce our intellectual property rights in and to DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;

- our ability to avoid third-party patent interference or intellectual property infringement claims;

- acceptance of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, if approved, as safe and effective by patients and the medical community;

- the willingness of third-party payors to reimburse physicians or patients for DAXI and any future products we may commercialize for therapeutic indications;

- the willingness of patients to pay out of pocket for DAXI and any future products we may commercialize for aesthetic indications;

- the continued acceptable safety profile of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates following approval.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidate to continue our business.

We may be unable to obtain regulatory approval for DAXI, topical product candidate, biosimilar product candidate or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business prospects, and our results of operations.

To gain approval to market a biologic product such as DAXI, DaxibotulinumtoxinA Topical or biosimilar, we must provide the FDA and foreign regulatory authorities with data that adequately demonstrate the safety, efficacy and quality of the product for the intended indication applied for in the BLA or other respective marketing applications. The development of biologic products is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, including in Phase 3 development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway, safety or efficacy observations, including previously unreported adverse events; and the need to conduct further supportive or unanticipated studies, even after initiating Phase 3 trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful or that additional supportive studies will not be required, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

For example, we completed DaxibotulinumtoxinA Topical clinical trials for the treatment of lateral canthal lines (“crow’s feet”) and primary axillary hyperhidrosis, but discontinued further clinical development in 2016 following the results from our REALISE 1 Phase 3 clinical trial for crow's feet. In 2016, we also initiated a Phase 2 trial of DAXI for the treatment of plantar fasciitis. In January 2018, we announced interim 8-week results from this study and subsequently completed the 16-week trial, which showed a strong placebo response, with the difference between the treatment groups not being statistically significant.

Our business currently depends substantially on the successful development, regulatory approval and commercialization of our product candidates. Based on discussion with the FDA at a Pre-Phase 3 meeting in the second quarter of 2016 and the minutes received following the meeting, we submitted an IND in the U.S. and initiated subject dosing in Phase 3 clinical studies of DAXI for the treatment of glabellar lines in 2016. In the first quarter of 2017, we completed patient enrollment in the two pivotal trials of our SAKURA Phase 3 program and in October 2017, we completed enrollment of SAKURA 3. In December 2017, we announced positive top-line results from the two pivotal trials. In December 2018, we announced top-line results for the SAKURA 3 open-label, long-term safety study. We are in the process of compiling the clinical data package, developing a 100-unit vial and completing drug substance and drug product validation, with stability, required for submission of a BLA. In June 2018, we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program for DAXI for the treatment of cervical dystonia. The program is expected to enroll approximately 300 patients in each of the two studies at multiple sites in the U.S., Canada, and Europe.

Such studies may increase the time, expense and uncertainty of our product development programs and potential approval and commercialization timelines, including, for example, because results of such studies may indicate to us a further need to refine the related product candidate.

We currently have no drug or biologic products approved for sale, and we may never obtain regulatory approval to commercialize DAXI, DaxibotulinumtoxinA Topical or biosimilar. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of a BLA from the FDA. We are also not permitted to market our product candidates in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

The FDA or any foreign regulatory body 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 an applicable foreign regulatory body that DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates are safe and effective for the requested indication;
- our inability to demonstrate preclinical proof of concept of DaxibotulinumtoxinA Topical, biosimilar or other products in future, new indications;
- the FDA's or an applicable foreign regulatory agency's disagreement with the trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that clinical and other benefits of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates outweigh any safety or other perceived risks;
- the FDA's or an applicable foreign regulatory agency's requirement for additional preclinical or clinical studies;
- the FDA's or an applicable foreign regulatory agency's non-approval of the formulation, labeling or the specifications of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the FDA's or an applicable foreign regulatory agency's failure to approve our manufacturing processes or facilities, or 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 an applicable foreign regulatory agency to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA or the applicable foreign regulatory agency also may approve DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future 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 the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates, and DAXI in particular, would delay or prevent commercialization of DAXI and would materially adversely impact our business, results of operations and prospects.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.

We and any third-party contract development and manufacturers or suppliers are required to comply with applicable cGMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Manufacturers and suppliers of materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, third party manufacturers and suppliers and any manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with cGMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

If, as a result of the FDA's inspections, it determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after approval and commercialization.

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, most of our resources have been dedicated to the research and preclinical and clinical development of our botulinum toxin product candidates, DAXI, DaxibotulinumtoxinA Topical or biosimilar. In particular, our clinical programs for DAXI, DaxibotulinumtoxinA Topical or biosimilar will require substantial additional funds to complete. As of June 30, 2019, we had a working capital surplus of $205.2 million and an accumulated deficit of $757.5 million, primarily as a result of our November 2015, December 2017 and January 2019 follow-on public offerings, and at-the-market ("ATM") offerings in 2015 and 2017. Our recorded net losses were $37.4 million and $34.1 million, and $72.7 million and $69.1 million, for the three and six months ended June 30, 2019 and 2018, respectively.

We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. As of June 30, 2019, we had capital resources consisting of cash and cash equivalents and investments of $241.9 million. We raised aggregate net proceeds of $126.2 million, $156.9 million and $107.6 million in our follow-on public offerings in November 2015, December 2017 and January 2019, respectively. In addition, we raised net proceeds of approximately $10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016, and raised net proceeds of approximately $38.2 million by selling an aggregate of 1,802,651 shares of our common stock under the 2016 ATM agreement. In March 2018, we terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement with Cantor Fitzgerald & Co., or Cantor Fitzgerald (the "2018 ATM Agreement"). Under the 2018 ATM Agreement, we may offer and sell common stock having aggregate proceeds of up to $125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of June 30, 2019. We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of DAXI, DaxibotulinumtoxinA Topical or biosimilar and development of any other indications and product candidates that we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, 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 clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of DAXI and any future product candidates. In addition, we have formed strategic collaborations, licensing and similar arrangements with third parties, such as the Mylan Collaboration and Fosun License Agreement, that we believe can complement or augment our product offerings, and may continue to do so in the foreseeable future.

We believe that our existing cash, cash equivalents, and investments including the net proceeds from our follow-on public offerings and ATM offerings will allow us to fund our operations for at least 12 months following the filing of this Form 10-Q. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional capital sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the results of our clinical trials for DAXI and preclinical trials of DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar;
- the number and characteristics of any additional product candidates we develop or acquire;

- the scope, progress, results and costs of researching and developing and conducting preclinical and clinical trials of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;

- the cost of commercialization activities if DAXI or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar are approved for sale, including marketing, sales and distribution costs;

- the cost of manufacturing DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates and any products we successfully commercialize and maintaining our related facilities;

- our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, Fosun licensing, and the terms of and timing such arrangements;

- the degree and rate of market acceptance of any future approved products;

- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;

- any product liability or other lawsuits related to our products;

- the expenses needed to attract and retain skilled personnel;

- any litigation, including litigation costs and the outcome of such litigation;

- the costs associated with being a public company;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Additional capital may not be available when needed, 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 preclinical studies, clinical trials, research, development, manufacturing, sales, marketing or other commercial activities for DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidate.

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

Even if our product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and use necessary for commercial success.

The commercial success of DAXI, and any future product candidates including DaxibotulinumtoxinA Topical or biosimilar, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians for approved indications. The degree and rate of physician adoption of DAXI and any future product candidates, if approved, will depend on a number of factors, including:

- the effectiveness and duration of effect of our product as compared to existing and future therapies;

- physician willingness to adopt a new therapy to treat glabellar lines, cervical dystonia, plantar fasciitis, adult upper limb spasticity, migraine or other aesthetic or therapeutic indications;
- patient satisfaction with the results and administration of our product and overall treatment experience;
- patient demand for the treatment of glabellar lines, cervical dystonia, plantar fasciitis or other aesthetic or therapeutic indications;
- the willingness of third-party payors to reimburse physicians or patients for DAXI and any future products we may commercialize for therapeutic indications;
- the willingness of patients to pay out of pocket for DAXI and any future products we may commercialize for aesthetic indications; and
- the revenue and profitability that our product will offer a physician as compared to alternative therapies.

If DAXI or any future product candidates are approved for use but fail to achieve the broad degree of physician adoption necessary for commercial success, our operating results and financial condition will be adversely affected.

Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

We expect to enter highly competitive pharmaceutical and medical device markets. Successful competitors in the pharmaceutical and medical device markets have the ability to effectively discover therapies, obtain patents, develop, test and obtain regulatory approvals for products, and have the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical staff. Numerous companies are engaged in the developing, patenting, manufacturing and marketing healthcare products which we expect will compete with those that we are developing. Many of these competitors are large, experienced companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities.

Upon marketing approval, the first expected use of our products will be in aesthetic medicine. Competition in aesthetic products is significant and dynamic, and is characterized by rapid and substantial technological development and product innovations. Numerous competitors have obtained patents protecting what they consider to be their intellectual property.

In aesthetic medicine, we plan to seek regulatory approval of DAXI for the treatment of glabellar lines. We anticipate that DAXI, if approved, will face significant competition from existing injectable botulinum toxins as well as unapproved and off-label treatments. Further, if approved, in the future we may face competition for DAXI from biosimilar products and products based upon botulinum toxin. To compete successfully, we will have to demonstrate that the treatment of glabellar lines with DAXI is a worthwhile aesthetic treatment and has advantages over other therapies. Competition could result in reduced profit margins and limited sales, which would harm our business, financial condition and results of operations.

Due to less stringent regulatory requirements, there are many more aesthetic products and procedures available for use in a number of foreign countries than are approved for use in the U.S. There are also fewer limitations on the claims that our competitors in certain countries can make about the effectiveness of their products and the manner in which they can market them.

We currently make our DAXI clinical drug product exclusively in one internal manufacturing facility. We plan to utilize internal and external facilities, including through one or more third-party contractors, in the future to support commercial production if our product candidates are approved. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business would be materially harmed.

We currently manufacture our own clinical drug product to support DAXI development in one internal manufacturing facility. In March 2017, we entered into an Althea Services Agreement. Under the Althea Services Agreement, Althea will provide us commercial fill/finish services and will serve as a second source of manufacturing for DAXI. We plan to utilize our internal and external Althea facility to support commercial production of DAXI, if approved. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of such manufacturing facilities is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved, jeopardize our ability to manufacture our products as promptly as our customers expect or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our customers' expectations, our business, prospects, financial results and reputation could be materially harmed.

We recognize revenue in accordance with complex accounting standards and changes in the interpretation or application of generally accepted accounting principles may materially affect our financial statements.

In May 2014, the Financial Accounting Standards Board (the "FASB") issued an accounting standard for revenue recognition, Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("ASC 606"). Further, in April 2016, the FASB amended ASC 606 to provide additional guidance on revenue recognition as it pertains to licenses of intellectual property. We adopted ASC 606 and its related amendments on January 1, 2018.

The nature of our business requires the application of complex revenue recognition rules. Significant judgment is required in the interpretation and application of complex accounting guidance such as ASC 606. Our judgments and assumptions are based on the facts and circumstances of the underlying revenue transactions. The SEC, the American Institute of Certified Public Accountants ("AICPA"), the FASB and various other regulatory or accounting bodies may issue new positions, interpretive views or updated accounting standards on the treatment of complex accounting matters such as revenue recognition that may materially affect our financial statements.

Impairment in the carrying value of long-lived assets could negatively affect our operating results.*

There were no indicators of impairment for the year ended December 31, 2018 or for the six months ended June 30, 2019. Under U.S. GAAP, long-lived assets, such as our fill/finish line, are required to be reviewed for impairment whenever adverse events or changes in circumstances indicate a possible impairment. If business conditions or other factors indicate that the carrying value of the asset may not be recoverable, we may be required to record additional non-cash impairment charges. Additionally, if the carrying value of our capital equipment exceeds current fair value as determined based on the discounted future cash flows of the related product, the capital equipment would be considered impaired and would be reduced to fair value by a non-cash charge to earnings, which could negatively affect our operating results. Events and conditions that could result in impairment in the value of our long-lived assets include adverse clinical trial results, changes in operating plans, unfavorable changes in competitive landscape, adverse changes in the regulatory environment, or other factors leading to reduction in expected long-term sales or profitability. We will evaluate the recoverability and fair value of our long-lived assets, including those related to other components of the fill/finish line, each reporting period to determine the extent to which further non-cash charges to earnings are appropriate. Additional impairment in the value of our long-lived assets may materially and negatively impact our operating results.

We have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. Currently, we have only one product candidate in clinical trials and no commercial sales, which make it difficult to assess our future viability.*

We are a clinical-stage biotechnology company. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We are not profitable and have incurred losses in each year since we commenced operations in 2002. 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 biotechnology industry. To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenue from product sales relating to DAXI, DaxibotulinumtoxinA Topical or biosimilar. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. As of June 30, 2019, we had a working capital surplus of $205.2 million and an accumulated deficit of $757.5 million. Our recorded net losses were $37.4 million and $34.1 million, and $72.7 million and $69.1 million for the three and six months ended June 30, 2019 and 2018, respectively. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize DAXI. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months following the filing of this Form 10-Q.

We expect to continue to incur losses for the foreseeable future, and we anticipate that these losses will increase as we continue our development of, seek regulatory approval for and begin to commercialize DAXI. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and manufacture, market and commercialize our products successfully. 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, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Even if DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.

Even if we obtain FDA or other regulatory approvals, DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates may not achieve market acceptance among physicians and patients, and may not be commercially successful.

The degree and rate of market acceptance of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates for which we receive approval depends on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- the proper training and administration of our products by physicians and medical staff;
- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of payors and patients;
- the willingness of patients to pay for DAXI, DaxibotulinumtoxinA Topical, and other aesthetic treatments in general, relative to other discretionary items, especially during economically challenging times;

- the willingness of third-party payors to reimburse physicians or patients for DAXI and any future products we may commercialize for therapeutic indications;
- the willingness of patients to pay out of pocket for DAXI and any future products we may commercialize for aesthetic indications;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue and continue our business.

Clinical drug 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. Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Furthermore, final results may differ from interim results. For example, any positive results generated to date in clinical trials for DAXI do not ensure that later clinical trials, including any DAXI clinical trials for the treatment of glabellar lines, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety profile and efficacy despite having progressed through preclinical studies and initial clinical trials.

A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. We have suffered similar setbacks with the clinical development of DaxibotulinumtoxinA Topical and we cannot be certain that we will not face other similar setbacks in the future for DAXI or other clinical development programs. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We have in the past and may in the future experience delays in our ongoing clinical trials, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a trial;
- reach agreement on acceptable terms with prospective 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;
- obtain IRB, approval at each site;
- recruit suitable subjects to participate in a trial;
- have subjects complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;

- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of product candidate for use in clinical trials.

Subject enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

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, 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, failure of inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, discovery of 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.

If we experience delays in the completion or termination of any 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. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval 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 of our product candidates.

We have no experience manufacturing our product candidates at full commercial scale. If our product candidates are approved, we will face certain risks associated with scaling up our manufacturing capabilities to support commercial production.

We have developed an integrated manufacturing, research and development facility located at our corporate headquarters. We manufacture drug substance and finished dose forms of the drug product at this facility that we use for research and development purposes and clinical trials. We do not have experience in manufacturing our product candidates at commercial scale. If our product candidates are approved, we may need to expand our manufacturing facilities, add manufacturing personnel and ensure that validated processes are consistently implemented in our facilities and potentially enter into additional relationships with third-party manufacturers. The upgrade and expansion of our facilities will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facilities and recruit necessary additional personnel. If we are unable to expand our manufacturing facilities in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including obtaining regulatory approvals of our product candidates, which could materially damage our business and financial position.

We currently contract with third-party manufacturers for certain components and services necessary to produce DAXI and expect to continue to do so to support further clinical trials and commercial scale production if DAXI is approved. This increases the risk that we will not have sufficient quantities of DAXI or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third-party manufacturers for certain components such as bulk peptide and services such as fill/finish services, necessary to produce DAXI for our clinical trials, and we expect to continue to rely on these or other manufacturers to support our commercial requirements if DAXI is approved. In particular, in March 2017, we entered into the Althea Services Agreement. We plan to utilize our internal and external Althea facility to support commercial production of DAXI, if approved. Some of our contracts with our manufacturers contain minimum order and pricing provisions and provide for early termination based on regulatory approval milestones.

Reliance on third-party manufacturers entails additional risks, including the reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third- party manufacturers may not be able to comply with cGMP or Quality System Regulation, or QSR, or similar regulatory requirements outside the U.S. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of DAXI, or any other product candidates or products that we may develop. Any failure or refusal to supply the components or services for DAXI or any other product candidates or products that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

We depend on single-source suppliers for the raw materials necessary to produce our product candidates. The loss of these suppliers, or their failure to supply us with these raw materials, would materially and adversely affect our business.

We and our manufacturers purchase the materials necessary to produce DAXI for our clinical trials from single-source third-party suppliers. There are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials and, if approved, ultimately for commercial sale. In particular, we outsource the manufacture of bulk peptide through American Peptide Company, Inc., or American Peptide, which was acquired by Bachem.

We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe that we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of DAXI or any future product candidates, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of our clinical trials, product testing and potential regulatory approval of DAXI or any future product candidates. If we or our manufacturers are unable to purchase these raw materials on acceptable terms and at sufficient quality levels or in adequate quantities if at all, the development of DAXI and any future product candidates, or the commercial launch of any approved products, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

Furthermore, if there is a disruption to our or our third-party suppliers' relevant operations, we will have no other means of producing DAXI or any future product candidates until they restore the affected facilities or we or they procure alternative facilities. Additionally, any damage to or destruction of our or our third party or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

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

We currently have limited marketing and sales capabilities and no field sales organization. To commercialize DAXI or any other future product candidates, if approved, in the U.S., Europe and other jurisdictions we seek to enter, 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 DAXI receives regulatory approval, we expect to market DAXI as applicable, through our own sales force in North America, and in Europe and other countries through either our own sales force or a combination of our internal sales force and distributors or partners, which may be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. 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 DAXI or any future product candidates. If we are not successful in commercializing DAXI or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

As we evolve from a company primarily involved in research and development to a company potentially involved in commercialization, we will need to increase the size of our organization and we may experience difficulties in managing this growth.

If we are successful in advancing DAXI through the development stage towards commercialization, we will need to expand our organization, including adding marketing, managerial, operational and sales capabilities, or contracting with third parties to provide these capabilities for us to manage our operations and clinical trials, continue our development activities and commercialize DAXI or any other product candidates, if approved. Our management, 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 and manufacturing operations effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

As our operations expand, we expect that we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to commercialize DAXI and to compete effectively will depend, in part, on our ability to manage any future growth effectively. Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations.

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, including our internal manufacturing facility, are located in the San Francisco Bay Area, which has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes 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 manufacturing facility, 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. In particular, because we manufacture botulinum toxin in our facilities, we would be required to obtain further clearance and approval by state, federal or other applicable authorities to continue or resume manufacturing activities. The disaster recovery and business continuity plans we have in place currently are limited and may not be 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 geographically concentrated and operating from single sites, thereby increasing their vulnerability 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.

We currently rely on third parties and consultants to conduct all our preclinical studies and clinical trials. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize DAXI or any future product candidates.

We do not have the ability to independently conduct preclinical studies or clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs and clinical data management organizations, to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, 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 preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, and good laboratory practices, or GLPs, for conducting, monitoring, recording and reporting the results of clinical and preclinical trials 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 also rely on consultants to assist in the execution, including data collection and analysis, of our clinical trials.

In addition, the execution of preclinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. These third parties may terminate their agreements with us upon as little as 30 days' prior written notice of a material breach by us that is not cured within 30 days. Many of these agreements may also be terminated by such third parties under certain other circumstances, including our insolvency or our failure to comply with applicable laws. In general, these agreements require such third parties to reasonably cooperate with us at our expense for an orderly winding down of services of such third parties under the agreements. If the third parties or consultants conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. We may be unable to recover unused funds from these third-parties. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for, and will not be able to, or may be delayed in our efforts to, successfully commercialize the product candidate being tested in such trials.

If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications, require labeling content that diminishes market uptake of our products or limits our marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved treatments and therapies;
- the potential advantages of the product over existing and future treatment products;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the willingness of third-party payors to provide adequate reimbursement for our approved products, and the willingness of payments to pay for our approved products in the absence of third-party reimbursement; and
- the price and cost-effectiveness of the product.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

If DAXI is approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, significant fines, penalties, and sanctions, product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products, such as DAXI, if approved. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Furthermore, the use of our products for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Any of these events could harm our business and results of operations and cause our stock price to decline.

Even if DAXI or any future product candidate is approved for commercialization, if there is not sufficient patient demand for such procedures, our financial results and future prospects will be harmed.

Treatment of glabellar lines or other aesthetic indications with DAXI is an elective procedure, the cost of which must be borne by the patient, and we do not expect it to be reimbursable through government or private health insurance. The decision by a patient to elect to undergo the treatment of glabellar lines with DAXI or the treatment of other aesthetic indications we may pursue may be influenced by a number of factors, including:

- the success of any sales and marketing programs that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians recommend DAXI to their patients;
- the extent to which DAXI satisfies patient expectations;
- our ability to properly train physicians in the use of DAXI or such that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the cost, safety and effectiveness of DAXI versus other treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and DAXI in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and
- general consumer confidence, which may be impacted by general economic and political conditions.

Our business, financial results and future prospects will be materially harmed if we cannot generate sufficient demand for DAXI or for any other future product candidate, once approved.

We are subject to uncertainty relating to third-party reimbursement policies which, if not favorable for DAXI or any future product candidates, could hinder or prevent their commercial success.*

Our ability to commercialize DAXI or any future product candidates for therapeutic indications such as cervical dystonia, adult upper limp spasticity, plantar fasciitis or migraine will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for DAXI or any future product candidates for therapeutic indications, or we may be required to sell them at a discount.

We expect that third-party payors will consider the efficacy, cost effectiveness and safety of DAXI in determining whether to approve reimbursement for DAXI for therapeutic indications and at what level. Our business would be materially adversely affected if we do not receive coverage and adequate reimbursement of DAXI for therapeutic indications from private insurers on a timely or satisfactory basis. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States; therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, coverage under certain government programs, such as Medicare and Medicaid, may not be available for certain of our product candidates. As a result, the coverage determination process will likely be a time-consuming and costly process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our business could also be adversely affected if third-party payors limit the indications for which DAXI will be reimbursed to a smaller patient set than we believe they are effective in treating.

In some foreign countries, particularly Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including DAXI, to other available therapies. If reimbursement for our product is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any future products we develop.

We face an inherent risk of product liability lawsuits as a result of the clinical testing of our product candidates and we 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 warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for DAXI or any future product candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- 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 any products we develop.

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 DAXI or any future products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $10.0 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 capital 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 DAXI we intend to expand our insurance coverage to include the sale of DAXI as applicable; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

We have been, and in the future may be, subject to securities class action and stockholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business.

We have been, and may in the future be, the target of securities class actions or stockholder derivative claims. On May 1, 2015, a securities class action complaint was filed on behalf of City of Warren Police and Fire Retirement System against us and certain of our directors and executive officers at the time of our follow-on public offering, and the investment banking firms that acted as the underwriters in our follow-on public offering. The Court granted final approval of the Settlement, as set forth in the Stipulation of Settlement, on July 28, 2017. While the litigation has ended, we may be subject to future securities class action and shareholder derivation actions, which may adversely impact our business, results of operations, financial position or cash flows and divert management's time and attention from the business.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, conduct our clinical trials and commercialize DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future products we develop.*

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly L. Daniel Browne, our President and Chief Executive Officer, Abhay Joshi, Ph.D., our Chief Operating Officer, Caryn G. McDowell, our Senior Vice President, General Counsel & Corporate Secretary, and Tobin C. Schilke, our Chief Financial 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, the completion of our planned clinical trials or the commercialization of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future products we develop.

Leadership transitions can be inherently difficult to manage. Resignations of executive officers may cause disruption in our business, strategic and employee relationships, which may significantly delay or prevent the achievement of our business objectives. Leadership changes may also increase the likelihood of turnover in other key officers and employees and may cause declines in the productivity of existing employees. The search for a replacement officer may take many months or more, further exacerbating these factors. Identifying and hiring an experienced and qualified executive officer are typically difficult. Periods of transition in senior management leadership are often difficult as the new executives gain detailed knowledge of our operations and may result in cultural differences and friction due to changes in strategy and style. During the transition periods, there may be uncertainty among investors, employees, creditors and others concerning our future direction and performance.

We could experience problems attracting and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense and the turnover rate can be high 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 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 previous research output.

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 clinical testing and potential approval of DAXI, a key element of our strategy is to discover, develop and commercialize a portfolio of botulinum toxin products for both aesthetic and therapeutic indications. We are seeking to do so through our internal research programs and may explore strategic collaborations for the development or acquisition of new products. While DAXI is in the clinical development stage, DaxibotulinumtoxinA Topical and all of our other potential product candidates remain in the discovery or preclinical stage. 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 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 on further study 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;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and
- intellectual property rights of third parties may potentially block our entry into certain geographies or make such entry economically impracticable.

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 problems that we encounter in developing and commercializing DAXI.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members of our board of directors.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Dodd-Frank Act, the Nasdaq listing rules and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company that is subject to these rules and regulations we may find it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers.

We need to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, and the failure to do so could have a material adverse effect on our business and stock price.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Beginning with the 2018 Annual Report on Form 10-K, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our common stock could decline and we could be subject to actions or investigations by the SEC, or other regulatory authorities, which would require additional financial and management resources.

We may experience difficulties maintaining our new enterprise resource planning system.*

During the three months ended June 30, 2019, we implemented a new enterprise resource planning ("ERP") system. ERP implementations are complex and time-consuming, and involve substantial expenditures on system software and implementation activities. The ERP system will be critical to our ability to provide important information to our management, obtain and deliver our products, provide services and customer support, send invoices and track payments, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results or otherwise operate our business. ERP implementations also require transformation of business and financial processes in order to reap the benefits of the ERP system; any such transformation involves risks inherent in the conversion to a new computer system, including loss of information and potential disruption to our normal operations. The implementation and maintenance of the new ERP system has required, and will continue to require, the investment of significant financial and human resources. Any disruptions, delays or deficiencies in the design or the ongoing maintenance of the new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if the system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess it adequately could be delayed.

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 and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including botulinum toxin type A, a key component of our 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. We are licensed with the Centers for Disease Control and Prevention and with the California Department of Health, Food and Drug Branch for use of botulinum toxin and to manufacture both the active pharmaceutical ingredient, or API, and the finished product in topical and injectable dose forms. 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 us and 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 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 may use third-party collaborators to help us develop, validate or commercialize any new products, and our ability to commercialize such products could be impaired or delayed if these collaborations are unsuccessful.

We may continue to license or selectively pursue strategic collaborations for the development, validation and commercialization of DAXI, DaxibotulinumtoxinA Topical, biosimilar and any future product candidates. For instance, in February 2018, we and Mylan entered into the Mylan Collaboration, pursuant to which we and Mylan will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize our biosimilar product candidate. In addition, in December 2018, we and Fosun entered into the Fosun License Agreement pursuant to which we have granted Fosun the exclusive rights to develop and commercialize DAXI in the Fosun Territory and certain sublicense rights. In any third-party collaboration, we would be dependent upon the success of the collaborators to perform their responsibilities with continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our product candidates will be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses. Our collaboration with Mylan is for the development of a biosimilar product, which is subject to risks inherent with the relatively short history of biosimilar product approvals in the United States. The biosimilar product would be subject to similar commercial risks as our DAXI and Daxibotulinumtoxin A Topical product candidates. In February 2019, we and Mylan participated in a Biosimilar Initial Advisory Meeting ("BIAM") with the FDA to discuss the feasibility of a 351(k) biosimilar submission and the necessary development pathway for the biosimilar product candidate. While we believe that such a pathway is viable, the successful development and commercialization of a biosimilar product in any indications of BOTOX® or BOTOX Cosmetic® would be subject to FDA requirements that would need to be assessed by us and Mylan in determining the development of the biosimilar product candidate. Such requirements may also limit our ability to begin Phase 3 development of the biosimilar in 2020, as presently planned or at all. Even if successfully developed, the biosimilar product would be subject to similar commercial risks as our DAXI and Daxibotulinumtoxin A Topical product candidates.

Unfavorable global economic conditions or trade relations 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 demand for aesthetic or therapeutic medical procedures may be particularly vulnerable to unfavorable economic conditions. We do not expect sales of DAXI for the treatment of glabellar lines to be reimbursed by any government or third-party payor and, as a result, demand for the first indications of each of our product candidates will be tied to discretionary spending levels of our targeted patient population. Future global financial crises may cause extreme volatility and disruptions in capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

In addition, changes in U.S. and foreign trade policies could trigger retaliatory actions by affected countries, resulting in "trade wars", which may reduce customer demand for goods exported out of the United States if the parties having to pay those retaliatory tariffs increase their prices, or if trading partners limit their trade with the United States. If these consequences are realized, the price to the consumer of aesthetic or therapeutic medical procedures from products exported out of the United States may increase, resulting in a material reduction in the demand for our future product candidates. Such a reduction may materially and adversely affect our potential sales and our business. In particular, under our Fosun License Agreement, we are responsible for manufacturing DAXI and supplying it to Fosun, which would then develop commercialize, market and sell it in mainland China, Hong Kong and Macau. If this arrangement is restricted in any way due to the US-China trade relation, the contingent payments we are entitled to receive under the agreement, which are based on product sales, among other things, may be adversely affected.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current or future economic climate and financial market conditions could adversely impact our business.

Adverse tax laws or regulations could be enacted or existing laws could be applied to us or our customers, which could increase the costs of our services and adversely impact our business.

The application of federal, state, local and international tax laws to services provided electronically is evolving. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time (possibly with retroactive effect), and could be applied solely or disproportionately to services provided over the internet. These enactments could adversely affect our sales activity due to the inherent cost increase the taxes would represent and ultimately result in a negative impact on our operating results and cash flows.

In addition, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us (possibly with retroactive effect), which could require us or our customers to pay additional tax amounts, as well as require us or our customers to pay fines or penalties and interest for past amounts. If we are unsuccessful in collecting such taxes from our customers, we could be held liable for such costs, thereby adversely impacting our operating results and cash flows.

Further, we have undertaken certain transactions to realize potential tax efficiencies in support of our expected global business expansion. These transactions are meant to align the global economic ownership of our intellectual property rights with our current and future business operations. We are uncertain as to whether the tax efficiencies sought by this alignment will materialize and may choose to unwind these transactions in the future.

On December 22, 2017, legislation that significantly revised the Internal Revenue Code of 1986 was signed into law. The legislation, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent, limitation of the tax deduction for interest expense to 30 percent of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 percent of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the federal tax law changes is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse.

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 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. For example, in January 2019, we discovered that our e-mail server suffered unauthorized intrusions in which proprietary business information was accessed. Although we do not believe that we have experienced any material losses related to security breaches, including recent cybersecurity incidents, there can be no assurance that we will not suffer such losses in the future. Breaches and other inappropriate access can be difficult to detect and any delay in identifying them could increase their harm. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Any such breaches of security and inappropriate access could disrupt our operations, harm our reputation or otherwise have a material adverse effect on our business, financial condition and results of operations.

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 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 study data from completed or ongoing or planned clinical studies 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, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media or individuals pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. For example, these may include the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009,

and its implementing rules and regulations, U.S. state breach notification laws and the EU General Data Protection Regulation (EU) 2016/679, or GDPR. We would also be exposed to a risk of loss, enforcement measures, penalties, fines, indemnification claims or litigation and potential civil or criminal liability, which could materially adversely affect our business, results of operations and financial condition.

Changes in and failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the U.S. and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our vendors' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In the event that we are subject to HIPAA or other U.S. privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our customers, or our vendors must comply. For example, the EU has adopted the GDPR, which went into effect in May 2018 and introduces strict requirements for processing the personal information of EU subjects, including clinical trial data. The GDPR is likely to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4 percent of the annual global revenue of the noncompliant company, whichever is greater. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Risks Related to Our Intellectual Property

If our efforts to protect our intellectual property related to DAXI, or any future product candidates, including DaxibotulinumtoxinA Topical and biosimilar, are not adequate, we may not be able to compete effectively.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to DAXI, DaxibotulinumtoxinA Topical, biosimilar, and our development programs. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thereby eroding our competitive position.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or license may fail to result in issued patents in the U.S. or foreign countries. Competitors in the field of cosmetics, pharmaceuticals, and botulinum toxin have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant. Our European Patent EP 2 661 276 for "Topical composition comprising botulinum toxin and a dye" was opposed in the European Patent Office by Allergan plc on May 2, 2018, and although this patent is not material to our business, we will continue to take appropriate measures to defend the patent. On May 10, 2019 our European Patent No. EP 2 490 986 B1 for "Methods and Systems For Purifying Non-Complexed Botulinum Neurotoxin" was opposed. We will vigorously defend this patent in the European Patent Office. We were informed in May 2019 that our patent application NC2018/0005351 pending in Colombia for "Injectable Botulinum Toxin Formulations And Methods of Use Thereof Having Long Duration of Therapeutic Effect" was opposed. We are vigorously responding to this pre-grant opposition. Furthermore, even if our patents and applications are unchallenged, they may not adequately protect our intellectual property or prevent others from designing around our claims.

In addition, the patent laws of the U.S. provide procedures for third parties to challenge the validity of issued patents. Patents issued from applications filed after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility. Under the inter partes review procedure, any third party may challenge the validity of any issued U.S. Patent in the United States Patent and Trademark Office, or USPTO, on the basis of prior art patents or printed publications. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates is challenged, then it could threaten our ability to commercialize DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market DAXI, or any future product candidates under patent protection would be reduced. The results of our REALISE 1 Phase 3 clinical trial may be relevant to our patent strategy for our DaxibotulinumtoxinA Topical program.

Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios and financial resources than we have.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and any other elements of our product development and manufacturing processes that involve proprietary know-how, information or technology that is not covered by patents.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, collaborators and advisers to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. A breach of confidentiality could significantly affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisers have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and other confidential information.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Competitors in the field of cosmetics, pharmaceuticals and botulinum toxin have developed large portfolios of patents and patent applications in fields relating to our business. For example, there are patents held by third parties that relate to the treatment with botulinum toxin-based products for indications we are currently developing. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product based on our current or future indications, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe upon our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation, inter partes review, post-grant review or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patents or patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, either alone or with our licensors or collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S. and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 where enforcement is not as strong as that in the U.S. 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 biotechnology, 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.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

Risks Related to Government Regulation

Our business and products are subject to extensive government regulation.

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the U.S., principally by the FDA, the U.S. Drug Enforcement Administration, the Centers for Disease Control, and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements, including those promulgated under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the PHSA, and Controlled Substances Act, may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, or exclusion from future participation in the Medicare and Medicaid programs.

After our products receive regulatory approval, we, and our direct and indirect suppliers, will remain subject to the periodic inspection of our plants and facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in the implementation of Risk Evaluation and Mitigation Strategies ("REMS") programs, completion of government mandated clinical trials, and government enforcement action relating to labeling, advertising, marketing and promotion, as well as regulations governing manufacturing controls noted above.

The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of DAXI or any future product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, which regulations differ from country to country. Neither we nor any collaboration partner are permitted to market DAXI or any future product candidates in the U.S. until we receive approval of a BLA from the FDA. We have not submitted an application or obtained marketing approval for DAXI anywhere in the world. After we submit a BLA for DAXI, the FDA may refuse to file the application if it determines that the application is not sufficiently complete to permit substantive review. Even if filed by FDA, our BLA may receive a Complete Response Letter identifying deficiencies that must be addressed, rather than an approval. Obtaining regulatory approval of a BLA can be a lengthy, expensive and uncertain process.

In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we or our collaborators must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical and clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

Regulatory approval of a BLA or BLA supplement is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense expended, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including the following:

- a product candidate may not be deemed safe, effective, or of required quality;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA might not approve our third-party manufacturers' processes or facilities; or

- the FDA may change its approval policies or adopt new regulations.

If DAXI or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain approval, our business and results of operations will be materially and adversely harmed.

Even if we receive regulatory approval for DAXI or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, may limit or delay regulatory approval and may subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, DAXI or any approved product will be subject to continual regulatory review by the FDA and/or non-U.S. regulatory authorities. Additionally, any product candidates, if approved, will be subject to extensive and ongoing regulatory requirements, including labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our collaborators receive for DAXI or any future product candidates may also be subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the applicable regulatory agency approves DAXI or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product 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 cGMP and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with DAXI or any future 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 the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or our strategic collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or other countries. 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.

If we fail to obtain regulatory approvals in foreign jurisdictions for DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar, we will be unable to market our products outside of the U.S.

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval procedures vary among countries and can involve additional clinical testing, or 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. 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 the necessary approvals to commercialize our products in geographies outside of the U.S.

If approved, DAXI or any other products may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so, we could be subject to sanctions that would materially harm our business.

Some participants in our clinical trials have reported adverse events after being treated with DAXI. If we are successful in commercializing DAXI, or any other products including DaxibotulinumtoxinA Topical or biosimilar, the FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be 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 we become aware of within the prescribed timeframe. We may also fail to appreciate 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 our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

We may in the future be subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

While we do not expect that DAXI, if approved for the treatment of glabellar lines, will subject us to all of the various U.S. federal and state laws intended to prevent healthcare fraud and abuse, we may in the future become subject to such laws for treatment of other indications. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state healthcare programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal healthcare programs and the levying of substantial civil and criminal penalties.

The federal false claims and civil monetary penalties laws, including the civil False Claims Act, or FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal healthcare program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

HIPAA 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.

The federal Physician Payments Sunshine Act, and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to Centers for Medicare & Medicaid Services information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members.

We may also be subject to analogous state laws and regulations, including: state anti-kickback and false claims laws, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, and state and local laws that require the registration of our pharmaceutical sales representatives.

State and federal authorities have aggressively targeted pharmaceutical manufacturers for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with physicians and other healthcare professionals, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct business. Further, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Legislative or regulatory healthcare reforms in the U.S. may make it more difficult and costly for us to obtain regulatory clearance or approval of DAXI, topical, or any future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. In addition, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of, or affect the price that we may charge for, DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could require, among other things:

- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.*

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

Risks Related to the Ownership of Our Common Stock

The trading price of our common stock is volatile, and purchasers of our common stock could incur substantial losses.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock markets in general and the markets for pharmaceutical biopharmaceutical and biotechnology stocks in particular have experienced extreme volatility that may have been for reasons that are related or unrelated to the operating performance of the issuer. The market price for our common stock may be influenced by many factors, including:

- regulatory or legal developments in the U.S. and foreign countries;
- results from or delays in clinical trials of our product candidates, including our ongoing ASPEN Phase 3 clinical program in cervical dystonia and our Phase 2 programs in plantar fasciitis, adult upper limb spasticity, forehead lines, and lateral canthal lines all with DAXI;
- announcements of regulatory approval or disapproval of DAXI or any future product candidates;
- FDA or other U.S. or foreign regulatory actions or guidance affecting us or our industry;
- introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;

- quarterly variations in our results of operations or those of our future competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our potential relationships with customers and strategic partners;
- the occurrence of trade wars or barriers, or the perception that trade wars or barriers will occur; and
- other factors described in this "Risk Factors" section.

These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In addition, in the past, stockholders have initiated class actions against pharmaceutical companies, including us, following periods of volatility in their stock prices. Such litigation instituted against us could cause us to incur substantial costs and divert management's attention and resources.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may cease to publish research on our company at any time in their discretion. A lack of research coverage may adversely affect the liquidity and market price of our common stock. We will not have any control of the equity research analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company, or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could cause the market price of our common stock to drop significantly, even if our business is doing well.*

Sales of a substantial number of shares of our common stock in the public market could occur at any time. In March 2018, we entered into the 2018 ATM Agreement. Under the 2018 ATM Agreement, we may offer and sell common stock having aggregate proceeds of up to $125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of June 30, 2019. In January 2019, we completed the 2019 follow-on public offering, pursuant to which we issued 6,764,705 shares of common stock at $17.00 per share, including the exercise of the underwriters' over-allotment option to purchase 882,352 additional shares of common stock, for net proceeds of $107.6 million, after underwriting discounts, commissions and other offering expenses.

If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. Any sales of securities by stockholders could have a material adverse effect on the trading price of our common stock.

Provisions in our corporate charter documents and under Delaware law could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.

Certain provisions in our amended and restated certificate of incorporation and amended and restated bylaws may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock. Our board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- no cumulative voting in the election of directors;
- the ability of our board of directors to issues shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- the exclusive right of our board of directors to elect a director to fill a vacancy or newly created directorship;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders;
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- the ability of our board of directors, by a majority vote, to amend the bylaws; and
- the requirement for the affirmative vote of at least 66 2/3 percent or more of the outstanding common stock to amend many of the provisions described above.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

Our amended and restated certificate of incorporation also 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.

A relatively small number of existing stockholders have substantial control over us, which could limit your ability to influence the outcome of key transactions, including a change of control.*

As of June 30, 2019, our directors, executive officers and each of our stockholders who own greater than 5 percent of our outstanding common stock and their affiliates, in the aggregate, beneficially owned approximately 61 percent of our common stock. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might affect the market price of our common stock.

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 our 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.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains.

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

For the six months ended June 30, 2019, there were no sales of unregistered securities.

Issuer Purchases of Equity Securities

We have not and do not currently intend to retire or repurchase any of our shares other than providing our employees with the option to withhold shares to satisfy tax withholding amounts due from employees upon the vesting of restricted stock awards in connection with our 2014 Equity Incentive Plan and 2014 Inducement Plan.

Period	Total Number of Shares Purchased (i)	Weighted-Average Price Paid per Share (ii)	Total Number of Share Purchased as Part of Publicly Announced Plan or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan or Programs (in thousands)
April 1 through April 30, 2019	3,249	$ 14.04	—	$ —
May 1 through May 31, 2019	2,407	11.13	—	—
June 1 through June 30, 2019	1,941	10.86	—	—
Total	7,597	$ 11.76	—	$ —

(i) Consists solely of shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued restricted stock awards.

(ii) The weighted-average price paid per share is the weighted-average of the fair market prices at which we calculated the number of shares withheld to cover tax withholdings for the employees.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filling Date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-36297	3.1	February 11, 2014	—
3.2	Amended and Restated Bylaws	S-1	333-193154	3.4	December 31, 2013	—
4.1	Form of Common Stock Certificate	S-1/A	333-193154	4.4	February 3, 2014	—
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act	—	—	—	—	X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act	—	—	—	—	X
32.1†	Certification of the Principal Executive Officer pursuant to18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	—	X
32.2†	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	—	X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibits 101)	—	—	—	—	X

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, and shall not be deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act. Such certifications shall not be deemed incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

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

REVANCE THERAPEUTICS, INC.

Date: August 6, 2019

By: /s/ L. Daniel Browne

L. Daniel Browne
President and Chief Executive Officer
(Duly Authorized Principal Executive Officer)

Date: August 6, 2019

By: /s/ Tobin C. Schilke

Tobin C. Schilke
Chief Financial Officer
(Duly Authorized Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, L. Daniel Browne, certify that:

1. I have reviewed this Form 10-Q of Revance Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2019

/s/ L. Daniel Browne

L. Daniel Browne

President and Chief Executive Officer

(Duly Authorized Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Tobin C. Schilke, certify that:

1. I have reviewed this Form 10-Q of Revance Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2019

/s/ Tobin C. Schilke

Tobin C. Schilke

Chief Financial Officer

(Duly Authorized Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), L. Daniel Browne, Chief Executive Officer of Revance Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: August 6, 2019

IN WITNESS WHEREOF, the undersigned has set his hands hereto as of the 6th day of August, 2019.

/s/ L. Daniel Browne

L. Daniel Browne
President and Chief Executive Officer
(Duly Authorized Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Revance Therapeutics, 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Tobin C. Schilke, Chief Financial Officer of Revance Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: August 6, 2019

IN WITNESS WHEREOF, the undersigned has set his hands hereto as of the 6th day of August, 2019.

/s/ Tobin C. Schilke

Tobin C. Schilke

Chief Financial Officer

(Duly Authorized Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Revance Therapeutics, 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.