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, 2020

OR

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

For the transition period from _____ to _____

Commission File Number 001-37345

ADURO BIOTECH, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**94-3348934**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

740 Heinz Avenue
Berkeley, California 94710
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (510) 848-4400

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	ADRO	The Nasdaq Global Select Market

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

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

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

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

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

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

The number of shares of Registrant's Common Stock outstanding as of July 29, 2020 was 81,059,005.

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In this Quarterly Report on Form 10-Q, "we," "our," "us," "Aduro" and the "Company" refer to Aduro Biotech, Inc. and its consolidated subsidiaries. Aduro, Aduro Biotech, the Aduro logo and other trade names, trademarks or service marks of Aduro are the property of Aduro Biotech, Inc. This report contains references to our trademarks and to trademarks belonging to other entities. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

ADURO BIOTECH, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 71,103	$ 59,624
Marketable securities	100,028	153,978
Accounts receivable	1,169	342
Income tax receivable	5,665	—
Prepaid expenses and other current assets	3,015	3,958
Total current assets	180,980	217,902
Marketable securities	14,995	—
Property and equipment, net	21,706	24,688
Operating lease right-of-use assets	20,334	21,110
Goodwill	8,177	8,167
Intangible assets, net	18,723	18,978
Restricted cash	468	468
Total assets	$ 265,383	$ 291,313
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,339	$ 414
Accrued clinical trial and manufacturing expenses	2,615	4,253
Accrued expenses and other liabilities	9,673	8,181
Operating lease liabilities	1,741	1,803
Deferred revenue	4,935	6,950
Total current liabilities	20,303	21,601
Contingent consideration	2,013	1,051
Deferred revenue	161,312	166,963
Deferred tax liabilities	3,531	3,527
Operating lease liabilities	30,855	31,636
Other long-term liabilities	753	940
Total liabilities	218,767	225,718
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized; 81,059,005 and 80,735,688 shares issued and outstanding at June 30, 2020 and December 31, 2019	8	8
Additional paid-in capital	557,263	552,077
Accumulated other comprehensive income	439	414
Accumulated deficit	(511,094)	(486,904)
Total stockholders' equity	46,616	65,595
Total liabilities and stockholders' equity	$ 265,383	$ 291,313

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

ADURO BIOTECH, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Collaboration and license revenue	$ 5,574	$ 4,888	$ 19,524	$ 8,826
Total revenue	5,574	4,888	19,524	8,826
Operating expenses:				
Research and development	11,108	16,657	26,936	34,151
General and administrative	9,284	7,832	17,103	16,056
Restructuring and related expense	2,046	367	6,354	3,361
Amortization of intangible assets	136	139	272	279
Total operating expenses	22,574	24,995	50,665	53,847
Loss from operations	(17,000)	(20,107)	(31,141)	(45,021)
Interest income	413	1,497	1,333	2,968
Other expense, net	(28)	(3)	(47)	(22)
Total other income	385	1,494	1,286	2,946
Loss before income tax	(16,615)	(18,613)	(29,855)	(42,075)
Income tax benefit	—	35	5,665	70
Net loss	$ (16,615)	$ (18,578)	$ (24,190)	$ (42,005)
Net loss per common share, basic and diluted	$ (0.21)	$ (0.23)	$ (0.30)	$ (0.53)
Shares used in computing net loss per common share, basic and diluted	80,862,621	80,032,022	80,810,211	79,847,960

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

ADURO BIOTECH, INC.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (16,615)	$ (18,578)	$ (24,190)	$ (42,005)
Other comprehensive loss:				
Unrealized gain on marketable securities, net of tax of $0	109	147	28	331
Foreign currency translation adjustments, net of tax of $0	470	404	(3)	(229)
Other comprehensive gain	579	551	25	102
Comprehensive loss	$ (16,036)	$ (18,027)	$ (24,165)	$ (41,903)

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

ADURO BIOTECH, INC.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2019	80,735,688	$ 8	$ 552,077	$ 414	$ (486,904)	$ 65,595
Issuance of common stock upon exercise of stock options	88,480	—	80	—	—	80
Release of restricted stock units	12,925	—	—	—	—	—
Stock-based compensation	—	—	2,035	—	—	2,035
Other comprehensive loss	—	—	—	(554)	—	(554)
Net loss	—	—	—	—	(7,575)	(7,575)
Balance at March 31, 2020	80,837,093	8	554,192	(140)	(494,479)	59,581
Issuance of common stock upon exercise of stock options	2,980	—	3	—	—	3
Issuance of common stock under Employee Stock Purchase Plan	42,916	—	40	—	—	40
Release of restricted stock units	176,016	—	—	—	—	—
Stock-based compensation	—	—	3,028	—	—	3,028
Other comprehensive income	—	—	—	579	—	579
Net loss	—	—	—	—	(16,615)	(16,615)
Balance at June 30, 2020	81,059,005	$ 8	$ 557,263	$ 439	$ (511,094)	$ 46,616

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2018	79,571,714	$ 8	$ 538,895	$ 940	$ (404,532)	$ 135,311
Issuance of common stock upon exercise of stock options	254,481	—	251	—	—	251
Release of restricted stock units	25,850	—	—	—	—	—
Stock-based compensation	—	—	3,703	—	—	3,703
Other comprehensive loss	—	—	—	(449)	—	(449)
Net loss	—	—	—	—	(23,427)	(23,427)
Balance at March 31, 2019	79,852,045	8	542,849	491	(427,959)	115,389
Issuance of common stock upon exercise of stock options	173,925	—	188	—	—	188
Issuance of common stock under Employee Stock Purchase Plan	58,748	—	164	—	—	164
Release of restricted stock units	45,556	—	—	—	—	-
Stock-based compensation	—	—	3,336	—	—	3,336
Other comprehensive income	—	—	—	551	—	551
Net loss	—	—	—	—	(18,578)	(18,578)
Balance at June 30, 2019	80,130,274	$ 8	$ 546,537	$ 1,042	$ (446,537)	$ 101,050

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

ADURO BIOTECH, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Cash Flows from Operating Activities		
Net loss	$ (24,190)	$ (42,005)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,837	2,175
Amortization of intangible assets	272	279
Impairment of property and equipment	1,202	1,177
Non-cash lease expense	768	436
Accretion of discounts and amortization of premiums on marketable securities	(418)	(856)
Stock-based compensation	5,063	7,039
Loss from remeasurement of fair value of contingent consideration	943	24
Gain on disposal of property and equipment	(544)	(2)
Deferred income tax	—	(70)
Changes in operating assets and liabilities:		
Accounts receivable	(820)	10,674
Income tax receivable	(5,665)	—
Prepaid expenses and other assets	938	612
Accounts payable	1,245	(349)
Deferred revenue	(7,666)	(6,763)
Accrued clinical trial and manufacturing expenses	(2,007)	1,359
Accrued expenses and other liabilities	1,056	(1,784)
Operating lease liabilities	(838)	468
Net cash used in operating activities	(28,824)	(27,586)
Cash Flows from Investing Activities		
Purchase of marketable securities	(113,683)	(133,478)
Proceeds from maturities of marketable securities	153,082	114,159
Purchase of property and equipment	(9)	(382)
Proceeds from sale of property and equipment	544	—
Net cash provided by (used in) investing activities	39,934	(19,701)
Cash Flows from Financing Activities		
Proceeds from employee stock purchase plan	40	164
Proceeds from exercise of stock options	83	439
Net cash provided by financing activities	123	603
Effect of exchange rate changes	246	(65)
Net increase (decrease) in cash, cash equivalents and restricted cash	11,479	(46,749)
Cash, cash equivalents and restricted cash at beginning of period	60,092	126,778
Cash, cash equivalents and restricted cash at end of period	$ 71,571	$ 80,029
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Purchase of property and equipment in accounts payable and accrued liabilities	$ 65	$ —
Reconciliation of Cash, Cash Equivalents and Restricted Cash		
Cash and cash equivalents	$ 71,103	$ 79,561
Restricted cash	468	468
Total cash, cash equivalents and restricted cash	$ 71,571	$ 80,029

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

1. Organization and Nature of Business

Aduro Biotech, Inc., and its wholly owned subsidiaries, or the Company, is an immunotherapy company focused on the discovery, development and commercialization of therapies that are designed to harness the body's natural immune system for the treatment of patients with challenging diseases. The Company is located in Berkeley, California and its wholly-owned subsidiary, Aduro Biotech Holdings, Europe B.V., or Aduro Biotech Europe, organized in the Netherlands. The Company operates in one business segment.

The Company's product candidates in the A Proliferation Inducing Ligand (APRIL) and Stimulator of Interferon Genes (STING) pathways are being investigated in cancer, autoimmune and inflammatory diseases. The Company's anti-APRIL antibody product candidate, BION-1301, an investigational monoclonal antibody that blocks APRIL binding to both the BCMA and TACI receptors, is being evaluated in patients with IgA nephropathy. The Company's lead STING pathway activator product candidate, ADU-S100 (MIW815), which is designed to activate the intracellular STING receptor, is being evaluated in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 monoclonal antibody, as a potential first-line treatment for patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). The Company is collaborating with leading global pharmaceutical companies to help expand and drive its product pipeline. The Company's strategy is to rapidly advance therapeutic candidates from its APRIL and STING programs through clinical development and regulatory approval.

On June 1, 2020, the Company entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Aspire Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, or Merger Sub, and Chinook Therapeutics U.S., Inc., a Delaware corporation, or Chinook, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Chinook, with Chinook continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger.

2. Basis of Presentation, Use of Estimates and Recent Accounting Pronouncements

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and follow the requirements of the Securities and Exchange Commission, or the SEC, for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the unaudited condensed consolidated financial statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of the Company's financial information. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other interim period or for any other future year.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 9, 2020.

The condensed consolidated financial statements include the accounts of Aduro Biotech, Inc. and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and reported amounts of revenue and expenses in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, clinical trial accruals, contingent consideration, income taxes, right-of-use assets, lease obligations, stock-based compensation, and valuation of intangibles and goodwill. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from these estimates.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2016-13 – Financial Instruments—Credit Losses (Topic 326). The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. In April 2019, the FASB issued ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments – Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments, which clarifies and corrects certain unintended applications of the guidance contained in each of the amended Topics. Additionally, in May 2019, the FASB issued ASU No. 2019-05, Financial Instruments – Credit Losses (Topic 326), which provides an option to irrevocably elect to measure certain individual financial assets at fair value instead of amortized cost. In November 2019, the FASB issued ASU No. 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842), which defers the effective date for ASU No. 2016-13 for smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted for all periods beginning after December 15, 2018. The Company does not plan to early adopt and is currently in the process of evaluating the impact the standard will have on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12 – Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12). The standard update simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC 740 and also improves consistent application by clarifying and amending existing guidance. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company has evaluated the impact of this guidance and has concluded that adoption of the standard will not have a material impact on its consolidated financial statements.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13 – Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement. The standard eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information, and modifies some disclosure requirements. The new standard is effective for fiscal years and interim periods beginning after December 15, 2019. The Company adopted the new standard on January 1, 2020. As the result of the adoption the Company is no longer required to disclose (1) the amount of and the reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, and (3) the valuation process for Level 3 fair value measurements. Additionally, the Company is required to disclose (1) the changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Refer to Note 3 “Fair Value Measurements” for the newly required disclosures resulting from the adoption of this standard.

3. Fair Value Measurements

The carrying amounts of certain of the Company’s financial instruments, including cash equivalents, accounts receivable and accounts payable approximate their fair values due to their short maturities. Assets and liabilities recorded at fair value on a recurring basis in the balance sheets, as well as assets and liabilities measured at fair value on a non-recurring basis or disclosed at fair value, are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company's cash equivalents, which include money market funds, are classified as Level 1 because they are valued using quoted market prices. The Company's cash equivalents consisting of corporate debt securities and commercial paper along with the Company's marketable securities consisting of available-for-sale securities are generally classified as Level 2 because their value is based on valuations using significant inputs derived from or corroborated by observable market data. When quoted prices in active markets for identical assets or liabilities are not available, the Company relies on non-binding quotes from its investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, or historical pricing trends of a security relative to its peers. To validate the fair value determination provided by its investment managers, the Company reviews the pricing movement in the context of overall market trends and trading information from its investment managers. In addition, the Company assesses the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy.

In certain cases where there is limited activity or less transparency around the inputs to valuation, securities are classified as Level 3. Level 3 liabilities consist of the contingent consideration liability.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 30,913	$ —	$ —	$ 30,913
U.S. government and agency securities	—	66,209	—	66,209
Corporate debt securities	—	17,702	—	17,702
Commercial paper	—	67,304	—	67,304
Total	$ 30,913	$ 151,215	$ —	$ 182,128
Financial Liabilities:				
Contingent consideration related to acquisition	$ —	$ —	$ 2,013	$ 2,013
Total	$ —	$ —	$ 2,013	$ 2,013

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 39,994	$ —	$ —	$ 39,994
U.S. government and agency securities	—	43,333	—	43,333
Corporate debt securities	—	54,590	—	54,590
Commercial paper	—	67,536	—	67,536
Total	$ 39,994	$ 165,459	$ —	$ 205,453
Financial Liabilities:				
Contingent consideration related to acquisition	$ —	$ —	$ 1,051	$ 1,051
Total	$ —	$ —	$ 1,051	$ 1,051

The acquisition-date fair value of the contingent consideration liability represents the future consideration that is contingent upon the achievement of specified development milestones for a product candidate. The fair value of the contingent consideration is based on the Company's probability-weighted discounted cash flow assessment that considers probability and timing of future payments. The fair value measurement is based on significant Level 3 unobservable inputs such as the probability of achieving development milestones, anticipated timelines and discount rate, the values of which as of June 30, 2020 are shown in the table below. Changes in the fair value of the liability for contingent consideration will be recognized in the consolidated statement of operations until settlement.

	Unobservable Input
Probability of attaining milestone	18.8%
Period of time to achieve milestone (in years)	7.5
Discount rate	10.0%

The Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of June 30, 2020 and December 31, 2019.

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

	Contingent Consideration
Balance at December 31, 2019	$ 1,051
Net change in fair value upon remeasurement	943
Foreign currency impact on contingent consideration	19
Balance at June 30, 2020	$ 2,013

The following tables summarize the estimated value of the Company's cash, cash equivalents and marketable securities and the gross unrealized holding gains and losses (in thousands):

	June 30, 2020			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 3,998	$ —	$ —	$ 3,998
Money market funds	30,913	—	—	30,913
Commercial paper	29,791	2	(1)	29,792
U.S. government and agency securities	6,400	—	—	6,400
Total cash and cash equivalents	$ 71,102	$ 2	$ (1)	$ 71,103
Marketable securities:				
U.S. government and agency securities	$ 59,800	$ 20	$ (11)	$ 59,809
Corporate debt securities	17,639	63	—	17,702
Commercial paper	37,493	20	(1)	37,512
Total marketable securities	$ 114,932	$ 103	$ (12)	$ 115,023

	December 31, 2019			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 8,149	$ —	$ —	$ 8,149
Money market funds	39,994	—	—	39,994
Commercial paper	11,482	—	(1)	11,481
Total cash and cash equivalents	$ 59,625	$ —	$ (1)	$ 59,624
Marketable securities:				
U.S. government and agency securities	$ 43,295	$ 40	$ (2)	$ 43,333
Corporate debt securities	54,563	33	(6)	54,590
Commercial paper	56,055	7	(7)	56,055
Total marketable securities	$ 153,913	$ 80	$ (15)	$ 153,978

The amortized cost and estimated fair value of the Company's available-for-sale marketable securities by contractual maturity are summarized below as of June 30, 2020 (in thousands):

	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Mature in one year or less	$ 99,936	$ 102	$ (10)	$ 100,028
Mature after one year through two years	14,996	1	(2)	14,995
Total available-for-sale marketable securities	$ 114,932	$ 103	$ (12)	$ 115,023

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Leasehold improvements	$ 27,084	$ 27,288
Lab equipment	6,046	8,817
Computer and office equipment	2,146	2,334
Furniture	1,427	1,590
Construction in progress	122	190
Total property and equipment	36,825	40,219
Less: accumulated depreciation	(15,119)	(15,531)
Property and equipment, net	$ 21,706	$ 24,688

Depreciation expense was $0.8 million and $1.1 million for the three months ended June 30, 2020 and 2019, respectively and $1.8 million and $2.2 million for the six months ended June 30, 2020 and 2019, respectively.

Accrued Expenses and Other Liabilities

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

	June 30, 2020	December 31, 2019
Compensation and related benefits	$ 4,539	$ 3,677
Professional and consulting services	3,410	2,845
Accrued research expense	895	890
Accrued purchases of property and equipment	23	31
Other	806	738
Total accrued expenses and other liabilities	$ 9,673	$ 8,181

5. Goodwill and Intangible Assets

Goodwill

The gross carrying amount of goodwill was as follows (in thousands):

Balance at December 31, 2019	$ 8,167
Foreign currency translation adjustment	10
Balance at June 30, 2020	$ 8,177

The Company tests goodwill for impairment on an annual basis on November 1, or more frequently if an impairment indicator exists. To determine if an impairment has occurred, the Company performs a quantitative test in which the Company compares the fair value of its single reporting unit to its carrying value. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, the Company records an impairment loss equal to that difference. As a result of the Company's planned closure of its European site, the Company performed a quantitative assessment of goodwill as of March 31, 2020, and concluded that there was no impairment of goodwill as the fair value of the Company's reporting unit exceeded its carrying value.

Intangible assets

The gross carrying amounts and net book value of intangible assets were as follows (in thousands):

	June 30, 2020		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
License agreement	$ 11,104	$ 2,591	$ 8,513
Total intangible assets with finite lives	11,104	2,591	8,513
Acquired IPR&D assets	10,210	—	10,210
Total intangible assets	$ 21,314	$ 2,591	$ 18,723

	December 31, 2019			
	Gross Carrying Amount	Impairment(1)	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:				
License agreement	$ 11,091	$ —	$ 2,311	$ 8,780
Total intangible assets with finite lives	11,091	—	2,311	8,780
Acquired IPR&D assets	15,297	5,099	—	10,198
Total intangible assets	$ 26,388	$ 5,099	$ 2,311	$ 18,978

(1) The amount includes effects of foreign currency exchange rates.

Intangible assets are carried at cost less accumulated amortization and impairment. Amortization is over a period of 20 years and the amortization expense is recorded in operating expenses. The Company tests its Acquired IPR&D intangible assets for impairment on an annual basis, or more frequently if an impairment indicator exists.

In the first quarter of 2020, due to the Company's decision to close its European site, the Company assessed its Acquired IPR&D intangible assets for impairment. Based on the qualitative assessment performed, no impairment of Acquired IPR&D intangible assets was recorded as of June 30, 2020.

Amortization expense was $0.1 million for each of the three months ended June 30, 2020 and 2019 and $0.3 million for each of the six months ended June 30, 2020 and 2019. Based on finite-lived intangible assets recorded as of June 30, 2020, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2020 (remaining six months)	$ 278
2021	555
2022	555
2023	555
2024	555
2025	555

6. Collaboration Agreements

Novartis Agreement

In March 2015, the Company entered into a collaboration and license agreement with Novartis Pharmaceuticals Corporation, or Novartis, pursuant to which the Company is collaborating worldwide with Novartis regarding the development and potential commercialization of product candidates containing an agonist of the molecular target known as STING in the field of oncology, including immuno-oncology and cancer vaccines. Under this agreement, or the Novartis Agreement, the Company granted Novartis a co-exclusive license to develop such products worldwide, an exclusive license to commercialize such products outside the United States and a non-exclusive license to support the Company in commercializing such products in the United States if it requests such support. The collaboration is guided by a joint steering committee with each party having final decision-making authority regarding specified areas of development or commercialization.

Under the Novartis Agreement, the Company received an upfront payment of $200.0 million in April 2015. During the second quarter of 2016, the Company earned a $35.0 million development milestone upon initiation of a Phase 1 trial for the first STING product candidate, ADU-S100, and recognized the payment as revenue in the period. The Company is also eligible to receive up to an additional $215.0 million in development milestones and up to an additional $250.0 million in regulatory approval milestones.

The Company is responsible for 38% of the joint development costs worldwide and Novartis is responsible for the remaining 62% of the joint development costs worldwide; provided that either party may opt out of early stage clinical trials subject to an obligation to fund and participate in any pivotal trials and reimburse certain early development costs if development of the product progresses into pivotal trials.

The Company will also receive 50% of gross profits on sales of any products commercialized pursuant to this collaboration in the United States and 45% of gross profits for specified European countries and Japan. For each of these profit share countries, each party will be responsible for its respective commercial sharing percentage of all joint commercialization costs incurred in that country.

For all other countries where the Company is not sharing profits, Novartis will be responsible for all commercialization costs and will pay the Company a royalty in the mid-teens on all net sales of product sold by Novartis, its affiliates and sublicensees, with such percentage subject to reduction post patent and data exclusivity expiration and subject to reduction, capped at a specified percentage, for royalties payable to third party licensors. Novartis' royalty obligation will run on a country-by-country basis until the later of expiration of the last valid claim covering the product, expiration of data exclusivity for the product or 12 years after first commercial sale of the product in such country.

With respect to the United States, specified European countries and/or Japan, the Company may elect for such region to either reduce by 50% or to eliminate in full the Company's development and commercialization cost sharing obligation. If the Company elects to reduce its cost sharing percentage by 50% in any such region, then its profit share in such region will also be reduced by 50%. If the Company elects to eliminate its development cost sharing obligation, then such region will be removed from the profit share, and instead Novartis will owe the Company royalties on any net sales of product for such region, as described above.

For revenue recognition purposes, the Company determined that the duration of the contract begins on the effective date in March 2015 and ends upon receipt of regulatory approval, estimated to occur in 2028. The Company's performance period commenced in May 2015. The transaction price consists of the $200.0 million upfront fee, a $35.0 million milestone payment received in the second quarter of 2016 upon commencement of a Phase 1 study, and $2.1 million in reimbursement of research and development costs through June 30, 2020. The Company determined that the remaining potential milestone payments are probable of significant reversal of cumulative revenue as their achievement is highly dependent on the successful completion of Phase 1 studies. Therefore, these payments are not included in the transaction price. Any consideration related to sales-based royalties and profit-sharing payments will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Novartis and have been excluded from the transaction price. The transaction price of $237.1 million is allocated to one combined performance obligation. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company concluded that it will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Novartis. In applying the cost-based input method of revenue recognition, the Company uses actual clinical study enrollment figures as well as actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of internal full-time equivalent effort and third-party contract costs relative to the level of patient enrollment in the study. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligations and it is dependent on the clinical timelines and progress under the research and collaboration agreement. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

Cost-sharing payments from Novartis are included in the transaction price and subject to the cost-based input method to determine the amount to be recognized in license and collaboration revenue in the Company's consolidated statements of operations, while cost-sharing payments to Novartis are accounted for as research and development expenses in the Company's consolidated statements of operations.

If the Company recognizes revenue from the sale of any products commercialized pursuant to this collaboration in the United States, it will retain 50% of the gross profits from such sales and will pay the remaining 50% of the gross profits to Novartis. The Company will receive from Novartis 45% of gross profits for specified European countries and Japan from the sale of any products commercialized pursuant to this collaboration in such countries. Profit sharing payments made to or received from Novartis will be aggregated by product by territory and reported as expenses or revenues, as applicable.

In December 2019, the Company received notification that Novartis has removed ADU-S100 (MIW815), an intratumoral STING pathway activator product candidate, from Novartis' portfolio based on clinical data generated to date. This decision was not the result of any safety concern. The collaboration and license agreement between Novartis and Aduro remains in effect, and both parties continue to jointly pursue STING pathway activation through systemic delivery as a therapeutic strategy. The removal of ADU-S100 from Novartis' portfolio did not have an impact on the overall transaction price nor the revenue recognition methodology being utilized by the Company.

The Company is funding the squamous cell carcinoma of the head and neck and preparation of the IND application for any non-muscle invasive bladder cancer studies evaluating ADU-S100 itself because Novartis has opted out of these trials.

For the three months ended June 30, 2020 and 2019, the Company recognized $3.9 million and $1.9 million, respectively, and for the six months ended June 30, 2020 and 2019, the Company recognized $5.7 million and $4.4 million, respectively, in revenue from its collaboration with Novartis. The remaining balance of the upfront fee of $163.3 million is included in deferred revenue at June 30, 2020.

Lilly Agreement

On December 18, 2018, the Company entered into a research collaboration and exclusive license agreement, or the Lilly Agreement, with Lilly for its cGAS-STING Pathway Inhibitor program for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases. Pursuant to the Lilly Agreement, the Company granted an exclusive and worldwide license under certain intellectual property rights controlled by the Company to research, develop, manufacture and commercialize certain cGAS-STING products for the treatment of autoimmune and other inflammatory diseases. The license granted is sublicensable during a specified time period.

Under the terms of the Lilly Agreement, the Company received an upfront payment of $12.0 million in the first quarter of 2019. The Company will also be eligible for development and commercial milestones of up to approximately $620.0 million per product. Lilly is also obligated to pay the Company tiered royalty payments at percentages in the single to low-double digits based on annual net sales of the licensed products. Lilly must pay such royalties on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last-to-expire valid claim of certain patents, (ii) the expiration of the data exclusivity period in such country or (iii) a specified anniversary of the first commercial sale of such product in such country. The Company will be reimbursed for up to a certain amount of research funding spent during the research term. In addition, the Company has the option to co-fund the clinical development of each product in exchange for an increase in royalty payments and a reduction in certain milestone payments to the extent relevant to such co-funded product. Lilly will be responsible for all costs of global commercialization.

For revenue recognition purposes, the Company determined that the Company's performance period commenced in January 2019 and ends upon completion of the research term, estimated to occur in 2021. The transaction price consists of the $12.0 million upfront fee and variable consideration related to reimbursement of research and development costs. The Company determined that the remaining potential milestone payments are probable of significant reversal of cumulative revenue as their achievement is highly dependent on the successful completion of research activities and advancement through clinical studies. Therefore, these potential milestone payments are not included in the transaction price. Any consideration related to sales-based royalties and profit-sharing payments will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Lilly and have been excluded from the transaction price. The transaction price is allocated to one combined performance obligation. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company concluded that it will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Lilly. In applying the cost-based input method of revenue recognition, the Company uses actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of internal full-time equivalent effort and third-party contract costs. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligation. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

For the three months ended June 30, 2020 and 2019, the Company recognized $1.7 million and $3.0 million, respectively, in revenue. For the six months ended June 30, 2020 and 2019, the Company recognized $3.9 million and $4.4 million, respectively, in revenue from the Lilly Agreement. The Company recorded $2.9 million in deferred revenue at June 30, 2020.

Merck License Agreement

In connection with the acquisition of Aduro Biotech Europe in October 2015, the Company became party to an agreement with Merck Sharp & Dohme Corp., or Merck. The agreement sets forth the parties' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for antibody product candidates. The Company identified the following promises under the agreement: 1) the license, 2) the obligation to provide research activities and 3) the obligation to participate on a Joint Research Committee. The Company determined that the promises were not distinct which resulted in them being combined into one performance obligation. The Company completed its performance obligation under the agreement by the end of 2016.

The Company received a milestone payment of $2.0 million in 2017 for the initiation of a Good Laboratory Practice, or GLP, toxicology study and $3.0 million in the first quarter of 2018 for the initiation of a Phase 1 trial for the anti-CD27 antibody and $10.0 million in the first quarter of 2020 for the initiation of a Phase II trial for the anti-CD27 antibody. The payments were recognized in revenue when received as the Company had no remaining performance obligation. The Company is eligible to receive future contingent payments, including up to $297.0 million in potential development milestone payments, and up to $135.0 million in commercial and net sales milestones for a product candidate. In addition, the Company is eligible to receive royalties in the mid-single digits to low teens based on net sales of the product. Future milestone payments and royalties will be recognized when earned as the Company has no remaining performance obligations under this agreement.

For the three months ended June 30, 2020, the Company recognized no revenue from its collaboration with Merck while for the six months ended June 30, 2020, the Company recognized a $10.0 million milestone payment related to the initiation of a Phase II trial for the anti-CD27 antibody.

7. Commitments and Contingencies

Leases

The Company leases one facility in Berkeley, California under an operating lease that has a remaining lease term of approximately 10 years. The Company also leased one facility in Oss, the Netherlands, under an operating lease that was set to expire in December 2020. In June 2020, the Company terminated its lease agreement for its leased facility in connection with the closure of its European site in Oss, the Netherlands. The Company will continue to pay the lease obligation, which is reimbursable to the Company if the landlord enters into a new lease agreement with a new tenant, until the original expiration of the lease agreement in December 2020. Both leases contain an option to extend for an additional term, however, the Company is not reasonably certain to exercise the option for the Berkeley lease and the Company will not be exercising the option for the Oss lease due to the closure of the Oss facility in June 2020. Refer to Note 10 "Restructuring and Related Expense" for additional information.

The Company is subleasing approximately 26,552 square feet in its Berkeley facility under subleases that expire on or prior to February 28, 2021. Sublease income was $0.4 million for each of the three months ended June 30, 2020 and 2019, and $0.7 million and $0.8 million for the six months ended June 30, 2020 and 2019, respectively.

During 2016, the Company established a letter of credit with Bank of America Merrill Lynch as security for the Berkeley lease in the amount of $0.5 million. The letter of credit is collateralized by a certificate of deposit for $0.5 million which has been included in restricted cash in the consolidated balance sheet as of June 30, 2020.

The maturity of the Company's operating lease liabilities as of June 30, 2020 is as follows (in thousands):

Undiscounted Lease Payments	Amounts
2020 (remaining six months)	$ 2,862
2021	5,332
2022	5,460
2023	5,569
2024	5,681
Thereafter	30,155
Total undiscounted lease payments	55,059
Present value adjustment	22,463
Total net lease liability	$ 32,596
Net lease liability - current	$ 1,741
Net lease liability - non-current	30,855
Total net lease liability	$ 32,596

Straight-line rent expense recognized for operating leases was $1.4 million and $1.2 million for the three months ended June 30, 2020 and 2019, respectively, and $2.7 million and $2.5 million for the six months ended June 30, 2020 and 2019, respectively. Variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases was $0.3 million for each of the three months ended June 30, 2020 and 2019, and $0.7 million and $0.6 million for the six months ended June 30, 2020 and 2019, respectively. The Company does not have any finance leases.

The following information represents supplemental disclosure for the condensed consolidated statement of cash flows related to operating leases (in thousands):

	Six months ended June 30,	
	2020	2019
Cash flows from operating activities		
Cash paid for amounts included in the measurement of lease liabilities	$ 2,798	$ 2,727

The following summarizes additional information related to operating leases:

	June 30, 2020	June 30, 2019
Weighted-average remaining lease terms (in years)		
Operating leases	9.4	10.3
Weighted-average discount rate		
Operating leases	12%	12%

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

Legal

The Company is not party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business.

Other Commitments

The Company has various manufacturing, clinical, research and other contracts with vendors in the conduct of the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for the products or services that the Company had received at the time the termination became effective as well as non-cancelable and non-refundable obligations, including payment obligations for costs or expenses incurred by the vendor for products or services before the termination became effective. In the case of terminating a clinical trial agreement at a particular site, the Company would also be obligated to provide continued support for appropriate medical procedures at that site until completion or termination.

8. Common Stock

The Company had reserved shares of common stock for future issuance as follows:

	June 30, 2020
Options issued and outstanding	11,317,276
Shares available for future stock option grants	10,941,502
Restricted stock units	526,995
Common stock warrants	50,162
Total	22,835,935

At-the-Market Sales Agreement

In August 2017, the Company entered into an “at-the-market” sales agreement, as amended in February 2019, or the 2017 Sales Agreement, with Cowen, through which the Company may offer and sell shares of its common stock having an aggregate offering of up to $100.0 million through Cowen, as the Company’s sales agent. The Company will pay Cowen a commission of up to 3% of the gross proceeds of sales made through the arrangement. There were no sales of shares of common stock pursuant to the 2017 Sales Agreement during the year ended December 31, 2019 or the six months ended June 30, 2020. As of June 30, 2020, the Company had an aggregate of $81.5 million remaining for future sales under the 2017 Sales Agreement, subject to the continued effectiveness of its shelf registration statement on Form S-3 (Registration No. 333-219639), which expires on August 11, 2020, or an effective replacement shelf registration statement.

9. Equity Incentive Plans

2015 Plan

In March 2015, the Company’s board of directors adopted and in April 2015 the Company’s stockholders approved the 2015 Equity Incentive Plan, or the 2015 Plan, which became effective upon the initial public offering of the Company’s common stock, or IPO, and provides for the granting of incentive stock options, nonstatutory stock options and other forms of stock awards to its employees, directors and consultants. The Company’s 2009 Stock Incentive Plan, or the 2009 Plan, terminated on the date the 2015 Plan was adopted. Options granted or shares issued under the 2009 Plan that were outstanding on the date the 2015 Plan became effective will remain subject to the terms of the 2009 Plan.

The 2015 Plan is administered by the board of directors or a committee appointed by the board of directors, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. The exercise price of incentive stock options and nonqualified stock options will be no less than 100% of the fair value per share of the Company’s common stock on the date of grant. If an individual owns capital stock representing more than 10% of the voting shares, the price of each share will be at least 110% of the fair value on the date of grant. Options expire after 10 years (five years for stockholders owning greater than 10% of the voting stock). The number of shares of common stock initially reserved for issuance under the 2015 Plan was 6,134,292 shares with an automatic annual increase to the shares issuable under the 2015 Plan to the lower of (i) 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (ii) a lower number determined by the board of directors. On January 1, 2020, the shares issuable under the 2015 Plan increased by 3,229,427. The Company had 10,941,502 shares available for future grant under the 2015 Plan as of June 30, 2020.

2009 Plan

The Company's 2009 Stock Incentive Plan, or the 2009 Plan, terminated on the date the 2015 Plan was adopted. Options granted or shares issued under the 2009 Plan that were outstanding on the date the 2015 Plan became effective will remain subject to the terms of the 2009 Plan. Prior to the 2009 Plan termination, the number of options available for grant was increased by 360,000 shares. At June 30, 2020, 2,691,784 options under the 2009 Plan remained outstanding.

Stock Options

The following table summarizes stock option activity for the six months ended June 30, 2020:

		Options Outstanding		
	Shares Available for Grant	Number of Shares Underlying Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value
				(In thousands)
Balance—December 31, 2019	8,751,436	10,297,444	$ 5.49	$ 680
Authorized	3,229,427	—		
RSUs forfeited, net	83,007	—		
Granted	(3,136,000)	3,136,000	3.14	
Exercised	—	(91,460)	0.91	
Canceled	2,013,632 (1)	(2,024,708)	5.87	
Balance—June 30, 2020	10,941,502	11,317,276	$ 4.81	$ 3,671
Options exercisable—June 30, 2020		6,264,788	$ 5.82	$ 3,369
Options vested and expected to vest—June 30, 2020		10,204,429	$ 4.97	$ 3,608

(1) This excludes 11,076 shares subject to canceled options for the six months ended June 30, 2020 initially granted from the legacy stock option plans. As these plans have been terminated, any options canceled are not added back to the existing option plan pool.

The aggregate intrinsic value represents the difference between the exercise price of the options and the closing price of the Company's common stock. The aggregate intrinsic value of options exercised during the six months ended June 30, 2020 was $0.1 million.

As of June 30, 2020, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $9.0 million, which the Company expects to recognize over an estimated weighted-average period of 2.9 years.

Restricted Stock Units (RSUs)

In September 2016, the Company's board of directors authorized the issuance of restricted stock units, or RSUs, under the 2015 Plan and adopted a form of restricted stock unit grant notice and restricted stock unit award agreement, which is intended to serve as a standard form agreement for RSU grants issued to employees, executive officers, directors and consultants.

The following table summarizes RSU activity for the six months ended June 30, 2020:

	RSUs Outstanding	
	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value Per Share
Balance—December 31, 2019	798,943	$ 7.40
Granted	109,124	3.37
Vested	(188,941)	3.99
Forfeited	(192,131)	8.34
Balance—June 30, 2020	526,995	$ 7.45

The fair value of RSUs is determined on the date of grant based on the market price of the Company's common stock on that date. As of June 30, 2020, there was $1.8 million of unrecognized stock-based compensation expense, net of estimated forfeitures, related to RSUs which is expected to be recognized over a weighted-average period of 1.8 years.

2015 Employee Stock Purchase Plan

In March 2015, the Company's board of directors adopted and in April 2015 the Company's stockholders approved the 2015 Employee Stock Purchase Plan, or 2015 ESPP, which became effective upon the IPO. The 2015 ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Internal Revenue Code, or the Code, and is administered by the Company's board of directors and the compensation committee of the board of directors.

The number of shares of common stock initially reserved for issuance under the 2015 ESPP was 720,000 shares with an automatic annual increase to the shares issuable under the 2015 ESPP equal to the lower of (i) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (ii) a lower number determined by the board of directors. There was no annual increase of shares issuable under the 2015 ESPP on January 1, 2020. The Company had 1,527,421 shares available for future issuance under the 2015 ESPP as of June 30, 2020.

The following table summarizes the assumptions used in the Black-Scholes option-pricing model to determine fair value of the Company's common shares to be issued under the 2015 ESPP:

	Six Months Ended June 30,	
	2020	2019
Expected term (in years)	0.5	0.5
Volatility	127.5%	58.9%
Risk-free interest rate	0.15%	2.43%
Dividend yield	—%	—%

Stock-based Compensation Expense

Total stock-based compensation expense recognized for employees and non-employees was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 1,363	$ 1,713	$ 2,226	$ 3,746
General and administrative	1,665	1,623	2,837	3,293
Total stock-based compensation expense	$ 3,028	$ 3,336	$ 5,063	$ 7,039

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

Fair Value of Common Stock—Since the Company's IPO, the Company has used the market closing price of its common stock as reported on the Nasdaq Global Select Market.

Expected Term—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term for employee options). The Company uses the contractual term to determine the non-employee award fair value at the grant date.

Expected Volatility—The Company's expected volatility is based on the historical volatility of the Company's common stock price since its IPO in 2015.

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

Expected Dividend—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of stock option awards granted was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2020	2019
Expected term (in years)	6.2	5.3 - 9.7
Volatility	75.0 - 79.7%	67.2 - 70.8%
Risk-free interest rate	0.45 - 1.34%	1.96 - 3.19%
Dividend yield	—%	—%

10. Restructuring and Related Expense

In January 2020, the Company's Board of Directors approved a restructuring to further extend the Company's operating capital and align personnel towards executing the clinical development strategy. As of June 30, 2020, the Company reduced its workforce by 27 employees (approximately 28% of total employees) and intends to reduce its workforce by an additional 11 employees in the remainder of the year under the restructuring plan. Additionally, in June 2020, the Company closed its European site in Oss, the Netherlands. As of June 30, 2020, the Company estimates that it will incur aggregate charges of approximately $6.8 million, including $2.4 million in one-time severance and employee termination related costs, approximately $4.1 million in one-time retention costs and relocation costs of approximately $0.3 million. During the three and six months ended June 30, 2020, the Company accrued approximately $2.0 million and $5.2 million, respectively, of restructuring compensation and paid approximately $1.5 million and $2.5 million, respectively, of restructuring compensation. As of June 30, 2020, the Company has a remaining restructuring compensation reserve balance of approximately $2.7 million. The restructuring is expected to be substantially complete by the end of the third quarter of 2020.

The restructuring plan includes the closure of the European site leased facility as of June 30, 2020. As a result, the Company fully impaired the European site's property and equipment, consisting of lab equipment, computer and office equipment, furniture, and leasehold improvements, during the six months ended June 30, 2020. Additionally, the Company accelerated the amortization of the ROU asset associated with the leased facility so that the ROU asset will be fully amortized by June 30, 2020 rather than by December 31, 2020, the expiration of the Oss lease. For the three and six months ended June 30, 2020, the Company recorded an additional ROU asset amortization expense of $0.1 million and $0.2 million, respectively. On June 10, 2020, the Company terminated its lease agreement for the European site's facility and will continue to pay the lease payments until December 31, 2020. The Company will be reimbursed for rent and fees paid from the termination date until December 31, 2020, if the landlord enters into a new lease agreement with a new tenant.

Restructuring and related expense consist of the following (in thousands):

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Restructuring compensation	$ 2,046	$ 5,152
Impairment of property and equipment	—	1,202
Total restructuring and related expense	$ 2,046	$ 6,354

For the three and six months ended June 30, 2019 in the consolidated statement of operations, the Company reclassified $0.4 million and $3.4 million, respectively, of restructuring and related expense associated with the January 2019 strategic reset from research and development and general and administrative to restructuring and related expense to be consistent with the presentation of the June 30, 2020 condensed consolidated financial statements.

11. Income Taxes

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted in response to the COVID-19 global pandemic. The CARES Act, among other things, permits certain net operating losses, or NOLs, to be carried back for the preceding five taxable years to offset 100% of taxable income.

Income tax benefit for the six months ended June 30, 2020 and 2019 was approximately $5.7 million and $0.1 million, respectively. The income tax benefit recorded for the six months ended June 30, 2020 was primarily related to the tax refund due to the carryback of NOLs and AMT credit refund. The income tax benefit for the six months ended on June 30, 2019 was primarily related to the foreign deferred tax benefit from the amortization of intangibles. The Company's policy is to recognize interest and penalties related to unrecognized tax benefits in income tax expense.

The Company files income tax returns in the United States and Netherlands. The federal and state income tax returns are open under the statute of limitations subject to tax examinations for the tax years ended December 31, 2016 through December 31, 2018. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period. For the Netherlands, the tax administration can impose an additional assessment within five years from the year in which the tax debt originated.

12. Net Loss per Common Share

Since the Company was in a loss position for all periods presented, diluted net loss per common share is the same as basic net loss per common share for all periods presented as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per common share calculations because they would be anti-dilutive were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Options to purchase common stock	11,317,276	10,797,308	11,317,276	10,797,308
Restricted stock units	526,995	1,290,260	526,995	1,290,260
Common stock committed under ESPP	65,921	180,471	65,921	180,471
Common stock warrants	50,162	61,717	50,162	61,717
Total	11,960,354	12,329,756	11,960,354	12,329,756

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2019, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Forward-Looking Statements

This discussion and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, strategies, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors" and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are an immunotherapy company focused on the discovery, development and commercialization of therapies that are designed to harness the body's natural immune system for the treatment of patients with challenging diseases. Our primary technologies related to the A Proliferation Inducing Ligand (APRIL) and cyclic GMP-AMP Synthase–Stimulator of Interferon Genes (cGAS-STING) pathways have led to what we believe is a strong pipeline of clinical candidates that are being investigated in cancer, autoimmune and inflammatory diseases. We are collaborating with leading global pharmaceutical companies to help expand and drive our product pipeline. Our strategy is to rapidly advance therapeutic candidates from our STING and APRIL technologies through clinical development and regulatory approval. Our anti-APRIL antibody product candidate, BION-1301, is designed to suppress the autoimmune response in patients with IgA nephropathy (IgAN). Our lead STING pathway activator product candidate, ADU-S100 (MIW815), is designed to selectively modulate innate and adaptive immune responses to enhance immune control in oncology.

APRIL is a soluble factor that binds to B-cell maturation antigen, or BCMA, and transmembrane activator and CAML interactor, or TACI, receptors thereby inducing signaling, and is believed to be implicated in IgA nephropathy and other indications. We are developing BION-1301, an investigational monoclonal antibody that blocks APRIL binding to both of its natural ligands, the BCMA and TACI receptors. BION-1301 is being evaluated in a Phase 1 clinical trial for the treatment of IgA nephropathy, a chronic autoimmune kidney disease with unclear causality. Because there currently are no approved therapies for IgA nephropathy with curative intent, we believe there is opportunity for BION-1301 to address a significant unmet patient need. We have completed dosing healthy volunteers in the first-in-human study of BION-1301 in IgA nephropathy and announced the dosing of the first patient with IgA nephropathy on June 24, 2020. We currently anticipate presenting interim results from this trial in the first half of 2021.

Our STING pathway activator technology is designed to activate the intracellular STING receptor, which we believe may result in a potent tumor-specific immune response. We are developing STING pathway activator product candidates in oncology under our worldwide collaboration with Novartis. ADU-S100 (MIW815), the first STING pathway activator to enter the clinic that we are aware of, is being investigated in a Phase 2 clinical trial of ADU-S100 in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 monoclonal antibody, as a potential first-line treatment for patients with recurrent or metastatic squamous cell carcinoma of the head and neck. We currently anticipate presenting interim results from this trial in the first half of 2021. We are also preparing the submission of an Investigational New Drug application (IND) for ADU-S100 as a single agent administered intravesically in patients with non-muscle invasive bladder cancer who are unresponsive to Bacillus Calmette-Guerin (BCG), an approved intravesical immunotherapy, in the second half of 2020, subject to any delays resulting from the COVID-19 pandemic. ADU-S100 has also been evaluated in a Phase 1 clinical trial as a single agent and in a Phase 1b combination trial with spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody, in patients with cutaneously accessible metastatic solid tumors or lymphomas.

In addition to our current STING pathway product candidates that activate the STING receptor, we are developing product candidates that are designed to prevent or control immune responses through the STING pathway as part of our cGAS-STING pathway inhibitor program under a research collaboration and exclusive license agreement with Eli Lilly and Company, or Lilly. Our cGAS-STING pathway inhibitor program involves the research and development of novel inhibitor product candidates for autoimmune and other inflammatory diseases.

Since commencing our operations, our efforts have been focused on research, development and the advancement of our product candidates into clinical trials. As a result, we have incurred significant losses. We have funded our operations primarily through the sale of common stock and licensing agreements with pharmaceutical partners. We incurred a net loss of $16.6 million and $18.6 million for the three months ended June 30, 2020 and 2019, respectively, and $24.2 million and $42.0 million for the six months ended June 30, 2020 and 2019, respectively. At June 30, 2020, our cash, cash equivalents and marketable securities totaled $186.1 million and our accumulated deficit was $511.1 million. We have intellectual property protection on our STING and APRIL programs and each of our product candidates, some of which we believe can be maintained into 2040.

In January 2020, our Board of Directors approved a restructuring to further extend our operating capital and align personnel towards executing our clinical development strategy. As of June 30, 2020, we reduced our workforce by 27 employees (approximately 28% of total employees) and intend to reduce our workforce by an additional 11 employees in the remainder of the year under the restructuring plan. As of June 30, 2020, we estimate that we will incur aggregate charges of approximately $6.8 million, including $2.4 million in one-time severance and employee termination related costs, approximately $4.1 million in one-time retention costs and relocation costs of approximately $0.3 million. The restructuring is expected to be substantially complete by the end of the third quarter 2020. At this time, we are actively focused on identifying and evaluating strategic options for our non-renal programs.

Potential Business Combination with Chinook

On June 1, 2020, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Aspire Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Aduro, and Chinook Therapeutics U.S., Inc., a Delaware corporation, or Chinook, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Chinook, with Chinook continuing as a wholly owned subsidiary of Aduro and the surviving corporation of the merger, or the Merger. The surviving corporation following the Merger is referred to herein as the combined company.

Merger Consideration

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, (a) each outstanding share of Chinook common stock and Chinook preferred stock, collectively, the Chinook Capital Stock, will be converted into the right to receive a number of shares of Aduro common stock equal to the exchange ratio described below, and (b) each outstanding unexercised option to purchase shares of Chinook common stock that, following assumption by Aduro at the effective time of the Merger, will be eligible to be registered on Form S-8, will be assumed by Aduro and will be converted into an option to purchase shares of Aduro common stock, with necessary adjustments to reflect the exchange ratio described below.

Under the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, the former Chinook securityholders, other than holders of Chinook convertible promissory notes, are expected to own approximately 50% of the outstanding shares of Aduro common stock on a fully-diluted basis and Aduro securityholders as of immediately prior to the Merger are expected to own approximately 50% of the outstanding shares of Aduro common stock on a fully-diluted basis, subject to certain assumptions, including, but not limited to, (a) our net cash (as defined in the merger agreement) as of closing being equal to $145.0 million and (b) Chinook’s cash and cash equivalents as of closing being equal to $10.0 million.

Note Purchase Agreement

On June 1, 2020, Chinook and certain investors named therein entered into a Note Purchase Agreement pursuant to which, immediately prior to the closing of the Merger, the investors will purchase convertible promissory notes in an aggregate amount of $25.0 million, or the Notes, which Notes are convertible into securities issued in an equity financing transaction that closes concurrently with or within 30 days following the Merger in which the aggregate gross purchase price paid to the combined company is no less than $15.0 million, or alternatively into shares of common stock of the combined company after closing of the Merger based on the volume weighted average closing trading price of a share of Aduro common stock on Nasdaq for the five trading days ending the trading day immediately prior to the date such Notes are converted, which must occur within 30 days following the Merger.

The conversion of the Notes into Aduro securities as well as any Merger Financing will result in material dilution to the percentage ownership of Aduro stockholders in the combined company. There can be no assurance that any Merger Financing will occur.

Support Agreements

Concurrently with the execution and delivery of the Merger Agreement, we entered into support agreements with certain executive officers, directors and stockholders of Chinook, who, as of July 1, 2020, owned an aggregate of approximately 98.0% of the outstanding Chinook Capital Stock on an as converted to common stock basis, pursuant to which, among other things, each of these stockholders agreed, solely in his, her or its capacity as a Chinook stockholder, to vote all of his, her or its shares of Chinook Capital Stock in favor of (i) the adoption of the Merger Agreement and approval of the Merger, (ii) the approval of the related transactions contemplated by the Merger Agreement, (iii) the conversion of Chinook preferred stock into shares of Chinook common stock and (iv) the approval of certain additional proposals in connection with the Merger that the Chinook board of directors may recommend. These Chinook stockholders also agreed to vote against (i) any competing acquisition proposal (as defined in the support agreement) and (ii) any action, proposal, agreement, transaction or proposed transaction that would reasonably be expected to materially impede, interfere with, delay, postpone, discourage or adversely affect the Merger or any of the other transactions contemplated by the Merger Agreement, subject to certain specified exceptions..

In addition, concurrently with the execution and delivery of the Merger Agreement, certain of our executive officers, directors and stockholders, who, as of July 1, 2020, owned an aggregate of approximately 22.9% of our outstanding common stock, entered into support agreements with Chinook, pursuant to which, among other things, each such stockholder has agreed, solely in his, her or its capacity as an Aduro stockholder, to vote all of his, her or its shares of Aduro common stock in favor of (i) the approval of the Merger Agreement, (ii) the transactions contemplated thereby, including the issuance of Aduro common stock to Chinook stockholders, (iii) if deemed necessary, an amendment to the amended and restated certificate of incorporation of Aduro to effect a reverse stock split, (iv) any proposal to adjourn or postpone the special meeting of Aduro stockholders to a later date, if there are not sufficient votes for the approval of the Merger Agreement and the transactions contemplated therein and (v) the approval of certain additional proposals in connection with the Merger that the Aduro board of directors may recommend. These Aduro stockholders also agreed to vote against (i) any competing acquisition proposal (as defined in the support agreement) with respect to Aduro and (ii) any action, proposal, agreement, transaction or proposed transaction that would reasonably be expected to materially impede, interfere with, delay, postpone, discourage or adversely affect the Merger or any of the other transactions contemplated by the Merger Agreement, subject to certain specified exceptions.

Lock-Up Agreements

Concurrently with the execution and delivery of the Merger Agreement, certain of our officers, directors and stockholders who, as of July 1, 2020, owned approximately 22.9% of the outstanding Aduro common stock and certain officers, directors and stockholders of Chinook who, as of July 1, 2020, owned approximately 98.0% of the Chinook Capital Stock on an as converted to common stock basis entered into lock-up agreements pursuant to which they accepted certain restrictions on transfers of Aduro securities for the 180-day period following the closing of the Merger.

Contingent Value Rights Agreement

At the effective time of the Merger, we will enter into a Contingent Value Rights Agreement, or a CVR Agreement, with Computershare Trust Company, N.A., as Rights Agent, pursuant to which our common stockholders of record as of the close of business on the last business day prior to the day on which the effective time of the Merger occurs will receive one contingent value right, or a CVR, for each outstanding share of Aduro common stock held by such stockholder on such date.

Each CVR will represent the contractual right to receive payments from us upon the actual receipt by us or certain of our affiliates of certain contingent proceeds derived from any consideration that is paid to us as a result of the disposition of any of our non-renal assets or revenue received from the license of certain non-renal assets, or as a result of our equity ownership in any subsidiary that is established to hold such non-renal assets or the subsequent disposition of any such equity securities, collectively, the CVR Milestones, net of any tax, transaction costs and certain other expenses.

The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no CVR Milestones occur, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any CVR Milestones will be achieved or that any holders of CVRs will receive payments with respect thereto.

The right to the contingent payments contemplated by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or any other instrument and will not be registered with the SEC. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in Aduro or the combined company or any of its affiliates. No interest will accrue on any amounts payable in respect of the CVRs.

Consideration of COVID-19

In response to the COVID-19 global pandemic, “shelter in place” orders and other public health guidance measures have been implemented across much of the United States and Europe, including in the locations of our offices, clinical trial sites, key vendors and partners. The COVID-19 global pandemic is rapidly evolving, and the timing of delays and overall impact to our clinical trials and business are currently unknown. In our Current Report on Form 8-K filed with the SEC on April 9, 2020, we provided an update on the current status of our clinical programs and business operations.

As previously disclosed, though we have dosed the first patient in Part 3 of the of the BION-1301 clinical trial for the treatment of IgA nephropathy and are continuing to activate sites and enroll patients, we have experienced, and expect that we will continue to experience delays, in our ability to activate additional sites and enroll patients at existing and any additional sites depending upon the duration and nature of COVID-19 public health guidance measures in much of the United States and Europe. These measures are also likely to impact our ability to conduct patient follow-up. As a result, our ability to report interim data in IgA nephropathy patients will likely be delayed until the first half of 2021.

As previously disclosed, though we are continuing to enroll patients in our Phase 2 clinical trial of ADU-S100 in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 monoclonal antibody, as a potential first-line treatment for patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN), we have experienced delays, and expect that we will continue to experience delays, in site activation, patient enrollment, our ability to conduct patient follow-up and our ability to complete analyses of data. As a result, our ability to report interim data in the SCCHN trial will likely be delayed until the first half of 2021.

In addition, we expect the evolving situation surrounding COVID-19 may delay our ability to conduct patient follow-up and our ability to complete analyses of data from our study with Novartis in ADU-S100 + Spartalizumab (PDR001) for the treatment of advanced/metastatic solid tumors or lymphomas, and, as a result, our ability to report complete dose escalation and enrichment results will likely be delayed.

Please also see the risk factor below titled “Public health crises such as pandemics or similar outbreaks could materially and adversely affect our clinical trials, business, financial condition and results of operations.”

Components of Operating Results

Revenue

We have not generated any revenue from product sales. Our revenue to date has been primarily derived from our collaboration and license agreements. Our collaboration agreements may include the transfer of intellectual property rights in the form of licenses, promises to provide research and development services and promises to participate on certain development committees with the collaboration party. The terms of such agreements include payment to us of one or more of the following: nonrefundable upfront fees, payment for research and development services, development, regulatory and commercial milestone payments, and royalties on net sales of licensed products.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development activities cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance based on a cost-based input method. Revenue from contingent development, regulatory and commercial milestones, when not deemed probable of significant reversal of cumulative revenue, is also recognized over the performance period based on a similar method. Where we have no remaining performance obligations, revenue from such milestones is recognized when the accomplishment of the milestones is deemed probable.

We expect that any revenue we generate from our current collaboration, research and license agreements and any future collaboration partners will fluctuate from year to year as a result of the timing and number of milestones and other payments.

Research and Development Expenses

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates, as well as the development of product candidates pursuant to our research and license agreements with Novartis, Lilly and Merck. We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates and technologies may be affected by a variety of factors including: the quality of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in obtaining regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative Expenses

General and administrative expenses include personnel costs, expenses for outside professional services, and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation. Outside professional services consist of legal, accounting and audit services, insurance expenses, investor relations activities, administrative services and other consulting fees. Allocated expenses consist of rent expense related to our offices and research and development facility.

Restructuring and Related Expense

Restructuring and related expense includes restructuring compensation charges and the impairment of property and equipment. Restructuring compensation charges consist of one-time severance, employee termination related costs, and retention costs. Specifically, as part of the closure of our European site in the second quarter of 2020, we impaired our property and equipment balance for certain property and equipment located at that site in the first quarter of 2020.

Interest Income

Interest income primarily consists of interest income from our cash equivalents and marketable securities.

Other Expense, Net

Other expense, net primarily consists of foreign currency transaction gains and losses.

Income Tax Benefit

We are subject to income taxes in the United States and foreign jurisdictions in which we do business. These foreign jurisdictions have statutory tax rates different from those in the United States. Accordingly, our effective tax rates will vary depending on the relative proportion of foreign to U.S. income, the availability of research and development tax credits, changes in the valuation of our deferred tax assets and liabilities and changes in tax laws. We regularly assess the likelihood of adverse outcomes resulting from the examination of our tax returns by the Internal Revenue Service, or IRS, and other tax authorities to determine the adequacy of our income tax reserves and expense. Should actual events or results differ from our current expectations, charges or credits to our income tax expense may become necessary.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Revenue:			
Collaboration and license revenue	$ 5,574	$ 4,888	$ 686
Total revenue	5,574	4,888	686
Operating expenses:			
Research and development	11,108	16,657	(5,549)
General and administrative	9,284	7,832	1,452
Restructuring and related expense	2,046	367	1,679
Amortization of intangible assets	136	139	(3)
Total operating expenses	22,574	24,995	(2,421)
Loss from operations	(17,000)	(20,107)	3,107
Interest income	413	1,497	(1,084)
Other expense, net	(28)	(3)	(25)
Loss before income tax	(16,615)	(18,613)	1,998
Income tax benefit	—	35	(35)
Net loss	$ (16,615)	$ (18,578)	$ 1,963

Revenue

Total revenue was $5.6 million for the three months ended June 30, 2020, an increase of $0.7 million compared to the three months ended June 30, 2019. The increase for the quarter was primarily due to fluctuation in revenue recognized under our Novartis collaboration which is dependent on clinical timelines and progress under the research and collaboration agreement.

Research and Development Expenses

The following table summarizes our research and development costs by program incurred during the three months ended June 30, 2020 and 2019. Each year, we present and describe our research and development expenses based on programs and categories that are considered critical to us at that time and all other non-critical programs and categories are reported in Other R&D and Other, respectively. Therefore, the presentation in the Research and Development Expense tables may change from year to year.

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
APRIL	$ 4,512	$ 5,013	$ (501)
STING	3,291	3,271	20
cGAS-STING	841	1,214	(373)
Other R&D	61	3,529	(3,468)
Subtotal	8,705	13,027	(4,322)
Stock-based compensation	1,363	1,713	(350)
Facility costs	1,040	1,917	(877)
Total research and development	$ 11,108	$ 16,657	$ (5,549)

The following table summarizes our research and development expenses incurred during the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Clinical trial and research expenses	$ 4,643	$ 7,791	$ (3,148)
Compensation and related personnel costs	2,361	3,862	(1,501)
Facility costs	1,040	1,917	(877)
Professional services	1,500	1,317	183
Stock-based compensation expense	1,363	1,713	(350)
Other	201	57	144
Total research and development	$ 11,108	$ 16,657	$ (5,549)

Research and development expenses allocated to our programs were $11.1 million for the three months ended June 30, 2020, a decrease of $5.5 million compared to the three months ended June 30, 2019. The decrease in expenses from 2019 to 2020 was primarily due to 2019 costs related to the deprioritized programs that substantially wound down in 2019 offset by higher costs as a result of focused spending towards our STING and APRIL programs. The decrease was further attributable to lower compensation and related personnel costs as well as stock-based compensation in 2020 due to reduced headcount as a result of the January 2020 restructuring. In June 2020, the Company sold a portion of its impaired assets resulting in a gain on disposal of approximately $0.5 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Professional services	$ 4,659	$ 2,470	$ 2,189
Stock-based compensation expense	1,665	1,623	42
Compensation and related personnel costs	1,482	1,902	(420)
Facility costs	998	974	24
Other	480	863	(383)
Total general and administrative	$ 9,284	$ 7,832	$ 1,452

General and administrative expenses were $9.3 million for the three months ended June 30, 2020, an increase of $1.5 million compared to the three months ended June 30, 2019. The increase was mainly due to professional service fees related to the Merger transaction, offset by lower personnel and stock-based compensation expense as a result of the January 2020 restructuring.

Restructuring and Related Expense

Restructuring and related expense was $2.0 million for the three months ended June 30, 2020, an increase of $1.7 million compared to the three months ended June 30, 2019. The increase was primarily due to severance and retention expenses recognized in the second quarter of 2020.

Interest Income

Interest income was $0.4 million for the three months ended June 30, 2020, a decrease of $1.1 million compared to the three months ended June 30, 2019. The decrease was primarily due to the lower cash balance and lower interest rates.

Income Tax Benefit

There was no income tax benefit for the three months ended June 30, 2020 compared to $35,000 for the three months ended June 30, 2019.

Comparison of the Six Months Ended June 30, 2020 and 2019

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Revenue:			
Collaboration and license revenue	$ 19,524	$ 8,826	$ 10,698
Total revenue	19,524	8,826	10,698
Operating expenses:			
Research and development	26,936	34,151	(7,215)
General and administrative	17,103	16,056	1,047
Restructuring and related expense	6,354	3,361	2,993
Amortization of intangible assets	272	279	(7)
Total operating expenses	50,665	53,847	(3,182)
Loss from operations	(31,141)	(45,021)	13,880
Interest income	1,333	2,968	(1,635)
Other expense, net	(47)	(22)	(25)
Loss before income tax	(29,855)	(42,075)	12,220
Income tax benefit	5,665	70	5,595
Net loss	$ (24,190)	$ (42,005)	$ 17,815

Revenue

Total revenue was $19.5 million for the six months ended June 30, 2020, an increase of $10.7 million compared to the six months ended June 30, 2019. $10.0 million of the increase was due to recognition of a development milestone payment received under our exclusive license and research agreement with Merck (known as MSD outside the United States and Canada) for Merck's initiation of a Phase 2 clinical trial of MK-5890, an anti-CD27 agonist, in non-small cell lung cancer (NSCLC). The remaining increase of $0.7 million was primarily due to the fluctuation in revenue recognized under our Novartis collaboration which is dependent on the clinical timelines and progress under the research and collaboration agreement.

Research and Development Expenses

The following table summarizes our research and development costs by program incurred during the six months ended June 30, 2020 and 2019. Each year, we present and describe our research and development expenses based on programs and categories that are considered critical to us at that time and all other non-critical programs and categories are reported in Other R&D and Other, respectively. Therefore, the presentation in the Research and Development Expense tables may change from year to year.

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
APRIL	$ 10,557	$ 10,505	$ 52
STING	6,833	6,124	709
cGAS-STING	1,968	2,270	(302)
Other R&D	2,609	7,989	(5,380)
Subtotal	21,967	26,888	(4,921)
Stock-based compensation	2,226	3,746	(1,520)
Facility costs	2,743	3,517	(774)
Total research and development	$ 26,936	$ 34,151	$ (7,215)

The following table summarizes our research and development expenses incurred during the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Clinical trial and research expenses	$ 13,147	$ 16,000	$ (2,853)
Compensation and related personnel costs	5,650	7,957	(2,307)
Facility costs	2,743	3,517	(774)
Stock-based compensation expense	2,226	3,746	(1,520)
Professional services	2,764	2,576	188
Other	406	355	51
Total research and development	$ 26,936	$ 34,151	$ (7,215)

Research and development expenses allocated to our programs were $26.9 million for the six months ended June 30, 2020, a decrease of $7.2 million compared to the six months ended June 30, 2019. The decrease in expenses from 2019 to 2020 was primarily due to 2019 costs related to the deprioritized programs that substantially wound down in 2019 offset by higher spending towards our STING and APRIL programs. The decrease was further attributable to lower compensation and related personnel costs as well as stock-based compensation in 2020 due to reduced headcount as a result of our strategic reset of January 2019 and the restructuring of January 2020.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Professional services	$ 7,805	$ 5,408	$ 2,397
Compensation and related personnel costs	3,562	4,063	(501)
Stock-based compensation expense	2,837	3,293	(456)
Facility costs	2,004	1,870	134
Other	895	1,422	(527)
Total general and administrative	$ 17,103	$ 16,056	$ 1,047

General and administrative expenses were $17.1 million for the six months ended June 30, 2020, an increase of $1.0 million compared to the six months ended June 30, 2019. The increase was mainly due to professional service fees related to the Merger transaction, the increase was partially offset by lower personnel and stock-based compensation expense as a result of both our strategic reset in January 2019 and the restructuring of January 2020.

Restructuring and Related Expense

Restructuring and related expense was $6.4 million for the six months ended June 30, 2020, an increase of $3.0 million compared to the six months ended June 30, 2019. The increase for the six-month period was primarily due to severance and retention expenses recognized as well as the impairment of property and equipment associated with the closure of our European site in Oss, the Netherlands as part of the January 2020 restructuring plan.

Interest Income

Interest income was $1.3 million for the six months ended June 30, 2020, a decrease of $1.6 million compared to the six months ended June 30, 2019. The decrease for the six months ended June 30, 2020 is primarily due to a lower cash balance and lower interest rates.

Income Tax Benefit

Income tax benefit was $5.7 million for the six months ended June 30, 2020 compared to $0.1 million for the six months ended June 30, 2019. The change was primarily related to the tax refund due to the carryback of Net Operating Loss and Alternative Minimum Tax credit refund under the CARES Act, that was enacted in response to the COVID-19 global pandemic.

Liquidity and Capital Resources

To date, our operations have been financed primarily through the public issuance of common stock, sale of convertible preferred stock and proceeds from our collaboration and license agreements. At June 30, 2020, we had cash, cash equivalents and marketable securities of $186.1 million.

In August 2017, we entered into an "at-the-market" sales agreement, as amended in February 2019, or the 2017 Sales Agreement, with Cowen and Company, LLC, or Cowen, through which we may offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, acting as sales agent. We agreed to pay Cowen a commission of up to 3% of the gross proceeds of sales made through the arrangement. There were no sales of shares of common stock pursuant to the 2017 Sales Agreement during the six months ended June 30, 2020. As of June 30, 2020, we had an aggregate of $81.5 million remaining for future sales under the 2017 Sales Agreement, subject to the continued effectiveness of our shelf registration statement on Form S-3 (Registration No. 333-219639), which expires on August 11, 2020, or an effective replacement shelf registration statement.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical, development costs including manufacturing, and other research and development services, laboratory and related supplies and legal and other professional services. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We expect to incur substantial expenditures in the foreseeable future for the development, manufacturing and potential commercialization of our product candidates.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing and potential milestones from existing collaboration agreements. We may also consider entering into additional collaboration arrangements or selectively partnering for clinical development and commercialization or outlicensing non-core assets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs. Any of these actions could harm our business, financial condition and results of operations. Please also see the discussion of the Merger under the section titled "Potential Business Combination with Chinook" above.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (28,824)	$ (27,586)
Investing activities	39,934	(19,701)
Financing activities	123	603
Effect of exchange rate changes	246	(65)
Net change in cash, cash equivalents, and restricted cash	$ 11,479	$ (46,749)

Operating Activities

Net cash used in operating activities was $28.8 million for the six months ended June 30, 2020, compared to $27.6 million for the six months ended June 30, 2019. Net cash used in operating activities was higher primarily due to the increase in operating expenses.

Investing Activities

Net cash provided by investing activities was $39.9 million for the six months ended June 30, 2020, compared to $19.7 million of net cash used for the six months ended June 30, 2019. The change was primarily due to greater maturities of marketable securities in 2020 as compared to 2019.

Financing Activities

Net cash provided by financing activities was $0.1 million for the six months ended June 30, 2020, compared to $0.6 million for the six months ended June 30, 2019. The change is primarily due to a lower amount of proceeds from the issuance of common stock under our stock incentive plans in 2020 as compared to 2019.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes in our critical accounting policies during the six months ended June 30, 2020, as compared to those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 9, 2020.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of June 30, 2020:

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
	(in thousands)				
Operating leases	$ 2,862	$ 10,792	$ 11,250	$ 30,155	$ 55,059
Total contractual obligations	$ 2,862	$ 10,792	$ 11,250	$ 30,155	$ 55,059

Recently Adopted Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our consolidated financial statements, refer to Note 2 “Basis of Presentation, Use of Estimates and Recent Accounting Pronouncements” in our condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The primary financial risk we are exposed to is foreign currency exchange, as certain operations, assets and liabilities are denominated in foreign currency. Foreign currency exposures arise from transactions denominated in a currency other than the functional currency and from foreign denominated revenue and profit translated into U.S. dollars. The primary foreign currency to which we are exposed is the Euro. We manage these risks through normal operating and financing activities and do not currently hedge our exposure to foreign currency exchange rate fluctuations.

Furthermore, we have positions in financial instruments including corporate debt securities and similar financial instruments. Financial markets are volatile and the markets for asset backed or similar securities could be illiquid. The value of these securities will continue to be impacted by external market factors. Should we need to convert these positions to cash, we may not be able to sell these instruments without significant losses or other market considerations.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

Our management, with the participation of our President and Chief Executive Officer and our Interim Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this Quarterly Report on Form 10-Q. Based on that evaluation, our President and Chief Executive Officer and our Interim Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were, in design and operation, effective.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure you that such actions will be sufficient to provide us with effective internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

We are not party to any material legal proceedings at this time. From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all of the other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes and the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to the Merger

The exchange ratio will not be adjusted based on the market price of Aduro common stock so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

At the effective time of the Merger, outstanding shares of Chinook capital stock will be converted into shares of Aduro common stock. Applying the exchange ratio, and without giving effect to the Chinook note financing, as further described below, the former Chinook securityholders immediately before the Merger, without giving effect to the Chinook convertible promissory notes, are expected to own approximately 50% of the aggregate number of shares of Aduro common stock following the Merger on a fully-diluted basis, and Aduro securityholders immediately before the Merger are expected to own approximately 50% of the aggregate number of shares of Aduro common stock following the Merger on a fully-diluted basis, subject to certain assumptions, including, but not limited to, (a) Aduro's net cash (as defined in the merger agreement) as of closing being equal to $145.0 million and (b) Chinook's cash and cash equivalents as of closing being equal to $10.0 million.

Any changes in the market price of Aduro stock before the completion of the Merger will not affect the number of shares Chinook stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger, the market price of Aduro common stock increases from the market price on the date of the Merger Agreement, then Chinook stockholders could receive merger consideration with substantially more value for their shares of Chinook capital stock than the parties had negotiated when they established the exchange ratio. Similarly, if before the completion of the Merger the market price of Aduro common stock declines from the market price on the date of the Merger Agreement, then Chinook stockholders could receive merger consideration with substantially lower value. The Merger Agreement does not include a price-based termination right.

Failure to complete the Merger may result in either us or Chinook paying a termination fee to the other party, which could harm our common stock price and future business and operations of each company.

If the Merger is not completed, we and Chinook are subject to the following risks:

- if the Merger Agreement is terminated under specified circumstances, Aduro or Chinook will be required to pay the other party a termination fee of $6.4 million and up to $2.0 million in expense reimbursements;
- the price of Aduro common stock may decline and could fluctuate significantly; and
- costs related to the Merger, such as financial advisor, legal and accounting fees, which Aduro estimates will total approximately $2.0 million, $3.0 million, and $0.3 million, respectively, a majority of which must be paid even if the Merger is not completed.

If the Merger Agreement is terminated and the board of directors of Aduro or Chinook determines to seek another business combination, there can be no assurance that either Aduro or Chinook will be able to find a partner with whom a business combination would yield greater benefits than the benefits to be provided under the Merger Agreement.

If the conditions to the Merger are not satisfied or waived, the Merger may not occur.

Even if the Merger is approved by the stockholders of Chinook and the merger proposal is approved by our stockholders, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in the section titled "The Merger Agreement—Conditions to the Completion of the Merger" of our Form S-4 Registration Statement, as filed with the SEC on July 22, 2020 (as amended, the Form S-4 Registration Statement). We and Chinook cannot assure you that all of the conditions to the consummation of the Merger will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or the closing may be delayed, and we and Chinook each may lose some or all of the intended benefits of the Merger.

The merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry-wide changes or other causes.

In general, neither we nor Chinook is obligated to complete the Merger if there is a material adverse effect impacting the other party between June 1, 2020, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes are excluded from the concept of a "material adverse effect." Such exclusions include but are not limited to changes in general economic or political conditions, industry wide changes, changes resulting from the announcement of the Merger, natural disasters, pandemics (including the COVID-19 pandemic), other public health events and changes in GAAP. Therefore, if any of these events were to occur affecting us or Chinook, the other party would still be obliged to consummate the closing of the Merger. If any such adverse changes occur and we and Chinook consummate the closing of the Merger, the stock price of the combined company may suffer. This in turn may reduce the value of the Merger to the stockholders of Aduro, Chinook or both. For a more complete discussion of what constitutes a material adverse effect on us or Chinook, see the section titled "The Merger Agreement—Representations and Warranties" of our Form S-4 Registration Statement.

If we and Chinook complete the Merger, the combined company will need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations.

Immediately prior to the execution and delivery of the Merger Agreement, Chinook entered into a Note Purchase Agreement with certain existing investors of Chinook named therein, pursuant to which the investors agreed to purchase, in the aggregate, $25.0 million in promissory notes convertible into securities of the combined company, referred to as the Chinook note financing. The notes are convertible into securities issued in an equity financing transaction that closes concurrently with or within 30 days following the Merger in which the aggregate gross purchase price paid to the combined company is no less than $15.0 million, or alternatively into shares of common stock of the combined company after closing of the Merger based on the volume weighted average closing trading price of a share of the combined company's common stock on Nasdaq for the five trading days ending the trading day immediately prior to the date such notes are converted, which must occur within 30 days following the Merger. The closing of the Chinook note financing is conditioned upon the closing of the Merger as well as certain other conditions. The Chinook note financing will have a dilutive impact on all securityholders of the combined company, including our pre-merger securityholders and Chinook's former securityholders, other than the holders of the notes. The Chinook note financing is more fully described under the section titled "Agreements Related to the Merger—Note Purchase Agreement" of our Form S-4 Registration Statement.

Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including our pre-merger securityholders and Chinook's former securityholders, other than the holders of the notes. It is also possible that the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company.

Some of our and Chinook directors and executive officers have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.

Directors and executive officers of Aduro and Chinook may have interests in the Merger that are different from, or in addition to, the interests of other Aduro stockholders generally. These interests with respect to our directors and executive officers may include, among others, acceleration of stock option or restricted stock unit vesting, retention bonus payments, extension of exercisability periods of previously issued stock option grants, severance payments if employment is terminated in a qualifying termination in connection with the Merger and rights to continued indemnification, expense advancement and insurance coverage. Certain current members of our board of directors will continue as directors of the combined company after the effective time of the Merger, and, following the closing of the Merger, will be eligible to be compensated as non-employee directors of the combined company pursuant

to our non-employee director compensation policy that is expected to remain in place following the effective time of the Merger. These interests with respect to Chinook's directors and executive officers may include, among others, certain of Chinook's directors and executive officers have options, subject to vesting, to purchase shares of Chinook common stock which, after the effective time of the Merger, will be converted into and become options to purchase shares of the common stock of the combined company; Chinook's executive officers are expected to continue as executive officers of the combined company after the effective time of the Merger; and all of Chinook's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. Further, certain current members of Chinook's board of directors will continue as directors of the combined company after the effective time of the Merger, and, following the closing of the Merger, will be eligible to be compensated as non-employee directors of the combined company pursuant to our non-employee director compensation policy that is expected to remain in place following the effective time of the Merger. The directors and executive officers own options and/or RSUs to purchase the shares of their respective companies.

The Aduro and Chinook boards were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the Merger, and recommend the approval of the Merger Agreement to Aduro and Chinook stockholders. These interests, among other factors, may have influenced the directors and executive officers of Aduro and Chinook to support or approve the Merger.

For more information regarding the interests of Aduro and Chinook directors and executive officers in the Merger, please see the sections titled "The Merger—Interests of Aduro Directors and Executive Officers in the Merger" and "The Merger—Interests of the Chinook Directors and Executive Officers in the Merger" of our Form S-4 Registration Statement.

Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger. Our stockholders will experience further dilution upon the conversion of the convertible promissory notes issued in the Chinook note financing.

If the Merger is not completed, our stock price may decline significantly.

The market price of our common stock is subject to significant fluctuations. During the 12-month period ended July 31, 2020, the closing sales price of Aduro's common stock on Nasdaq ranged from a high of $4.04 on February 20, 2020 to a low of $0.90 on October 25, 2019. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of our common stock will likely be volatile based on whether stockholders and other investors believe that we can complete the Merger or otherwise raise additional capital to support our operations if the Merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of our common stock is exacerbated by low trading volume. Additional factors that may cause the market price of our common stock to fluctuate include:

- the initiation of, material developments in, or conclusion of litigation to enforce or defend our intellectual property rights or defend against claims involving the intellectual property rights of others;
- the entry into, or termination of, key agreements, including commercial partner agreements;
- announcements by commercial partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the combined company's product candidates, including with respect to other products and potential products in that market;
- the introduction of technological innovations or new therapies that compete with our future products;
- the loss of key employees;
- future sales of its common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

Aduro and Chinook securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.

After the completion of the Merger, the current stockholders of Aduro and Chinook will own a smaller percentage of the combined company than their ownership of their respective companies prior to the Merger. Immediately after the Merger, without giving effect to the Chinook note financing, our securityholders as of immediately prior to the Merger are expected to own approximately 50% of the outstanding shares of the combined company on a fully-diluted basis and former Chinook securityholders, without giving effect to the Chinook convertible promissory notes, are expected to own approximately 50% of the outstanding shares of the combined company on a fully-diluted basis, subject to certain assumptions, including, but not limited to, (a) our net cash (as defined in the merger agreement) as of closing being equal to $145.0 million and (b) Chinook's cash and cash equivalents as of closing being equal to $10.0 million. The chief executive officer of Chinook will serve as the chief executive officer of the combined company following the completion of the Merger.

During the pendency of the Merger, we and Chinook may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect their respective business prospects.

Covenants in the Merger Agreement impede the ability of Aduro and Chinook to make acquisitions during the pendency of the Merger, subject to specified exceptions. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, proposing, seeking or knowingly encouraging, facilitating or supporting any inquiries, indications of interest, proposals or offers that constitute or may reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to such party's stockholders, but the parties may be unable to pursue them. For more information, see the section titled "The Merger Agreement—Non-Solicitation" of our Form S-4 Registration Statement.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of Aduro and Chinook from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances as described in further detail in the sections titled "The Merger Agreement—Non-Solicitation—Aduro" and "The Merger Agreement—Non-Solicitation—Chinook" of our Form S-4 Registration Statement. In addition, if we terminate the Merger Agreement under specified circumstances, either Aduro or Chinook would be required to pay the other party a termination fee of $6.4 million and reimburse up to $2.0 million of expenses. This termination fee may discourage third parties from submitting competing proposals to us or our stockholders, and may cause our board of directors to be less inclined to recommend a competing proposal.

Because the lack of a public market for Chinook's capital stock makes it difficult to evaluate the fair market value of Chinook's capital stock, we may pay more than the fair market value of Chinook's capital stock and/or the stockholders of Chinook may receive consideration in the Merger that is less than the fair market value of Chinook's capital stock.

The outstanding capital stock of Chinook is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of Chinook's capital stock. Because the percentage of Aduro equity to be issued to Chinook stockholders was determined based on negotiations between the parties, it is possible that the value of the Aduro common stock to be received by Chinook stockholders will be less than the fair market value of Chinook's capital stock, or Aduro may pay more than the aggregate fair market value for Chinook's capital stock.

Our stockholders may not receive any payment on the CVRs, and the CVRs may expire valueless.

The right of our stockholders to receive any future payment for or derive any value from the CVRs will be contingent solely upon the occurrence of the CVR Milestones within the time periods specified in the CVR Agreement and the consideration received being greater than the amounts permitted to be withheld or deducted by us under the CVR Agreement. There is no guarantee that we will be able to successfully partner or sell any of our non-renal assets or establish a viable entity to manage the development of these assets. In the event that no CVR Milestones occur within the time periods specified in the CVR Agreement or the consideration received is not greater than the amounts permitted to be withheld or deducted by us, no payments will be made under the CVR Agreement, and the CVRs will expire valueless.

Following the effective time of the Merger, subject to ongoing clinical trial obligations and obligations to use commercially reasonable efforts to complete dispositions for which a sale agreement has been entered into, neither we nor Chinook will have any obligation to develop the non-renal assets, or to expend any effort or resources to divest or otherwise monetize the non-renal assets.

Furthermore, the CVRs will be unsecured obligations of the combined company and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto may be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined company.

The tax treatment of the CVRs is unclear.

The U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments under, the CVRs, and there can be no assurance that the IRS would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

For example, as discussed in the section titled “Agreements Related to the Merger—Contingent Value Rights Agreement—Material U.S. Federal Income Tax Consequences of the CVRs of Holders of Aduro Common Stock” of our S-4 Registration Statement, we do not intend to report the issuance of the CVRs as a current distribution of property with respect to our stock, but it is possible that the IRS could assert that our stockholders are treated as having received a distribution of property equal to the fair market value of the CVRs on the date the CVRs are distributed, which could be taxable to our stockholders without the corresponding receipt of cash. In addition, it is possible that the IRS or a court could determine that the issuance of the CVRs (and/or any payments thereon) and the proposed reverse stock split described in our S-4 Registration Statement constitute a single “recapitalization” for U.S. federal income tax purposes with the CVRs constituting taxable “boot” received in such recapitalization exchange. In such case, the tax consequences of the CVRs and the reverse stock split would differ from those described in our S-4 Registration Statement, including with respect to the timing and character of income.

Our ability to utilize our net operating loss carryforwards and tax credit carryforwards may be subject to limitations.

Our ability to use our federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. In addition, a corporation that undergoes an “ownership change” under Section 382 of the Code, is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards, or NOLs, to offset future taxable income and its ability to utilize tax credit carryforwards. As of December 31, 2019, we reported U.S. federal, state and foreign NOLs of approximately $153.8 million, $107.8 million, and $66.5 million, respectively.

Under Section 382 of the Code, our ability to utilize NOLs or other tax attributes, such as federal tax credits, in any taxable year may be limited if we experienced an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. Similar rules may apply under state tax laws. We believe that we have experienced an ownership change in the past, and may experience ownership changes in the future and/or subsequent shifts in our stock ownership (some of which are outside of our control). Finally, the Merger, if consummated, may constitute an ownership change (within the meaning of Section 382 of the Code) which could eliminate or otherwise substantially limit our ability to use our federal and state NOLs. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could potentially result in increased future tax liability to us.

Risks Related to the Proposed Reverse Stock Split

The reverse stock split may not increase the combined company's stock price over the long-term.

Our Form S-4 Registration Statement includes a proposal to approve an amendment to our amended and restated certificate of incorporation to effect a reverse stock split of our issued and outstanding common stock within a range to be determined by our board of directors and agreed to by Chinook. The principal purpose of the reverse stock split is to increase the per-share market price of our common stock above the minimum bid price requirement under the Nasdaq rules so that the listing of Aduro and the shares of our common stock being issued in the Merger on Nasdaq will be approved. It cannot be assured, however, that the reverse stock split will accomplish this objective for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of our common stock, it cannot be assured that the reverse stock split will increase the market price of our common stock by a multiple of the reverse stock split ratio mutually agreed by us and Chinook, or result in any permanent or sustained increase in the market price of our common stock, which is dependent upon many factors, including our business and financial performance, general market conditions, and prospects for future success. Thus, while our stock price might meet the continued listing requirements for Nasdaq initially, it cannot be assured that it will continue to do so.

The reverse stock split may decrease the liquidity of the combined company's common stock.

Although our board believes that the anticipated increase in the market price of the combined company's common stock resulting from the proposed reverse stock split could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for the combined company's common stock. In addition, the reverse stock split may not result in an increase in the combined company's stock price necessary to satisfy Nasdaq's initial listing requirements for the combined company.

The reverse stock split may lead to a decrease in the combined company's overall market capitalization.

Should the market price of the combined company's common stock decline after the reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of the combined company's common stock will remain the same after the reverse stock split is effected, or that the reverse stock split will not have an adverse effect on the combined company's stock price due to the reduced number of shares outstanding after the reverse stock split.

Risks Related to Our Business

We have incurred net losses in every year since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future.

We are an immunotherapy company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have financed our operations primarily through the sale of common stock, and licensing agreements with pharmaceutical partners. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We incurred a net loss of $16.6 million and $18.6 million for the three months ended June 30, 2020 and 2019, respectively, and $24.2 million and $42.0 million for the six months ended June 30, 2020 and 2019, respectively. At June 30, 2020, we had an accumulated deficit of $511.1 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

We will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Our operations have consumed substantial amounts of cash since inception. At June 30, 2020, our cash and cash equivalents and marketable securities were $186.1 million. We expect to continue to spend substantial amounts to continue the development of our product candidates. If we are able to gain regulatory approval for any of our product candidates, we will require significant additional amounts of cash in order to launch and commercialize any such product candidates. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and costs associated with, obtaining regulatory approvals for our product candidates if clinical trials are successful;
- the cost of commercialization activities for our product candidates, if any of our product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization and product launch;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any;
- competing therapies and combinations; and
- other market developments.

We do not have any committed external source of funds or other support for our development efforts other than our license agreements, including our collaboration and license agreement with Novartis, which may be terminated by Novartis upon 180 days' notice, our license agreement with Merck, which may be terminated by Merck upon 120 days' notice, and our collaboration and license agreement with Lilly, which may be terminated following a specified notice period. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms.

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, including our "at-the-market" offering, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. 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, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or research and development programs or our commercialization efforts.

Our corporate strategy and restructuring plan may not be successful.

On January 9, 2020, we announced a restructuring plan to further extend our operating capital and align personnel towards executing our clinical development strategy. The success of this restructuring will depend on our ability to reduce operating expenses, reduce our facilities footprint, retain senior management and other highly qualified personnel and generate multiple clinical data readouts over the next several years. In connection with the restructuring we intend to reduce our workforce by approximately 59%. Our workforce after these actions may not be sufficient to fully execute our strategy, and we may not be able to effectively attract or retain senior management or other qualified employees needed to implement this strategy. If we are unable to successfully execute our strategy, our business, financial condition and results of operations may be materially and adversely affected.

We intend to sublease a significant amount of space in our headquarters in Berkeley, California. If we are unable to sublease our facilities on favorable terms, our subtenants are unable to meet their obligations under the subleases or our landlord recaptures the subleased space, we may be responsible for unexpected costs or the value of the lease asset may be reduced, which could impact our financial results.

At June 30, 2020, we had approximately 110,853 square feet of leased space in Berkeley. In connection with our restructuring plan, we expect to sublease a significant portion of our Berkeley facility to third parties. The COVID-19 global pandemic may result in reduced sublease demand or the amount of rent we are able to obtain. In the event that we are unable to sublease our excess space on favorable terms, or at all, or if we are able to sublease space but our subtenants fail to make lease payments to us or otherwise default on their obligations to us, we could incur substantial payment obligations to our landlord. In the event our estimates regarding our ability to sublet our available space are incorrect, we would be required to adjust our restructuring reserves, which could have a material impact on our financial results. In addition, in the event that we sublease 50% or more of our Berkeley facility to third parties, our landlord may recapture such subleased space, which would require us to reduce the value of the operating lease right-of-use asset on our balance sheet and could have a material impact on our financial results.

Risks Related to the Development and Commercialization of Our Current and Future Product Candidates

Our product candidates are based on novel technologies, and the development and regulatory approval pathway for such product candidates is unproven and may never lead to marketable products.

We do not have any products that have gained regulatory approval. Our immunotherapy product candidates are designed to stimulate and/or regulate innate and adaptive immune responses as potential treatments for cancer, autoimmune and inflammatory diseases. Any products we develop may not effectively modulate the immune response. The scientific evidence to support the feasibility of immunotherapy product candidates is preliminary and limited. Our business and future success depend on our ability to obtain regulatory approval of, and then successfully commercialize, our product candidates. Advancing these novel therapies creates significant challenges for us, including, among others:

- obtaining approval from regulatory authorities to conduct clinical trials with our product candidates;
- successful completion of preclinical studies and successful enrollment of clinical trials;
- successful completion of our clinical trials, including a favorable risk-benefit outcome;
- receipt of marketing approvals from the U.S. Food and Drug Administration, or FDA, and similar regulatory authorities outside the United States;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing commercial manufacturing, supply and distribution arrangements;
- establishing a commercial infrastructure;
- acceptance of our products by patients, the medical community and third-party payors;
- establishing market share while competing with other therapies;
- successfully executing our pricing and reimbursement strategy;
- a continued acceptable safety and adverse event profile of our products following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering our products.

All of our product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive regulatory approval for any of our product candidates. If we are unable to develop or receive marketing approval for our product candidates in a timely manner or at all, our business, financial condition and results of operations may be materially and adversely affected.

We may not be successful in our efforts to use and expand our technologies to build a pipeline of product candidates.

A key element of our strategy is to use and expand our technologies to build a pipeline of product candidates, combine our product candidates with existing and novel therapies, and progress these product candidates and combinations through clinical development for the treatment of various diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various indications, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods. See also the risk factor titled, "Our corporate strategy and restructuring plan may not be successful."

Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. Our clinical trials may fail to demonstrate adequately the safety and efficacy of one or more of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective, or in the case of biologics, safe, pure and potent, for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

Additionally, because our product candidates are based on new technologies and costs to treat potential side effects that may result from our product candidates are uncertain, our clinical trial costs may be significantly higher than for more conventional therapeutic technologies or drug products.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot be certain that we will not face similar setbacks. Most product candidates that commence clinical trials are never approved as commercial products. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. We cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Any delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

We may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. In addition, due to delays in clinical trials related to the COVID-19 global pandemic, we expect that our clinical development program timelines will be negatively affected. See also the risk factor titled, "Public health crises such as pandemics or similar outbreaks could materially and adversely affect our clinical trials, business, financial condition and results of operations."

The commencement or completion of clinical trials can be delayed or aborted for a variety of reasons, including delays or failures related to:

- the COVID-19 global pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- generating sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies;
- obtaining regulatory approval to commence a trial;

- identifying and recruiting suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board/ethics committee, or IRB/EC, approval at each site;
- recruiting suitable patients to participate in a trial;
- achieving an acceptable distribution of such patients based on treating institution and geography;
- patients not completing a trial or not completing post-treatment follow-up;
- clinical sites deviating from trial protocol, instructions or dropping out of a trial;
- regulatory agency-imposed clinical holds;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs/ECs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose a clinical hold or 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, a negative finding from an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or safety concerns raised by other clinical trials of therapies with similar mechanisms of action.

If we experience delays in the completion, or termination, of any clinical trial for our product candidates, the commercial prospects of that product candidate will be harmed, and our ability to generate product revenues from the product candidate 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.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Actual or potential conflicts of interest arising from our relationships with investigators could adversely impact the FDA approval process.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. We also provide grants to investigators' institutions from time to time. If certain of these relationships exceed specific financial thresholds, they must be reported to the FDA. If these relationships and any related compensation paid results in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay in approval, or rejection, of our marketing applications by the FDA.

Our product candidates may cause undesirable side effects or may have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, if approved, or result in significant negative consequences.

Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized, and any such side effects or adverse events could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or negatively affect our ability to market our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

To date, patients treated with our product candidates have experienced drug-related side effects or adverse events, or AEs, including AEs that were considered moderate or severe. Examples of the AEs experienced include among others, fevers, chills, injection sight pain, headaches, increased lipase and elevated amylase, tumor pain, dyspnea and respiratory failure. We cannot provide assurances that there will not be further adverse events.

If unacceptable side effects arise in the development of our product candidates, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials, require us to conduct additional animal or human studies or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, if side effects are observed in competing product candidates that are perceived to have similarities to ours, regulators or patients may infer that our product candidates could cause similar side effects. Any of these occurrences may materially and adversely affect our business, financial condition and results of operations.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- the FDA could require a Risk and Evaluation Medication Strategy, or REMS, which could require the creation and management of a medication guide, communication plan or other elements to ensure safe use;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could materially and adversely affect our business, financial condition and results of operations.

We may encounter difficulties enrolling patients in our clinical trials.

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- patients' willingness to enroll or continue to participate in a clinical trial, which may be impacted by the COVID pandemic;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used treatment methods, in some cases potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in our clinical trials.

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

Public health crises such as pandemics or similar outbreaks could materially and adversely affect our clinical trials, business, financial condition and results of operations.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 global pandemic, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States and Europe, including in the locations of our offices, clinical trial sites, key vendors and partners. We expect that our clinical development program timelines will be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. Further, due to "shelter in place" orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members excluding those necessary to maintain operations and those doing laboratory work. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

As a result of the COVID-19 global pandemic, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;

- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions.

These and other factors arising from the COVID-19 global pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could materially and adversely affect our business, financial condition and results of operations.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 global pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

The market opportunities for our product candidates may be small or limited to those patients who are ineligible for established therapies or for whom prior therapies have failed.

Our projections of the number of people who have the indications that we are targeting and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. If the market opportunities for our product candidates are smaller than we estimate, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. Initially our oncology product candidates may only be approved as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

We are subject to a multitude of manufacturing, supply chain, storage and distribution risks, any of which could substantially increase our costs and limit the supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including:

- The manufacturing of drug and biologic products is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If foreign microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, these manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, disease outbreaks, including the current COVID-19 global pandemic, power failures and numerous other factors;
- We and our contract manufacturers must comply with the FDA's current good manufacturing practices, or cGMP, regulations and guidelines. Any failure to follow cGMP or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of product candidates for our clinical studies, the termination or hold on a clinical study, or the delay or prevention of a filing review or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions or criminal prosecution; and
- Our product candidates are sensitive to temperature, which must be controlled during storage and transportation, which adds complexity and expense. We rely on third parties to provide controlled temperature storage and shipping. If any third-party provider fails to maintain proper temperature control or if a shipment is delayed in transit for a prolonged period of time, the product candidate could become unsuitable for use.

Any adverse developments affecting manufacturing operations for our product candidates and/or damage that occurs during shipping may result in delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Inability to meet the demand for any of our product candidates, if approved, could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community, which could materially and adversely affect our business, financial condition and results of operations.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no marketing capabilities and no sales or distribution capabilities and have no marketed products. We intend to develop an in-house commercial organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We cannot assure you that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or elsewhere.

A variety of risks associated with conducting clinical trials and marketing our product candidates internationally could materially and adversely affect our business, financial condition and results of operations.

We conduct clinical trials, and plan to seek regulatory approval of our product candidates outside of the United States. The acceptance of study data by the FDA, other comparable foreign regulatory authorities from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. For example, in cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

We are subject to additional risks related to operating in foreign countries in conducting clinical trials and if we obtain the necessary approvals, including:

- differing legal and regulatory requirements in foreign countries, including future legal and regulatory requirements of the United Kingdom (where we are conducting a clinical trial) following the withdrawal of the United Kingdom from the European Union;
- economic weakness, including recession or depression resulting from the current COVID-19 global pandemic or inflation, or political instability in particular foreign economies and markets, including any instability resulting from the withdrawal of the United Kingdom from the European Union;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, including the current COVID-19 global pandemic;
- business interruptions resulting from natural or man-made disasters and geo-political actions, including pandemics, including the current COVID-19 global pandemic, war and terrorism;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations, including clinical trials;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations; and
- challenges to and protecting our contractual and intellectual property rights, including in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations may materially and adversely affect our business, financial condition and results of operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our business, financial condition and results of operations will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results.

Many major multinational pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies, universities and other research institutions continue to invest time and resources in developing novel approaches to immunotherapies. Promising results have spurred significant competition from major pharmaceutical and biotechnology companies alike. Our competitors in the STING pathway activator technology include Merck & Co., Inc., Bristol-Myers Squibb Company/IFM Therapeutics, GlaxoSmithKline plc, Synlogic, Inc., Spring Bank Pharmaceuticals, Inc., Codiak Biosciences, Inc., Eisai, Co., Ltd./H3 Biomedicine, Inc., AbbVie (following its acquisition of Mavupharma), Curadev, Trillium Therapeutics Inc., Mersana Therapeutics, Stingray Therapeutics, Ryvu Therapeutics, Cancer Therapeutics CRC, ImmuneSensor Therapeutics, Nimbus Therapeutics and STINGINN LLC. Our competitors for the anti-APRIL program include Otsuka Pharmaceutical Co., Ltd. (following its acquisition of Visterra, Inc.) and Merck KGaA (EMD Serono). Our competitors for the cGAS-STING pathway inhibitor program include Pfizer Inc., Spring Bank Pharmaceuticals, Inc., GlaxoSmithKline plc, Curadev, Sirenas, LLC, Nimbus Therapeutics/ Bristol-Myers Squibb Company, IFM Due (a subsidiary of IFM Therapeutics, LLC), AbbVie (following its acquisition of Mavupharma), ImmuneSensor Therapeutics and STINGINN LLC. While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, among others. Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing, market access and manufacturing organizations and well-established sales forces.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Even if we obtain regulatory approval of our product candidates, the availability and prices of our competitors' products could limit the demand and the prices we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our President and Chief Executive Officer, our Chief Medical Officer and our Interim Chief Financial Officer and our Chief Administrative Officer. As previously disclosed, our former Chief Scientific Officer resigned effective as of June 30, 2020 in connection with our restructuring plan and the closure of our European site in Oss, the Netherlands, where our Chief Scientific Officer was based. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. The Northern California region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees.

We may need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis or reasonable economic terms when needed, or at all. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not succeed in further developing and commercializing our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those used by our CROs or other contractors, consultants or vendors, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors, consultants or vendors are vulnerable to damage from, among others, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electronic failures, cyberattacks or cyber intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization or similar disruptive problems. 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. Any such material system failure or security breach could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. The COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from "hackers" hoping to use the recent COVID-19 pandemic to their advantage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages or outages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates, in some cases on a patient by patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters is in Northern California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

For example, the current COVID-19 global pandemic has disrupted businesses globally. We cannot at this time predict the specific extent, duration, or full impact that the COVID-19 global pandemic will have on our financial condition and operations, including ongoing and planned clinical trials, or the financial condition and operations of our CROs, contract manufacturers or other partners. We believe that there will be an impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals and others in the medical community.

The use of APRIL or STING product candidates as potential immunotherapy treatments, even if approved, may not become broadly accepted by physicians, patients, hospitals and others in the medical community. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates may be approved;
- physicians, hospitals and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- side effects or results reported for competing products or product candidates that are perceived to have similarities to ours;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including limitations or warnings;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- adverse publicity or ethical or social controversies related to the use of our technologies or similar technologies;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve or maintain market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical 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 or 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 product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

We currently hold product liability insurance in amounts that we believe are customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, which could inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may 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. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Our Reliance on Third Parties

We have entered into licensing agreements with third parties for certain product candidates and as a result have placed restrictions on our development of certain product candidates for particular indications. We may elect to enter into additional licensing or collaboration agreements to partner our product candidates in territories we currently retain. Our dependence on such relationships may adversely affect our business.

We have, and we may seek to enter into additional, collaboration agreements with other pharmaceutical or biotechnology companies. In the event we grant exclusive rights to such partners, we would be precluded from potential commercialization of our product candidates within the territories in which we have a partner. For example, we have entered into a collaboration and license agreement with Novartis for the development and commercialization of STING Activator product candidates in oncology. Under this agreement, we have granted Novartis a co-exclusive license to develop such products worldwide and an exclusive license to commercialize such products outside of the United States. We have also entered into a research collaboration and exclusive license agreement with Lilly for our cGAS-STING Pathway Inhibitor program for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases and a worldwide development and commercialization agreement with Merck for the development of an anti-CD27 antibody. Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. Any termination of our collaboration agreements, or a decision by a partner to reduce its development efforts under a collaboration agreement, will terminate or reduce the funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development programs. For example, effective December 2019, Novartis determined to remove ADU-S100 from its portfolio and we are funding the current ADU-S100 trials on our own.

Our commercialization strategy for our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we seek to partner. Despite our efforts, we may be unable to secure additional collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. For example, under our collaboration and license agreement with Novartis, we are responsible for a share of the worldwide joint development costs, which may be significant. If we elect to reduce our share of development funding as provided for under the agreement, our share in profits would decrease or convert to a royalty. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our potential future collaborators could delay or terminate their agreements with us, and as a result our product candidates may never be successfully commercialized.

Further, our collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our product candidates receive less attention or resources than we would like, or they may be terminated altogether. In addition, we could have disputes with our collaborators, including regarding development plans or the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of our product candidates or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or otherwise conduct the trials as required or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates when expected or at all.

We depend and plan to continue to depend upon independent investigators, other third parties and collaborators, such as universities, medical institutions, CROs and strategic partners, to conduct our preclinical and clinical trials under agreements with us. We have to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We rely and plan to continue relying heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they 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 protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of, or successfully commercialize, our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If our relationships with any third parties conducting our trials are terminated, we may be unable to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with third parties conducting our clinical trials, we cannot assure you that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material and adverse effect on our business, financial condition and results of operations.

We rely on third party contract manufacturers to provide clinical supplies of our product candidates. If these parties do not successfully carry out their contractual duties or encounter problems in manufacturing our product candidates, it could increase our costs, limit supply of our product candidates and interfere with obtaining product commercialization approvals.

We currently rely on outside vendors to manufacture clinical supplies of our product candidates and have limited experience manufacturing our product candidates. In order to develop our product candidates, apply for regulatory approvals and commercialize our products, if approved, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities.

We may manufacture limited quantities of clinical trial materials ourselves in the future, but we currently rely on a limited number of contract manufacturing organizations, or CMOs, for our clinical product supplies. There are risks inherent in the manufacture of drug and biologic products that could affect the ability of our CMOs to meet our delivery time requirements or provide adequate amounts of material to meet our needs. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production. Typical manufacturing problems include longer lead times, low product yields, quality control failures, product instability, operator error, shortages of raw materials, shortages of qualified facilities or personnel, storage mistakes and unpredictable production costs. If contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, thereby interrupting supply.

If in the future we develop our own manufacturing capabilities by building our own manufacturing facilities, we will incur significant expenditures. In addition, the construction and qualification of a drug substance facility may take several years to complete and there are many risks inherent in the construction of a new facility that could result in delays and additional costs, including the need to obtain access to necessary equipment and third-party technology, if any. In addition, we would likely need to continue to hire and train qualified employees to staff our facilities.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval process and we will need to meet, and will need to contract with CMOs who can meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. In addition, if we receive the necessary regulatory approval for any product candidate, we also expect to rely on third parties to produce materials required for commercial supply. If we are unable to obtain or maintain CMOs for these product candidates, or to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize our products.

To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we depend, and will depend in the future, on these third parties to perform their obligations in a timely manner and consistent with contractual and regulatory requirements. The failure of any CMO to perform its obligations as expected, or, to the extent we manufacture all or a portion of our product candidates ourselves, our failure to execute on our manufacturing requirements, could materially and adversely affect our business, financial condition and results of operations.

If any CMO with whom we contract fails to perform its obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We may not realize the benefits of acquisitions or strategic transactions, including our proposed merger with Chinook and our acquisition of Aduro Biotech Europe.

We signed the merger agreement with Chinook on June 1, 2020 and, subject to satisfaction of the closing conditions in the merger agreement, including obtaining approval of our stockholders for the issuance of common stock in the merger and resulting change of control and the Chinook's stockholders adoption and approval of the merger, expect to close the merger in the second half of 2020. We acquired Aduro Biotech Europe in October 2015. We may also acquire or license other businesses, products or technologies, as well as pursue strategic alliances, joint ventures or investments in complementary businesses from time to time. The success of mergers and acquisitions depends on a number of risks and uncertainties, including:

- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to identification, negotiation or management of any strategic alliances or joint ventures or acquisition integration challenges;
- increases in expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- stock issuances that dilute existing stockholders;
- competition for appropriate strategic alternatives;
- difficulty negotiating or executing any such arrangements; and
- possible write-offs or impairment charges relating to acquired businesses.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. For example, subsequent to our acquisition of Aduro Biotech Europe we have incurred intangible asset impairment charges of $9.0 million and related reductions in deferred tax benefit of $2.2 million related to the Aduro Biotech Europe business. Further, in January 2020, we announced plans to shut down our Netherlands operations, which resulted in impairment and other charges. While BION-1301 was originally developed by Aduro Biotech Europe, it is currently uncertain whether the Aduro Biotech Europe acquisition will result in any product candidates that are ultimately approved for sale. Additionally, foreign acquisitions are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries. See also the risk factor titled, "Impairment of goodwill and other intangible assets may result in significant impairment charges, which would adversely affect our financial condition and results of operations."

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates or ultimately be unable to obtain regulatory approval for our product candidates, in which case our business will be substantially harmed.

We will not be permitted to market any of our product candidates in the United States until approval from the FDA is received. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. We have not previously submitted a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, or similar marketing applications filings to comparable foreign authorities. A BLA or NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency, or safety and effectiveness for each desired indication. The BLA or NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of immunotherapies for cancer. We also intend to obtain regulatory approval of future oncology product candidates regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involve cancers of certain origins. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission, or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

For instance, in the European Economic Area, or EEA, which is comprised of the Member States of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

- Community MAs – These are issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and are valid throughout the entire territory of the EEA. The Centralized Procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the EU.
- National MAs – These are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Requirements for the conduct of clinical trials in the European Union including GCP are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the EU member states. Under this system, approval must be obtained from the competent national authority of each EU. member state in which a study is planned to be conducted. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the EU passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new EU clinical trials legislation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in 2021.

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

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the products may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidates. We will be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. The FDA may also require a risk evaluation and mitigation strategy, or REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports and registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval. We will also have to comply with requirements concerning advertising and promotion for any of our product candidates that receive regulatory approval.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or adverse publicity;
- holds on clinical trials;
- refusal by regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of regulatory approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Any new legislation addressing drug or biologic products could result in delays in product development or commercialization, or increased costs to assure compliance. In addition, the FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to 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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, 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, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 global pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 global pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Successful sales of our product candidates, if approved, depend, in part, on the availability of adequate insurance coverage and reimbursement from third-party payors. In addition, because our product candidates represent new treatments, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Additionally, obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our products or procedures using our products, could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Further, we plan to develop our product candidates for use in combination with other products, which may make them cost prohibitive or less likely to be covered by third-party payors. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific, clinical and cost-effectiveness data and support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions.

Our product candidates may be subject to government price controls that may affect our revenue.

There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, at the federal level such scrutiny has resulted in several recent congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Congress and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Outside of the United States, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

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

Third-party payors, whether domestic or foreign, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to health care systems that could impact our ability to sell our products profitably. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted. The Affordable Care Act and its implementing regulations, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government’s comparative effectiveness research and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year (this requirement was commonly referred to as the “individual mandate”). On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. For example, there have been several recent Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer's patient programs, and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, Congress and the Trump administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set prices that we believe are fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers, patients and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we research, develop, sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), their immediate family members, certain other healthcare professionals starting in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" made to such physician owners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting arrangements with physicians, some of whom receive stock options as compensation for services provided, could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have a material and adverse effect on our business, financial condition and results of operations.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, imprisonment, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from participation in federal and state healthcare programs and the curtailment or restricting of our operations, any of which could harm our ability to operate our business and our financial results. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us and our third-party manufacturers. We and our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our and our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could materially and adversely affect our business, financial condition and results of operations.

We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

Privacy and data security have become significant issues in the United States, Europe and in many other jurisdictions where we may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we are subject to diverse laws and regulations relating to data privacy and security. Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. We do not believe that we are currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process and in the course of our research collaborations. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR and/or the UK Data Protection Act 2018.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Economic Area and/or the United Kingdom into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. By way of example, the California Consumer Privacy Act, or CCPA, effective January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the General Data Protection Regulation, or GDPR, took effect. The GDPR is applicable in each EU and EEA member state and applies to companies established in the EU and EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EU and EEA, including, for example, through the conduct of clinical trials. The GDPR imposes stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. Further, recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the U.S. For example, on July 16, 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-US Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities which had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. Penalties and fines for failure to comply with the GDPR are significant, including fines of up to €20.0 million or 4% of total worldwide annual turnover, whichever is higher. Additionally, following the United Kingdom's withdrawal from the European Union, we will have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, each regime having the ability to fine up to the greater of €20.0 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our compounds or biologic products will result in the issuance of patents that effectively protect our technology or products, or if any of our issued patents or if any of our or our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor's patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. For example, two of our patents, U.S. Patent Nos. 7,842,289 and 7,935,804, have previously been subject to reexamination proceedings in the U.S. Patent and Trademark Office, or USPTO, at the request of a third party.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, and to use our related proprietary technologies without infringing the intellectual property rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could also be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business, financial condition and results of operations.

While our product candidates are in preclinical studies and clinical trials, we believe that their use in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which generally exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use that we intend to promote, do not infringe other parties' patents and other proprietary rights. We cannot assure you they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

In addition, we are testing our product candidates administered with other product candidates or products that are covered by patents held by other companies or institutions. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with our product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

If we breach any of our license agreements, it could have a material adverse effect on our commercialization efforts for our product candidates.

Our commercial success depends on our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our licensors' or collaborators' proprietary technologies without infringing the property rights of third parties. For example, we have entered into license agreements with Karagen Pharmaceuticals, Inc. and the Regents of the University of California and a consortium of universities led by Memorial Sloan Kettering related to STING Activators, and we expect to enter into additional licenses in the future. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

We have granted Lilly and Merck rights to control certain matters related to our intellectual rights for our licensed products. Our inability to control the filing, prosecution, maintenance and enforcement of such patents could materially and adversely affect our business, financial condition and results of operations.

As part of our license and collaboration agreements with Merck and Lilly related to anti-CD27 and cGAS STING pathway molecules, respectively, we have granted Merck and Lilly the first rights to prosecute certain patent rights and we are required to consult with Merck and Lilly with respect to infringement and defense matters related to certain licensed patents. Further, Merck has rights to determine the strategy for patent term extensions for anti-CD27 and we are required to cooperate with Lilly with respect to obtaining patent term extensions for certain patents related to the cGAS STING pathway program. Our inability to control these intellectual property rights could materially harm our business. For example, if a third party is infringing our patent covering anti-CD27, by marketing a product that is identical or similar to anti-CD27, Merck would have the initial right to enforce the patent against the third party and may make decisions with which we may not agree. Further, Merck may decide not to apply for extension of any term of a licensed patent that may otherwise be eligible for extension, which could decrease the royalties for the sale of products relating to such patents.

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

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

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

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic and/or biosimilar product manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

Generic or biosimilar product manufacturers may develop, seek approval for, and launch generic or biosimilar versions, respectively, of our products. The FDA has published four draft guidance documents on biosimilar product development. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA. To date, no biosimilar or interchangeable biologic has been licensed under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, framework, although such approvals have occurred in Europe, and it is anticipated that the FDA will approve a biosimilar in the relatively near future. If any of our product candidates are approved by the FDA, the approval of a biologic product biosimilar to one of our products could materially and adversely affect our business, financial condition and results of operations. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our products, if approved by the FDA.

Some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many countries, including European Union countries, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as our product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Currently, we own or license patent families that cover STING Activators, which, expire, or if issued will expire, between 2025 and 2038, subject to any extensions. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

The BPCIA established legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing branded product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biologic product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biologic product, and the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biologic. Alternatively, a third party could submit a BLA for a similar or identical product any time after approval of our biologic product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biologic product.

Additionally, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Changes in patent law could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

For instance, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, U.S. patent applications containing or at that at any time contained a claim not entitled to priority before March 16, 2013 are subject to a "first to file" system, in which the first inventor to file a patent application will be entitled to the patent. This "first to file" system requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, 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.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material and adverse effect on our business, financial condition and results of operations.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

We may be subject to claims by third parties asserting that our licensors, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds or biologics that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or our licensors might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have licensed may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants and collaborators 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. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially and adversely affect our business, financial condition and results of operations.

Risks Related to Our Financial Results

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, in addition to existing agreements with Novartis, Merck and Lilly, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as approved by the compensation committee and sub-committees, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for our product candidates or competing product candidates;
- competition from existing and potential future drugs that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our product candidates;
- the level of demand for our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- market conditions or trends in our industry or the economy as a whole, including as a result of economic recession or depression and market volatility related to the COVID-19 global pandemic and global health concerns.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

Impairment of goodwill and other intangible assets may result in significant impairment charges, which would adversely affect our financial condition and results of operations.

Goodwill and other intangible assets represent a significant portion of our assets. Goodwill is the excess of cost over the fair market value of net assets acquired in business combinations. We review our goodwill and acquired IPR&D intangible assets at least annually for impairment. Impairment may result from, among other things, failure to realize the anticipated benefits of past or any future acquisitions or strategic transactions, decisions to discontinue acquired businesses or assets, deterioration in our stock price, adverse market conditions and adverse changes in applicable laws or regulations. For example, in 2018 and 2019, we have incurred IPR&D intangible impairment charges related to our acquired entity, Aduro Biotech Europe. Any impairment of goodwill or other intangible assets would result in a non-cash charge against earnings, which would adversely affect our results of operations.

Our portfolio of marketable securities is subject to market, interest and credit risk that may reduce its value.

We maintain a portfolio of marketable securities for investment of our cash, and securities included in our portfolio have recently been downgraded. Changes in the value of our portfolio of marketable securities could adversely affect our earnings. In particular, the value of our investments may decline due to additional downgrades of securities included in our portfolio, increases in interest rates, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the securities included in our portfolio and other factors. In addition, the COVID-19 pandemic could adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and is likely to continue to be, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume and as a result of the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-K among others.

In addition, the stock market in general, and the Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors, such as the current COVID-19 global pandemic and resulting market volatility, may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition and results of operations.

If our stock price trades below $1.00 for 30 consecutive trading days, our common stock may be subject to delisting from the Nasdaq Global Select Market.

If at any time the bid price of our common stock closes at below $1.00 per share for more than 30 consecutive trading days, we may be subject to delisting from the Nasdaq Global Select Market. If we receive a delisting notice, we would have 180 calendar days to regain compliance, which would mean having a bid price above the minimum of $1.00 for at least 10 consecutive days in the 180-day period. During this 180-day period, we would anticipate reviewing our options to regain compliance with the minimum bid requirements, including conducting a reverse stock split. To the extent that we are unable to resolve any listing deficiency, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock. As of June 30, 2020, our stock had traded at a 52-week low of $0.94 per share, and a 52-week high of $3.87 per share. Our closing share price on June 30, 2020 was $2.31.

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

Our common stock is currently traded on the Nasdaq Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market for our shares on the Nasdaq Global Select Market or any other exchange in the future. If there is no active market for our common stock, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our common stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation, if any, of their common stock.

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

Our executive officers, directors and 5% stockholders together beneficially own a significant percentage of our voting stock. These stockholders may be able to determine the outcome of matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that other stockholders believe are in their best interests.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. These accounting principles are subject to interpretation by the Financial Accounting Standards Board, or FASB, and the SEC. A change in these policies or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations, and may require us to make costly changes to our operational processes and accounting systems.

Our revenue to date has been primarily derived from research and license agreements, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue.

Our revenue is primarily derived from our research and license agreements, from which we receive upfront fees, contract research payments, milestone and other contingent payments based on clinical progress, regulatory progress or net sales achievements and royalties. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from significant payments based on the execution of new research and license agreements, the timing of clinical outcomes, regulatory approval, commercial launch or the achievement of certain annual sales thresholds. The amount of our revenue derived from research and license agreements in any given period will depend on a number of unpredictable factors, including our ability to find and maintain suitable collaboration partners, the timing of the negotiation and conclusion of collaboration agreements with such partners, whether and when we or our collaboration partners achieve clinical, regulatory and sales milestones, the timing of regulatory approvals in one or more major markets, reimbursement levels by private and government payers, and the market introduction of new drugs or generic versions of the approved drug, as well as other factors. Our past revenue generated from these agreements is not necessarily indicative of our future revenue. If any of our existing or future collaboration partners terminates our collaboration, fails to develop, obtain regulatory approval for, manufacture or ultimately commercialize any product candidate under our collaboration agreement, our business, financial condition, and results of operations could be materially and adversely affected.

Once we are no longer an emerging growth company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

As a public company we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which requires, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company we may take advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the “say on pay” voting requirements pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. After we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which may allow us to take advantage of some of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer an emerging growth company or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

We will remain an emerging growth company until the earliest of (1) December 31, 2020, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion or (b) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of certain shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. For example, on August 2, 2017, we filed a registration statement on Form S-3 to register for resale shares held by Morningside Venture (IV) Investments Limited and Ultimate Keen Limited, which together hold 14,908,031 shares of our common stock. We have registered all currently reserved shares of common stock that we may issue under our equity compensation plans and intend to register in the future any additional reserved or issued shares of common stock. These registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2015 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, nonemployee directors and consultants. Future grants of restricted stock units, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock.

Additionally, the number of shares of our common stock reserved for issuance under our 2015 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2025, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Further, the number of shares of our common stock reserved for issuance under our 2015 ESPP will automatically increase on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2025, by 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which means that all stockholder actions must be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing or cause us to take other corporate actions stockholders may desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and our amended and restated bylaws provide that federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act, either of these provisions could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated bylaws provide that federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. These provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the provisions in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

If securities or industry analysts publish inaccurate or 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. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline.

Item 2. Recent Sales of Unregistered Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit No	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
2.1†	Agreement and Plan of Merger and Reorganization, dated June 1, 2020, by and among Aduro Biotech, Inc., Aspire Merger Sub, Inc. and Chinook Therapeutics U.S., Inc.	8-K	001-37345	2.1	06/02/2020	
3.1	Restated Certificate of Incorporation of Aduro Biotech, Inc.	8-K	001-37345	3.1	04/20/2015	
3.2	Amended and Restated Bylaws of Aduro Biotech, Inc.	S-1/A	333-202667	3.5	04/06/2015	
3.3	Amendment to Amended and Restated Bylaws of Aduro Biotech, Inc., dated July 16, 2020	8-K	001-37345	3.1	07/17/2020	
4.1	Form of common stock certificate.	S-1/A	333-202667	4.1	04/06/2015	
4.2	Amended and Restated Investor Rights Agreement, by and among Aduro Biotech, Inc. and the stockholders named therein, dated December 19, 2014.	S-1	333-202667	4.2	03/11/2015	
10.1	Note Purchase Agreement, dated as of June 1, 2020, by and among Chinook Therapeutics U.S., Inc. and certain investors named therein	8-K	001-37345	10.1	06/02/2020	
10.2	Form of Convertible Promissory Note	8-K	001-37345	10.2	06/02/2020	
10.3	Form of Support Agreement by and between Aduro Biotech, Inc. and certain stockholders of Chinook Therapeutics U.S., Inc.	8-K	001-37345	10.3	06/02/2020	
10.4	Form of Support Agreement by and between Chinook Therapeutics U.S., Inc. and certain stockholders of Aduro Biotech, Inc.	8-K	001-37345	10.4	06/02/2020	
10.5	Form of Lock-Up Agreement	8-K	001-37345	10.5	06/02/2020	
10.6	Form of CVR Agreement	8-K	001-37345	10.6	06/02/2020	
10.7	Consulting Agreement, dated as of June 1, 2020, by and between Aduro Biotech, Inc. and Andrea van Elsas, Ph.D.	8-K	001-37345	10.7	06/02/2020	
10.8+	Amended and Restated Executive Employment Agreement by and between the Company and Stephen T. Isaacs, dated July 2, 2020	8-K	001-37345	10.1	07/02/2020	
10.9+	Amendment to the Aduro Biotech, Inc. Amended and Restated Severance Plan and Summary Plan Description	8-K	001-37345	10.2	07/02/2020	
10.10+	Letter Agreement by and between the Company and Blaine Templeman, dated July 29, 2020	8-K	001-37345	10.3	07/02/2020	
31.1	Certification of the Chief Executive Officer Pursuant to Securities Exchange Act of Rules 13A-14(A) and 15D-14(A).					X
31.2	Certification of the Interim Chief Financial Officer Pursuant to Securities Exchange Act Rules 13A-14(A) and 15D-14(A).					X

Exhibit No	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
32.1*	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline 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	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

+ Indicates management contract or compensatory plan, contract or agreement.

† All schedules and exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish a copy of such schedules and exhibits, or any section thereof, to the SEC upon request.

* The certifications attached as Exhibit 32.1 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” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

Aduro Biotech, Inc.

Date: August 3, 2020

By: /s/ Stephen T. Isaacs
Stephen T. Isaacs
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Aduro Biotech, Inc.

Date: August 3, 2020

By: /s/ William G. Kachioff
William G. Kachioff
Interim Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

Certification of the Chief Executive Officer
Pursuant to
Securities Exchange Act of Rules 13A-14(A) and 15D-14(A)

I, Stephen T. Isaacs, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aduro Biotech, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 3, 2020

/s/ Stephen T. Isaacs
Stephen T. Isaacs
Chairman, President and Chief Executive Officer

Exhibit 31.2

Certification of the Interim Chief Financial Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, William G. Kachioff, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aduro Biotech, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 3, 2020

/s/ William G. Kachioff
William G. Kachioff
Interim Chief Financial Officer

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Aduro Biotech, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2020 (the "Report"), Stephen T. Isaacs, Chairman, President and Principal Executive Officer of the Company, and William G. Kachioff, Interim Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 3, 2020

/s/ Stephen T. Isaacs
Stephen T. Isaacs
Chairman, President and Chief Executive Officer

/s/ William G. Kachioff
William G. Kachioff
Interim Chief Financial 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 Aduro Biotech, 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.